Abstract

Rehabilitation techniques of sensorimotor complications post stroke fall loosely into one of two categories; the compensatory approach or the restorative approach. While some overlap exists, the underlying philosophies of care are what set them apart. The goal of the compensatory approach towards treatment is not necessarily on improving motor recovery or reducing impairments but rather on teaching patients a new skill, even if it only involves pragmatically using the non-involved side (Gresham et al. 1995). The restorative approach focuses on traditional physical therapy exercises and neuromuscular facilitation, which involves sensorimotor stimulation, exercises and resistance training, designed to enhance motor recovery and maximize brain recovery of the neurological impairment (Gresham et al. 1995). In this review, rehabilitation of mobility and lower extremity complications is assessed. An overview of literature pertaining to the compensatory approach and the restorative approach is provided. Treatment targets discussed include balance retraining, gait retraining, strength training, cardiovascular conditioning and treatment of contractures in the lower extremities. Technologies used to aid rehabilitation include assistive devices, electrical stimulation, and splints.
Key Points

- The restorative (Bobath) approach is as beneficial as the Motor Learning approach at improving motor recovery.
- Early intensive therapy may improve gait, general motor function and independent function in individuals with stroke within the first 3 months but not after 6 months.
- Trunk-specific balance training and balance-focused exercise programs may improve balance post stroke.
- Whole body and local vibration, thermal stimulation, balance-focused exercises, and interventions involving feedback may not improve balance outcomes.
- It is unclear whether task-specific balance training programs, and virtual reality training improve on balance, gait, and functional recovery post stroke.
- Exercise-based falls prevention programs may not reduce the rate of falls post-stroke.
- Lower extremity exercises involving resistive and strength training may improve lower limb mobility, gait and cadence however, their effect on balance is unclear.
- Treadmill training without body weight support may improve lower limb impairments pertaining to gait velocity and function but not balance.
- Body-weight supported treadmill training may not be superior to conventional therapy at improving gait, motor function, or balance.
- Virtual reality may improve gait and balance when combined with treadmill training. When delivered alone, it may only improve balance.
- Auditory feedback may improve gait and muscle activity.
- The evidence for the effectiveness of EMG-Biofeedback is conflicting and limited. Further research is required.
- More research is needed to determine the effectiveness of bilateral leg training on lower limb motor function.
- Mental practice or motor imagery may improve gait and balance outcomes post-stroke.
- Hippotherapy may not improve gait outcomes. More research is needed to determine the effect of hippotherapy on balance.
- Rhythmic auditory stimulation training may improve gait and balance outcomes post-stroke.
- Mirror therapy in combination with rTMS improves balance; however, when delivered alone, mirror therapy does not provide additional benefits to gait and lower limb motor function relative to conventional therapy.
- Self-management programs may not improve gait or balance post stroke.
- Caregiver mediated programs may improve gait and balance outcomes post-stroke; however additional research is need.
• Strength training may not improve gait speed or lower limb strength, while progressive resistance training may help with lower limb strength.

• Cardiovascular training in the form of fitness and mobility programs, aquatic therapy, and community/outpatient exercise programs as well as supervised programs may improve gait. Further research is required to identify the effectiveness of cycling programs, and home-based exercise programs on mobility and balance.

• Additional research is required to investigate the impact of wheelchairs for improving mobilization post stroke.

• Quad canes and walkers improve gait and balance more than when using a one-point cane or when no cane is provided.

• Ankle foot orthoses (AFOs) may improve gait and range of motion; however not when combined with posterior tibial nerve denervation. More research is needed to determine if AFOs are beneficial for improving balance.

• The Gait trainer may improve gait but only when used in the acute phase of stroke. The Lokomat may not be beneficial at improving gait or balance in the acute phase of stroke recovery; however, more research is needed to determine if patients in the chronic or subacute phase can benefit from using this device.

• Transcutaneous electrical nerve stimulation may improve gait, spasticity, balance, muscle strength, and ankle dorsiflexion range of motion.

• Functional electrical stimulation, peroneal nerve stimulation, and interferential current stimulation may improve gait; however, neuromuscular electrical stimulation was not found to have the same beneficial effect.

• Repetitive peripheral magnetic stimulation may improve foot muscle strength and ankle range of motion.

• Amphetamines may not improve lower limb functional impairments.

• Methylphenidate may improve motor recovery; however, the evidence is currently limited.

• More research is needed to determine the effectiveness of L-DOPS on lower limb motor function.

• More research is needed to determine the effect of Levodopa on lower limb improvement following stroke.

• More research is needed to determine the effectiveness of Ropinirole in lower limb motor recovery.

• More studies are needed to investigate the effectiveness of Citalopram at improving lower limb motor function.

• Fluoxetine may improve motor recovery following stroke; however, further research is necessary.

• Almitrine in combination with Raubasine may improve functional outcomes following stroke; however more research is needed.

• Piracetam may improve motor function but not ADL performance and neurological status following stroke.

• Splints and tilt tables are both effective in the prevention of ankle contracture.
• Treatment with botulinum toxin improves lower-limb spasticity, but may not improve functional outcomes.
• Neurolysis in the lower limb may reduce spasticity, ankle clonus, and improve Achilles tendon flexion. More research is needed to determine whether phenol or alcohol injections improve spasticity.
• Oral pharmacological agents may be effectively used in the management of spasticity, although some may be associated with side effects.
• Further research is required to determine the efficacy of ITB for reducing post-stroke spasticity.
• Transcutaneous electrical stimulation and functional electrical stimulation may improve spasticity outcomes post-stroke.
• Evidence is inconclusive for the effect of rehabilitation programs, ankle exercises, robotic training and other physical therapies on spasticity post-stroke.
• Repetitive transcranial magnetic stimulation at high and low frequencies may be effective in improving balance, gait, and ADL performance.
• Transcranial direct current stimulation treatment may not improve gait or balance outcomes.
• Galvanic vestibular stimulation may not improve pusher behavior or lateropulsion; however, further research is necessary.
• Acupuncture may not improve lower extremity motor function or ADLs.
• Acupressure may improve functional recovery.
• Traditional Chinese medicine may not improve lower limb function compared to placebo.
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9.1 Approaches to Therapy

There are two basic approaches to rehabilitating sensorimotor disorders in spastic hemiplegia or hemiparesis with or without sensory or perceptual disorders. These two approaches are: (1) the compensatory or (2) the restorative approach also referred to the remediation approach. Although not exclusive of each other, they do reflect differing philosophies.

9.1.1 The Compensatory Approach

The goal of the compensatory approach towards treatment is not necessarily on improving motor recovery or reducing impairments but rather on teaching patients a new skill, even if it only involves pragmatically using the non-involved side (Gresham et al. 1995). The aim is to teach an adaptive approach, one-handed if necessary, with a focus on improving activities of daily living. Furthermore, Gresham et al. (1995) noted that there is a paucity of evidence indicating whether such an approach is effective. There is anecdotal evidence that the compensatory approach may suppress neurological recovery (Bobath 1978), a concept supported by evidence that the forced-use approach can enhance motor control in selected patients (Taub et al. 1993; Wolf et al. 1989).

9.1.2 The Restorative Approach

The restorative approach focuses on traditional physical therapy exercises and neuromuscular facilitation, which involves sensorimotor stimulation, exercises and resistance training, designed to enhance motor recovery and maximize brain recovery of the neurological impairment (Gresham et al. 1995). Research utilizing new technology such as functional MRI has certainly demonstrated the potential of the central nervous system to at least partially recover in response to specific training and stimulation.

There are several restorative approaches used in stroke rehabilitation. Although each one has its own proponents, there is little evidence that suggests any one of these approaches is superior to another (Ashburn et al. 1993; Duncan 1997; Ernst 1990; Partridge & De Weerdt 1995; Pomeroy & Tallis 2000). A Cochrane review also concluded that there was insufficient evidence that one therapy approach was superior to another (Pollock et al. 2003). Eleven trials were included in the analysis, which evaluated both the neurophysiological approach and the motor learning approach. The authors identified several potential factors, which may have contributed to the null findings: i) an inability to identify all relevant trials due to lack of consistent terminology, ii) The poor methodological quality of many of the 11 trials, iii) the heterogeneity of interventions, outcome assessments and patient characteristics, and iv) poor descriptions and classification of the interventions provided.

Paci (2003) evaluated 15 trials, which had assessed the effectiveness of the Bobath approach and concluded that there was insufficient evidence that this approach was superior to others. Paci (2003) also noted that the methodological shortcomings of the studies included in the review do not allow for a conclusion of non-efficacy.

A Cochrane review authored by Pollock et al. (2006) examining the efficacy of various treatment approaches for lower limb rehabilitation also concluded that using a mix of components from different therapy approaches is more effective than no treatment or placebo control, and that no one therapy approach is superior to another. In addition, Kollen et al. (2009) conducted a systematic review evaluating the Bobath approach to other therapy approaches in terms of sensorimotor control of upper and lower limb, dexterity, mobility, activities of daily living, health-related quality of life, and cost-
effectiveness using data from 16 RCTs. Only limited evidence was found for balance control in favor of Bobath. The authors concluded that overall, the Bobath Concept is not superior to other approaches. Based on best evidence synthesis, no evidence is available for the superiority of any approach. The authors also noted the methodological shortcomings of many of the studies reviewed.

Several RCTs and a retrospective study evaluating the effects of Bobath therapy on motor function and disability are summarized in table 9.1.2.1 below.

**Table 9.1.2.1 Summary of RCTs Evaluating the Bobath Therapy Approach**

<table>
<thead>
<tr>
<th>Author, Year Study Design (PEDro Score)</th>
<th>Intervention</th>
<th>Main Outcome(s) Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Langhammer and Stanghelle (2000) RCT (8) N=61</td>
<td>E: Motor Relearning Programme (MRP) C: Bobath</td>
<td>• Hospital stays (+ Bobath) • Motor Assessment Scale (+ MRP) (- at 1 and 4 yr F/U) • Sodring Motor Evaluation Scale (+ MRP) (- at 1 and 4 yrs F/U) • Life Quality Test (-)</td>
</tr>
<tr>
<td>Salbach et al. (2004) RCT (8) N=91</td>
<td>E1: Motor relearning (lower) E2: Motor learning (upper extremity-control)</td>
<td>• Six-minute walk test (-) • Berg Balance Scale (-) • Gait Velocity (+)</td>
</tr>
<tr>
<td>Brock et al. (2011) RCT (7) N=26</td>
<td>E: Bobath + addition of task practice C: Task practice</td>
<td>• Rivermead Motor Assessment (-) • Motor Assessment Scale (-)</td>
</tr>
<tr>
<td>Van Vliet et al. (2005) RCT (7) N=120</td>
<td>E: Motor Relearning Programme C: Bobath</td>
<td>• Motor Assessment Scale (+ Bobath) • Stroke Impact Scale (+ Bobath)</td>
</tr>
<tr>
<td>Wang et al. (2005) RCT (7) N=44</td>
<td>E: Bobath C: Orthopedic approach</td>
<td>• Motor Assessment Scale (+ Bobath) • Stroke Impact Scale (+ Bobath)</td>
</tr>
<tr>
<td>Chan et al. (2006) RCT (7) N=52</td>
<td>E: Motor relearning C: Conventional therapy</td>
<td>• Berg Balance Scale (+) • Timed Up &amp; Go Test (-) • FIM-motor (+) • Modified Lawson Instrumental Activities of Daily Living Test (+) • Community Integration Questionnaire (+)</td>
</tr>
<tr>
<td>Richards et al. (1993) RCT (6) N=27</td>
<td>E1: Bobath E2: Mixed C: Conventional</td>
<td>• Balance (-) • Gait velocity (-)</td>
</tr>
<tr>
<td>Gelber et al. (1995) RCT (5) N=20</td>
<td>E: Bobath C: Traditional techniques</td>
<td>• Functional Independence Measure (-) • Length of Stay (-)</td>
</tr>
<tr>
<td>Pollock et al. (2002) RCT (5) N=28</td>
<td>E: Bobath C: Mixed techniques</td>
<td>• Proportion of patients achieving 'normal' symmetry of weight distribution during various tasks (-)</td>
</tr>
<tr>
<td>Dean et al. (1997)</td>
<td>E: Motor relearning</td>
<td>• 10 Meter Walk Test (-)</td>
</tr>
</tbody>
</table>
RCT (5)
N=20

<table>
<thead>
<tr>
<th>Study</th>
<th>Design</th>
<th>N=62</th>
<th>E1: Mixed</th>
<th>E2: Neurophysiological</th>
<th>Outcome Measures</th>
</tr>
</thead>
<tbody>
<tr>
<td>Stern et al. (1970)</td>
<td>RCT</td>
<td></td>
<td></td>
<td></td>
<td>• Kenny Institute of Rehabilitation Activities of Daily Living scale (-)</td>
</tr>
<tr>
<td>Chung et al. (2014)</td>
<td>Retrospective</td>
<td>N_{Start}=45</td>
<td>N_{End}=45</td>
<td>E1: Motor learning</td>
<td>E2: Bobath approach</td>
</tr>
</tbody>
</table>

- Indicates non-statistically significant differences between treatment groups
+ Indicates statistically significant differences between treatment groups

**Discussion**

The evidence for the restorative approach is almost exclusively empirical and evidence supporting its usage is limited. Miller et al. (1998) noted that although there is evidence to demonstrate a short-term benefit of facilitation techniques, part of the restorative approach, there is a lack of evidence that would suggest functional clinical outcomes are improved. Two recent studies have shown that the restorative approach increases length of hospital rehab stay without improving outcomes (Langhammer & Stanghell 2000; Patel et al. 1998). Langhammer and Stranghelle conducted an RCT comparing the Bobath approach (remedial type of therapy) and the Motor Relearning Programme (MRP), in which, the MRP resulted in shorter hospital stays and improved motor function (Langhammer & Stanghelle 2000).

Despite an improvement in functional mobility and ADL performance, Lennon et al. (2006) reported that normal movement patterns were not restored following therapy using the Bobath principles. In the case of Patel et al. (1998), a non-randomized comparative study, there was a suggestion that the restorative approach actually increases the number of patients who are institutionalized. Results from the two more recent studies, of equal methodological quality, comparing two compensatory therapy approaches to a restorative (Bobath) approach were conflicting (Van Vliet et al. 2005; Wang et al. 2005). Treatment times were similar in both studies (15-20 sessions each), as was the time from stroke onset to randomization (2-3 weeks). Patient characteristics appeared to be similar. Although the patients in the Hafsteinsdottir et al. study were not randomized the authors controlled for a number of covariates in their analysis including age, living situation education, modified Rankin scale scores, Barthel Index, MMSE and depression (Hafsteinsdottir et al. 2005). In this multi-centered trial the sample size was also larger than any previous RCT conducted to date. While the authors acknowledge the potential for bias using a non-randomized design they also noted that randomization is impractical in a clinical setting where most institutions use one treatment approach exclusively. This study was also the first to assess quality of life associated with different treatment approaches.

Chan et al. (2006) reported greater improvement in a series of performance-based tasks associated with the motor relearning approach compared to a “conventional approach”. These authors included both ‘sequential’ and function-based components into their protocol, which the authors believed was responsible, in part, for the superior outcomes. Lennon et al. (2006) suggested that current evidence reveals no real differences between therapy approaches; a finding that may be explained, in part, by the fact that they all share common treatment components.

**Conclusions Regarding Restorative and Compensatory Approaches**

There is level 1a evidence that Motor Learning and Bobath may improve motor recovery but they are not superior to one another.
The restorative (Bobath) approach is as beneficial as the Motor Learning approach at improving motor recovery.

9.2 Intensity of Training

The role of intensity in the rehabilitation of the lower limb has been the subject of debate. While several meta-analyses investigating the benefit of augmented physical therapy have been published, most of these included studies which evaluated the outcomes such as improvement in ADL function and were not specific to measures of gait or mobility. For example, the results of a meta-analysis of seven randomized controlled trials examining the effects of differing intensities of physical therapy showed significant improvements in activities of daily living (ADL) function and reduction of impairments with higher intensities of treatment (Langhorne et al. 1996). Another meta-analysis of nine studies (eight RCTs and one non-randomized experiment) looking at the effects of intensity of stroke rehabilitation found a small but statistically significant intensity-effect on ADL and functional outcome parameters (Kwakkel et al. 1997). However, Cifu and Stewart found only 3 moderate quality studies and one meta-analysis looking at the intensity of rehabilitation services and functional outcome (Cifu & Stewart 1999). These authors concluded that the intensity of rehabilitation services was only weakly associated with improved functional outcomes after stroke.

Kwakkel et al. (2004) conducted a further meta-analysis, evaluating the benefit of augmented physical therapy, including 20 studies which had assessed many interventions: occupational (upper extremity), physiotherapy (lower extremity), leisure therapy, home care and sensorimotor training. After adjusting for differences in treatment intensity contrasts, augmented therapy was associated with statistically significant treatment effects for the outcomes of ADL and walking speed, although not for upper extremity therapy, assessed using the Action Research Arm test. Augmented therapy was found to be more effective when initiated within six months of the stroke.

The term, “intensity”, most frequently refers to the frequency of repetitions within a given period of time, although more correctly, is defined as the amount of mechanical output of physical activity. However, such measurement is not usually possible within a clinical setting. Therefore, establishing a dose-response relationship is problematic in stroke rehabilitation. Many factors preclude the routine recommendation of standard amounts of therapy time an individual patient should receive, with many guideline recommendations regarding intensity and duration of therapy to reflect consensus by clinicians rather than research evidence (Foley et al. 2012). Therefore, it is extremely difficult to know how early therapy should be initiated post stroke or how much additional therapy would confer benefit. In a prospective cohort study, a relationship between lower limb exercise dose (mean daily number of exercise repetitions) and improved walking speed was found (Scrivener et al. 2012). Kwakkel (2006) has demonstrated an association between effect size and additional treatment time, and Foley et al. (2012) have found that the total amount of occupational therapy (OT) time is a significant predictor of gains in functional independence measure (FIM) scores. Furthermore, researchers have reported that intensive practice of function-focused physiotherapy predicts greater than expected gains in mobility (Bode et al., 2004), with a treatment time of 3 hours or longer being associated with greatest functional improvements (Wang et al. 2013). Interestingly, in a descriptive study looking at patient’s perspectives regarding an intense (3 hrs/day for 10 consecutive days) task-specific mobility training therapy intervention, patient’s described this type of intervention as “difficult, but doable” (Merlo et al. 2013).

Overall, several studies have evaluated the intensity (amount received and timing) of therapy interventions of assessments of gait and mobility. Please see Table 9.2.1 for the outline of each study.
<table>
<thead>
<tr>
<th>Author, Year</th>
<th>Study Design (PEDro Score)</th>
<th>Sample Size (N)</th>
<th>Intervention</th>
<th>Main Outcome(s) Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Kwakkel et al., (1999)</td>
<td>RCT (8)</td>
<td>N=101</td>
<td>E1: Arm training  E2: Leg training  C: Basic rehabilitation</td>
<td>• Functional Ambulation Categories - Walking: ○ At 6, 12, 20, 26, 52 wk (+)</td>
</tr>
<tr>
<td>Partridge et al., (2000)</td>
<td>RCT (8)</td>
<td>N=170</td>
<td>E: Community physiotherapy treatment  C: No treatment control group</td>
<td>• River Mobility Index: 3mo (+); 6 &amp; 9mo (-)</td>
</tr>
<tr>
<td>Green et al., (2002)</td>
<td>RCT (8)</td>
<td>N=170</td>
<td>E: Community physiotherapy treatment  C: No treatment control group</td>
<td>• River Mobility Index (RMI): 3mo (+); 6 &amp; 9mo (-)</td>
</tr>
</tbody>
</table>
| Langhammer et al., (2007) | RCT (8) | N=75 | E: Intensive outpatient exercise program  C: Regular exercise | • Modified Ashworth Scale: 3, 6, 12mo (-)  
• Activities of Daily Living: 3, 6, 12mo (-)  
• 6-minute Walk Test: 3, 6, 12mo (-)  
• Berg Balance Scale: 3, 6, 12mo (-)  
• Timed Up & Go Test: 3, 6, 12mo (-) |
| Wellwood (2004) | RCT (7) | N=70 | E: Augmented physiotherapy  C: Normal physiotherapy | • River Mobility Index: 1, 3, 6mo (-)  
• Motricity Index: 1, 3, 6mo (-)  
• Barthel index: 1, 3, 6mo (-)  
• Nottingham Extended Activities of Daily Living Index: 3 & 6mo (-)  
• Quality of Life: 6mo (-) |
| Hesse et al., (2011) | RCT (7) | N=50 | E1: Three two-month blocks of therapy at home, each block contained four 30 to 45 minute sessions per week, totaling 96 sessions  E2: Two 30 to 45 minute sessions per week, totally 104 sessions | • Rivermead Mobility Index: 2, 4, 6, 8, 10, 12mo (-)  
• Rivermead ADLs: 2, 4, 6, 8, 10, 12mo (-)  
• Timed Up & Go Test: 2, 4, 6, 8, 10, 12mo (-)  
• Modified Ashworth Scale: 2, 4, 6, 8, 10, 12mo (-)  
• River Mobility Index: 1, 3, 6mo (-)  
• Activities of Daily Living: 1, 3, 6mo (-)  
• Barthel index: 1, 3, 6mo (-)  
• Nottingham Extended Activities of Daily Living Index: 3 & 6mo (-)  
• Quality of Life: 6mo (-) |
| Wade et al., (1992) | RCT (6) | N=94 | E: Physiotherapy upon immediate entry into study  C: No therapy | • 10 Meter Walk Test: 2wk to 17wk (+), 17wk to 31wk (+), 31wk to 44wk (-)  
• Nottingham Extended Activities of Daily Living Index: All (-)  
• Hospital Anxiety & Depression Scale: All (-)  
• Gait speed (+) |
| Wade et al., (1992) | RCT (6) | N=94 | E: Physiotherapy upon immediate entry into study  C: No therapy | • Gait speed (+) |
| Richards et al., (1993) | RCT (6) | N=27 | E: Early intensive therapy  C: Conventional therapy | • Gait speed: at 6wk (+); at 3, 6mo (-) |
| Bai et al., (2012) | RCT (5) | N=364 | E: Early rehabilitation that followed a three-stage rehabilitation program  C: Conventional rehabilitation | • Modified Barthel Index: 1, 3, 6mo (+)  
• Fugl-Meyer Assessment: 1, 3, 6mo (+)  
• 6 Minute Walk Test: 4yr (-) |
9. Mobility and the Lower Extremity

| RCT (4) | C: Regular exercise only | • Berg Balance Scale: 4yr (-)  
| N_{Start}=75 | | • Timed Up-and-Go Test: 4yr (-)  
| N_{End}=37 | | |

- Indicates non-statistically significant differences between treatment groups  
+ Indicates statistically significant differences between treatment groups

Discussion
The studies included in this review encompassed both acute and chronic stroke patients. In general, benefits have been reported for intensive therapy early on (within the first 3 months) but have failed to be maintained (at 6-12 months).

In a retrospective analysis of 993 stroke patients receiving rehabilitation in a skilled nursing facility, Jette et al. (2005) reported that patients who received less than one hour of therapy per day (combined OT/PT/SLP) had longer lengths of stay compared to patients who received 1-1.5 hours per day (21.4 vs. 15-17 days). However there was no difference in LOS between patients receiving 1-1.5 hours per day and those receiving more than 1.5 hours. Although a greater level of therapy intensity was associated with shortened LOS, the total daily therapy time would be considered very modest and likely not representative of most inpatient rehabilitation programs.

Conclusions Regarding Intensity of Training

There is level 1a and limited level 2 evidence that early intensive therapy may improve gait and general motor function.

There is conflicting level 1a evidence regarding the effect of augmented physical therapy on gait at follow-up.

Early intensive therapy may improve gait, general motor function and independent function in individuals with stroke within the first 3 months but not after 6 months.

9.3 Balance Retraining and Falls Prevention

9.3.1 Balance Retraining
Impaired postural control has been identified as a key component of mobility problems post stroke (de Haart et al. 2004; Pohl et al. 2004), arising from motor, sensory and cognitive impairments. In fact, Pohl et al. (2004) identified improvement in balance as the strongest predictor of distance gained in walking among poor performers (those who walked less than 213 metres) three months following stroke. Trunk flexion and extension muscle weakness and asymmetric weight bearing may contribute to difficulties in walking and performing ADLs following stroke (Karatas et al. 2004; Winstein et al. 1989) and may be treated using force platform technology with either visual or auditory feedback. However, a Cochrane review authored by Barclay-Goddard et al. (2004) concluded that while biofeedback therapy (visual or auditory) can improve standing balance, functional balance is not significantly improved; although the conclusions were based on a small number of RCTs (see Table 9.3.1.1). Whole body vibration shows promise as a potentially promising therapy to improve proprioceptive control of posture following stroke (van Nes et al. 2004).
van Peppen et al. (2006) conducted a systematic review of the effectiveness of visual feedback therapy on postural control and gait following stroke, which included 8 studies, six of which were RCTs; the remainder were controlled trials (see Table 9.3.1.2). There were no significant treatment effects for symmetry of weight distribution in bilateral standing, postural sway, balance control, walking ability or gait speed. Lubetzky-Vilnai and Kartin (2010) conducted a narrative, systematic review, including the results from 22 studies (9 RCTs) examining the effectiveness of balance training programs following stroke. The authors noted variations in the dosage and type of interventions assessed, the chronicity of stroke among participants, the length of the programs and the length of follow-up. Regardless, they reported that there was evidence to support the use of individual balance training in the acute stage of stroke and either group or individual sessions among patients in the sub-acute or chronic stages of stroke.

Table 9.3.1.1 RCTs Included in Two Systematic Reviews of Biofeedback Training

<table>
<thead>
<tr>
<th>Author, Year</th>
<th>Study Design (PEDro Score)</th>
<th>Sample Size (N)</th>
<th>Intervention</th>
<th>Main Outcome(s): Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Barclay-Goddard et al. (2004) (Cochrane Review)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Chen et al. 2002</td>
<td>RCT (9)</td>
<td>NStart=48 NEnd=48</td>
<td>E: Early sitting, standing, and walking (in conjunction with the CBA (ECBA) or ECBA-combined group</td>
<td>• Lower extreme mobility scores (+)</td>
</tr>
<tr>
<td>Geiger et al. 2001</td>
<td></td>
<td></td>
<td>C: Contemporary Bobath Approach (CBA)-only group</td>
<td>• Basic mobility scores (+)</td>
</tr>
<tr>
<td>Lee et al. 1996</td>
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<td></td>
<td>• Overall STREAM scores (+)</td>
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<td>Sackley et al. 1997</td>
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<td>• Berg Balance Scale (+)</td>
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<td>Shumway-Cook et al. 1988</td>
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<td>Walker et al. 2000</td>
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<td>Wong et al. 1997</td>
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<tr>
<td>Van Peppen et al. (2006)</td>
<td>RCT (9)</td>
<td>NStart=48 NEnd=48</td>
<td>E1: Whole body vibration</td>
<td>At 0, 6, and 12 weeks:</td>
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<td></td>
<td></td>
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<td>E2: Exercise therapy on music</td>
<td>• Berg Balance Scale (-)</td>
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<td>• Trunk Control Test (-)</td>
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<td>• Rivermead Mobility Index (-)</td>
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<td>• Barthel Index (-)</td>
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<td>• Functional Ambulation Categories (-)</td>
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<td>• Somatosensory threshold (-)</td>
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</table>

Treatment of balance disorders post-stroke are outlined in Table 9.3.1.2.

Table 9.3.1.2 Summary of RCTs Examining Balance Treatments

<table>
<thead>
<tr>
<th>Author, Year</th>
<th>Study Design (PEDro Score)</th>
<th>Sample Size (N)</th>
<th>Intervention</th>
<th>Main Outcome(s): Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tang et al. (2014)</td>
<td>RCT (9)</td>
<td>NStart=48 NEnd=48</td>
<td>E: Early sitting, standing, and walking (in conjunction with the CBA (ECBA) or ECBA-combined group</td>
<td>• Lower extreme mobility scores (+)</td>
</tr>
<tr>
<td>Lee et al. (2015)</td>
<td>RCT (9)</td>
<td>NStart =36 NEnd=36</td>
<td>E1: Proprioception training for 25min + additional balance tasks</td>
<td>• Korean Berg Balance Scale (+)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>E2: Proprioception training for 30min</td>
<td>• Joint position sense error (+)</td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td>• Affected/unaffecte side weight bearing ratio (+)</td>
</tr>
<tr>
<td>Fargalit et al. (2013)</td>
<td>RCT (9)</td>
<td>NStart=40 NEnd=40</td>
<td>E1: Sit-to-stand training (STS) and an exercise program.</td>
<td>• Sit-to-stand repetitions in 3 mins (+)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>E2: Symmetrical foot position training and an exercise program.</td>
<td>• Timed Up-and-Go Test (+)</td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td>• Berg Balance Scale (+)</td>
</tr>
<tr>
<td>Van Nes et al. (2006)</td>
<td>RCT (9)</td>
<td>N=53</td>
<td>E1: Whole body vibration</td>
<td>At 0, 6, and 12 weeks:</td>
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<td></td>
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<td>E2: Exercise therapy on music</td>
<td>• Berg Balance Scale (-)</td>
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<td>• Trunk Control Test (-)</td>
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<td>• Rivermead Mobility Index (-)</td>
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<td>• Barthel Index (-)</td>
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<td>• Functional Ambulation Categories (-)</td>
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<td>• Somatosensory threshold (-)</td>
</tr>
<tr>
<td>Study</td>
<td>Design</td>
<td>N Start</td>
<td>N End</td>
<td>Conditions</td>
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<tr>
<td>Matsumoto et al. (2014)</td>
<td>RCT</td>
<td>22</td>
<td>22</td>
<td>E: Thermal stimulation C: Relaxation therapy</td>
</tr>
<tr>
<td>Karthikbabu et al. (2011)</td>
<td>RCT</td>
<td>N=30</td>
<td></td>
<td>E: Task-specific trunk exercises on an unstable surface C: Task-specific trunk exercises on a stable surface</td>
</tr>
<tr>
<td>Jieji et al. (2012)</td>
<td>RCT</td>
<td>100</td>
<td>92</td>
<td>E: Cognitive dual-task training (balance training + cognitive training) C: Conventional Balance training</td>
</tr>
<tr>
<td>Lau et al. (2012)</td>
<td>RCT</td>
<td>82</td>
<td></td>
<td>E: Whole body vibration training that used an exercise vibration protocol C: Received an exercise protocol different from the vibration protocol</td>
</tr>
<tr>
<td>Dragan et al. (2014)</td>
<td>RCT</td>
<td>22</td>
<td>22</td>
<td>E: Body postural support during gait training C: Conventional gait training using a cane</td>
</tr>
<tr>
<td>Bower et al. (2014)</td>
<td>RCT</td>
<td>30</td>
<td>21</td>
<td>E: Wii-based exercises C: Balance group</td>
</tr>
<tr>
<td>Miklitsch et al. (2013)</td>
<td>RCT</td>
<td>40</td>
<td>40</td>
<td>E: Balance training using a mini-trampoline C: Group balance training</td>
</tr>
<tr>
<td>Howe et al. (2005)</td>
<td>RCT</td>
<td>35</td>
<td></td>
<td>E: Usual care + physiotherapy + additional therapy sessions C: Usual care, + physiotherapy</td>
</tr>
<tr>
<td>Yelnik et al. (2008)</td>
<td>RCT</td>
<td>68</td>
<td></td>
<td>E: Multisensorial Rehabilitation, an approach based on higher intensity of balance tasks and exercise during visual deprivation C: Conventional neurodevelopmental theory-based treatment</td>
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<tr>
<td>Study</td>
<td>Methodology</td>
<td>Intervention 1</td>
<td>Intervention 2</td>
<td>Outcomes</td>
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<tr>
<td><strong>Gok et al.</strong> (2008)</td>
<td>RCT (7)</td>
<td>E: Balance training with a Kinaesthetic Ability Training device + Conventional Rehabilitation</td>
<td>C: Conventional Rehabilitation</td>
<td>Static and dynamic balance indices (+)</td>
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<td>Fugl-Meyer Assessment – balance subscore (+)</td>
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<td>Fugl-Meyer Assessment – total motor subscore (-)</td>
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<td>Functional Independence Measure – locomotor subscore (-)</td>
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<td>Standing equilibrium (-)</td>
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<td>Timed Up-and-Go Test (-)</td>
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<tr>
<td><strong>Chen et al.</strong> (2011)</td>
<td>RCT (7)</td>
<td>E: Tai Chi</td>
<td>C: General exercises</td>
<td>Dynamic balance indices (+)</td>
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<td>Fugl-Meyer Assessment – balance subscore (+)</td>
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<td>Fugl-Meyer Assessment – total motor subscore (-)</td>
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<td></td>
<td>Functional Independence Measure – locomotor subscore (-)</td>
</tr>
<tr>
<td><strong>Saeyns et al.</strong> (2012)</td>
<td>RCT (7)</td>
<td>N=33</td>
<td>E: Truncal exercises</td>
<td>C: Sham treatment</td>
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<td>Timetti Test (+)</td>
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<td>Four Test Balance Scale (+)</td>
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<tr>
<td><strong>Lee et al.</strong> (2012)</td>
<td>RCT (7)</td>
<td>N=40</td>
<td>E: Balance training + Conventional physiotherapy</td>
<td>C: Conventional physiotherapy</td>
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<td>Functional Ambulation Categories (+)</td>
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<td>Timed Up-and-Go test (+)</td>
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<td>Berg Balance Scale (+)</td>
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<tr>
<td><strong>Liang et al.</strong> (2012)</td>
<td>RCT (7)</td>
<td>NStart=30 NEnd=25</td>
<td>E: Thermal stimulation</td>
<td>C: Occupational therapy</td>
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<td>Fugl-Meyer Assessment (-)</td>
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<td>Modified Motor Assessment Scale (-)</td>
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<td>Functional Ambulation Classification (-)</td>
</tr>
<tr>
<td><strong>Lee et al.</strong> (2014)</td>
<td>RCT (7)</td>
<td>NStart=21 NEnd=20</td>
<td>E: Augmented reality-based postural control training in addition to general physical therapy</td>
<td>C: General physical therapy only</td>
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<td>Step length for the paretic and nonparetic side (+)</td>
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<td>Stride length for the paretic and nonparetic side (+)</td>
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<td>Functional Independence Measure for gait (-)</td>
</tr>
<tr>
<td><strong>Jung et al.</strong> (2014)</td>
<td>RCT (7)</td>
<td>NStart=18 NEnd=17</td>
<td>E: Weight-shift Training Group</td>
<td>C: Conventional Exercise Program</td>
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<tr>
<td><strong>Lee et al.</strong> (2013)</td>
<td>RCT (7)</td>
<td>NStart=34 NEnd=31</td>
<td>E: Local vibration stimulus training program</td>
<td>C: Sham local vibration stimulus training</td>
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<td></td>
<td>Postural sway distance eyes closed (+)</td>
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<td>Postural sway velocity eyes open (+)</td>
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<td>Postural sway velocity eyes closed (+)</td>
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<td>Gait speed (+)</td>
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<td>Cadence (+)</td>
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<td>Single limb support time (+)</td>
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<tr>
<td><strong>Bang et al.</strong> (2014)</td>
<td>RCT (7)</td>
<td>E: Unstable surface training after treadmill training</td>
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<td>Timed Up-and-Go Test (+)</td>
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<td>6-minute Walk Test (+)</td>
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<td>Design</td>
<td>N Start/N End</td>
<td>Intervention</td>
<td>Comparison</td>
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<td>• Postural Assessment Scale for Stroke (-)</td>
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<td>• LE STREAM (+)</td>
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<td>• Mob-STREAM (+)</td>
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<td>• Modified Ashworth Scale (+)</td>
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<tr>
<td>Goljar et al. (2010)</td>
<td>RCT (6)</td>
<td>50/39</td>
<td>E: Balance trainer device group</td>
<td>C: Control group</td>
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<td></td>
<td>• Timed Up-and-Go Test (-)</td>
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<td>• Berg Balance Scale (-)</td>
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<td>• 10-meter Walk Test (-)</td>
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<td>Cheng et al. (2001)</td>
<td>RCT (6)</td>
<td>54</td>
<td>E: Symmetrical standing and repetitive sit-to-stand training with a standing biofeedback trainer</td>
<td>C: Conventional stroke rehabilitation</td>
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<td>• Sit-to-stand performance (-)</td>
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<td>• Rate of rise in force (-)</td>
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<td>• Sway in center of pressure (-)</td>
</tr>
<tr>
<td>Morioka et al. (2003)</td>
<td>RCT (6)</td>
<td>28/26</td>
<td>E: Perceptual learning exercises</td>
<td>C: No perceptual-learning exercises</td>
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<td>• Total locus length with eyes open (+)</td>
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<td>• Enveloped Area with eyes open (+)</td>
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<td>De Seze et al. (2001)</td>
<td>RCT (6)</td>
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<td>E: Bon Saint Come device for axial postural rehab</td>
<td>C: Conventional neurorehabilitation</td>
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<td>• Postural Assessment Structural Scale without orthesis (+), with orthesis (+)</td>
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<td>• Gait Ratio (+)</td>
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<td>• Gait Speed on 10-metre test, tricipital and quadricipital spasticity on the Ashworth Modified Scale (-)</td>
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<td>• Motor Spasticity (-)</td>
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<td></td>
<td>• Range of Ankle motion (Maximal ankle dorsiflexion) (+)</td>
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<td>• Motricity Index (-)</td>
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<td></td>
<td>• Functional Ambulation Classification without orthesis (+), with orthesis (-)</td>
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<td>• Functional Independence Measure(+)</td>
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<td>Sackley &amp; Lincoln et al. (1997)</td>
<td>RCT (6)</td>
<td>26</td>
<td>E: Biofeedback training</td>
<td>C: Sham feedback</td>
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<td>• Rivermead Motor Function Assessment (+)</td>
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<td>• Nottingham 10-point ADL Scale (+)</td>
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<td></td>
<td>• Stance symmetry (+)</td>
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<td>• Sway (+)</td>
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<tr>
<td>Eser et al. (2008)</td>
<td>RCT (6)</td>
<td>41</td>
<td>E: Balance training using force platform biofeedback + Conventional program</td>
<td>C: Conventional inpatient rehabilitation</td>
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<td></td>
<td>• Brunnstrom stages (-)</td>
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<td>• Rivermead Motricity Index (-)</td>
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<td>• Functional Independence Measure (+)</td>
</tr>
<tr>
<td>Verheyden et al. (2009)</td>
<td>RCT (6)</td>
<td>33</td>
<td>E: Individual and supervised trunk exercises</td>
<td>C: Conventional therapy</td>
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<td>Trunk Impairment Scale:</td>
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<td>• Total score (-)</td>
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<td>• Static balance subscale (-)</td>
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<td>• Dynamic sitting balance subscale (+)</td>
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<td>• Coordination (-)</td>
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<td>Schmid et al. (2012)</td>
<td>RCT (6)</td>
<td>47</td>
<td>E: Yoga Therapy</td>
<td>C: No therapy</td>
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<td></td>
<td>• Fear of falling (-)</td>
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<td>• Berg Balance Scale (-)</td>
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<td>• Activities-Specific Balance Confidence Scale (-)</td>
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<td>• Stroke Specific Quality of Life Scale (-)</td>
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<td>Puckree et al. (2014)</td>
<td>RCT (6)</td>
<td>50/50</td>
<td>E: Physiotherapy program focused on balance and stability exercises</td>
<td>C: Regular physiotherapy</td>
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<td></td>
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<td></td>
<td>• Berg Balance Scale (-)</td>
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<tr>
<td>Chung et al. (2013)</td>
<td></td>
<td></td>
<td>E: Core stabilization exercises</td>
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<td>• Affected side step length or stride length (-)</td>
</tr>
<tr>
<td>Study Authors</td>
<td>Design</td>
<td>Participants</td>
<td>Intervention</td>
<td>Outcomes</td>
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</tbody>
</table>
| Tankisheva et al. (2014) | RCT (6) | N<sub>Start</sub>=15 N<sub>End</sub>=15 | E: Whole Body Vibration C: No additional training program | • Isometric knee extension strength (+)  
• Isokinetic knee extension strength (+)  
• Postural control (-) |
| Marin et al. (2013)    | RCT (6) | N<sub>Start</sub>=20 N<sub>End</sub>=20 | E: Whole Body Vibration C: Sham | • Lower limb muscle architecture (-)  
• Maximal isometric voluntary contraction of the knee extensors (-)  
• Berg Balance Scale (-) |
| Kyochul et al. (2014)  | RCT (6) | N<sub>Start</sub>=30 N<sub>End</sub>=30 | E: Stair gait exercise for 30 mins. C: Flat surface gait exercise for 30 mins. | • Length of Romberg (cm) (-)  
• Average speed of Romberg (cm/s) (-)  
• Weight bearing of foot print (%) (-)  
• Anterior length in limit of stability (cm<sup>2</sup>) (-)  
• Posterior length in limit of stability (cm<sup>2</sup>) (-)  
• Surface area ellipse of Romberg (mm<sup>2</sup>) (+)  
• Length/area of Romberg (cm/m<sup>2</sup>) (+) |
| Lee et al. (2015)      | RCT (6) | N<sub>Start</sub>=21 N<sub>End</sub>=21 | E: Whole Body Vibration training C: Conventional rehabilitation | • Berg Balance Scale (+) |
| Immink et al. (2014)   | RCT (6) | N<sub>Start</sub>=25 N<sub>End</sub>=22 | E: Yoga C: No Treatment | • Modified Ashworth Scale (-)  
• Berg Balance Scale (-) |
| Kyung-Pil et al. (2015)| RCT (5) | N<sub>Start</sub>=24 N<sub>End</sub>=24 | E: Treadmill with horizontal impeding force C: Treadmill without horizontal impeding force | • Timed Up-and-Go Test (+)  
• CGS (+)  
• MGS (+)  
• Cadence (+)  
• Step length (+) |
| Allison et al. (2007)  | RCT (5) | N<sub>Start</sub>=17 N<sub>End</sub>=15 | E: Standing balance training C: Conventional physiotherapy | • Berg Balance Scale (+)  
• Rivermead Motor Assessment Scale (-)  
• Trunk Control Test (-) |
| Yavuzer et al. (2006)  | RCT (5) | N=25 | E: Conventional rehabilitation + balance training using the Nor-Arm Target Balance training system C: Conventional rehabilitation without balance training | • Pelvic excursion in frontal plane (+)  
• Vertical ground reaction force (+) |
| Wong et al. (1997)     | RCT (5) | N=60 | E: Standing training table + performance of pushing and pulling load tasks using resistive movements of the upper limb E2: Standing biofeedback training device | • Percentage of postural symmetry (+)  
• Immediate learning effect (+) |
• Gait Speed (-)  
• Timed Up-and-Go Test (-) |
<p>| Pollock et al. (2002)  | RCT (5) | N=28 | E1: Bobath E2: Mixed techniques | • Proportion of patients achieving 'normal' symmetry of weight distribution during various tasks (-) |
| Katz-Leurer et al. (2006) | RCT (5) | | E: Daily Cycle Training Program C: Routine inpatient rehabilitation or | • Postural Assessment Scale for Stroke (dynamic, standing and total) scores (+) |</p>
<table>
<thead>
<tr>
<th>Study</th>
<th>Methodology</th>
<th>Participants</th>
<th>Interventions</th>
<th>Outcomes</th>
</tr>
</thead>
<tbody>
<tr>
<td>N=24</td>
<td>Rehabilitation</td>
<td></td>
<td>Fugl-Meyer Assessment (+) FIM (motor) scores (+)</td>
<td></td>
</tr>
<tr>
<td>You et al. (2012)</td>
<td>RCT (5)</td>
<td>Start N=30; End N=27</td>
<td>E: Standing one-leg weight bearing balance exercise with the aid of a device to keep specified degrees of flexion at the hip and knee C: Conventional version (no device) of the one-leg weight bearing balance exercise</td>
<td>• Berg Balance Scale (-) • Gait (-) • Timed Up-and-Go Test (-)</td>
</tr>
<tr>
<td>Jung et al. (2012)</td>
<td>RCT (5)</td>
<td>N=22</td>
<td>E: Virtual reality treadmill training C: Treadmill training only for the same duration.</td>
<td>• Timed Up-and-Go Test (+) • Activities-specific balance confidence (+)</td>
</tr>
<tr>
<td>Cho et al. (2012)</td>
<td>RCT (5)</td>
<td>N=22</td>
<td>E: Virtual reality balance training C: Standard therapy</td>
<td>• Berg Balance Scale (+) • Timed Up-and-Go Test (+) • Postural sway velocity (anterior/posterior and medio-lateral movement (-)</td>
</tr>
<tr>
<td>Krawczyk et al. (2014)</td>
<td>RCT (5)</td>
<td>Start N=51; End N=51</td>
<td>E: Closed chain group C: Standard rehabilitation</td>
<td>• 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 (-) • Rivermead Mobility Assessment – Lower extremity (-) • Berg Balance Scale (-)</td>
</tr>
<tr>
<td>Ko et al. (2015)</td>
<td>RCT (5)</td>
<td>Start N=52; End N=52</td>
<td>E: Space Balance 3D training C: Conventional rehabilitation</td>
<td>• Berg Balance Scale (-) • Timed Up-and-Go Test (-) • Postural Assessment Scale (-)</td>
</tr>
<tr>
<td>Chen et al. (2002)</td>
<td>RCT (4)</td>
<td>N=41</td>
<td>E: Visual feedback balance training with the “Smart Balance Master’ device C: Conventional physical and occupational therapy</td>
<td>• Maximum stability (static balance) (-) • Centre of gravity alignment (static balance) (-) • Axis velocity (dynamic balance) (+) • Directional control (dynamic balance) (-) • End point excursion (dynamic balance) (-) • Sphincter control (+)</td>
</tr>
<tr>
<td>Shumway-Cook et al. (1988)</td>
<td>RCT (4)</td>
<td>N=50</td>
<td>E: Postural sway biofeedback using a static force plate system C: Conventional physical therapy practices</td>
<td>• Total sway excursion (-) • Total sway area (-)</td>
</tr>
<tr>
<td>Bayouk et al. (2006)</td>
<td>RCT (4)</td>
<td>N=16</td>
<td>E: Exercises performed under conditions of vision (eyes closed/open) and surface manipulation (firm/hard surface) C: Exercises performed under normal conditions</td>
<td>The center of pressure 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 (-) 4. eyes closed, soft surface, (-) 10-m walking test (-)</td>
</tr>
</tbody>
</table>
### Table

<table>
<thead>
<tr>
<th>Study</th>
<th>Group Details</th>
<th>Outcomes</th>
</tr>
</thead>
</table>
| **Seo et al. (2012)**         | E: Standard physical therapy + Dual task training  
C: Standard physical therapy | Sway path (-)  
Sway area (+)  
Max velocity (+) |
| **Kim et al. (2012)**         | E: Nintendo Wii + exercise + electrical stimulation  
C: Electrical stimulation + exercise | Functional Independence Measure (-)  
Modified Motor Assessment Scale (+)  
Postural Assessment Scale (+) |
| **Hoseinabadi et al. (2013)** | E: Physical therapy program  
C: Control treatment | Berg Balance Scale (+)  
Barthel Index (+)  
Modified Ashworth Scale (+) |
| **Lim et al. (2012)**         | E: Abdominal Drawing-in maneuver + bridge exercise  
C: Bridge exercise alone | Sway area (+)  
Sway length (+)  
Sway velocity (+) |
| **Kim, Cha et al. (2015)**    | E: Gait training with constraint-induced movement therapy  
C: Gait training only | Trunk Impairment Scale: dynamic sitting balance (-) |
| **Mun et al. (2014)**         | E: Unstable support surface group  
C: Stable support surface group | Berg Balance Scale (-)  
Timed Up-and-Go Test (-)  
10-meter Walk Test (-)  
6-min Walk Test (-)  
Step length (cm) (affected side) (+) |
| **Geiger et al. (2001)**      | E: Biofeedback/ Forceplate training  
C: Physical therapy | Berg Balance Scale (-)  
Timed Up-and-Go Test (-) |
| **HoYoung et al. (2015)**     | E: Tai Chi exercises  
C: Conventional Therapy | 10 Meter Walk Test (+)  
Timed Up and Go Test (+) |
| **Yoon et al. (2013)**        | E1: Self-controlled feedback  
E2: Yoked feedback  
C: No feedback | Body sway amplitudes (+) |
| **Han et al. (2013)**         | E1: Land exercise group  
E2: Underwater exercise group | Joint position sense errors (+)  
Sway area (eyes open and closed) (+)  
Berg Balance Scale (+) |

- Indicates non-statistically significant differences between treatment groups  
+ Indicates statistically significant differences between treatment groups

### Discussion

Although balance is a concern with stroke patients, particularly elderly stroke patients, and has been shown to have some prognostic value, treatments aimed at correcting balance were generally not impressive in demonstrating a significant impact on outcomes. A variety of therapy approaches were assessed including visual feedback, task-specific methods, platform training, whole body vibration, yoga, virtual reality technology, additional strength training, cycle and treadmill training.

Many different approaches including additional therapy and a variety of devices were examined among patients in both the acute and rehabilitation phases of stroke. Although a majority of studies demonstrated a benefit of balance training, the heterogeneity of interventions and outcome measures does not allow for definitive conclusions regarding the effect of balance training post-stroke.
Overall, balance training through various physiotherapy and cardiovascular exercises including the use of virtual reality devices shows conflicting findings regarding balance outcomes and those measuring lower limb motor function and kinematics. Other treatments such as those involving vibration therapy or feedback/biofeedback training failed to show an improvement in balance and gait functions.

**Conclusions Regarding Balance Disorders**

*There is level 1a evidence that whole body and local vibration training programs may not improve balance or gait.*

*There is level 1a evidence that trunk-specific training may improve balance outcomes.*

*There is conflicting level 2 evidence regarding the effect of virtual reality balance training on gait and balance outcomes.*

*There is level 1a and level 2 evidence that feedback training may not improve balance or motor function of the lower limb.*

**Trunk-specific balance training and balance-focused exercise programs may improve balance post stroke.**

**Whole body and local vibration, thermal stimulation, balance-focused exercises, and interventions involving feedback may not improve balance outcomes.**

**It is unclear whether task-specific balance training programs, and virtual reality training improve on balance, gait, and functional recovery post stroke.**

**9.3.2 Falls Prevention**

Falls are relatively common among the elderly. Each year 30% of those over the age of 65 will experience a fall (Weber et al. 1996). Those having experienced a stroke are at greater risk. During inpatient rehabilitation the reported incidence of falls ranged from 25%-39% (Dromerick & Reding 1994; Nyberg & Gustafson 1995). Upon return to the community, the risk is increased further. Forster & Young (1995) reported that up to 73% of persons had fallen within 6 months of discharge from hospital following stroke. Falls can result in injuries, which range from mild, involving soft tissues, to severe, including hip fracture. Fortunately, most falls are minor; less than 10% of falls result in fracture (Campbell et al. 1990; Tinetti et al. 1988). Loss of bone mineral density following stroke increases the risk of hip fracture, especially among women, above that seen in community-dwelling older people.

In addition to advancing age, factors associated with falls include female sex, depression, cognitive impairment, functional disability, medications, urinary incontinence and poor balance (Eng et al. 2008). Additional specific risk factors among stroke survivors include greater standing sway, impulsivity and slower response times (Hyndman et al. 2002). Due to visuospatial neglect, proprioceptive impairments and attention deficits, persons with right-sided stroke are at increased risk of falling compared to persons with left-sided lesions (Eng et al. 2008).
There is limited evidence regarding falls prevention programs following stroke. A study protocol designed specifically to address this intervention has been published (Batchelor et al. 2009). The FLASSH (FaLls prevention After Stroke Survivors return Home) project has been designed as a RCT to evaluate the effectiveness of a multi-factorial falls prevention program for stroke survivors who are at high risk of falling when they return home after rehabilitation. The intervention consists of a home exercise program as well as individualised falls prevention and injury minimisation strategies based on identified risk factors for falls. Participants will be advised to undertake the exercise program at least 5 times per week. The study aims to recruit a target of 214 subjects. The primary outcome is the number of falls at 12 months, using a falls diary.

Several RCTs have assessed the effectiveness of exercise intervention programs to reduce the risk of falls post stroke, one during inpatient rehabilitation and the other among community dwelling stroke survivors (Table 9.3.2.1).

Table 9.3.2.1 Summary of RCTs Examining Falls Prevention Programs

<table>
<thead>
<tr>
<th>Author, Year Study Design (PEDro Score)</th>
<th>Sample Size (N)</th>
<th>Intervention</th>
<th>Main Outcome(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Marigold et al. (2005)</td>
<td>RCT (8)</td>
<td>E: Agility training C: Stretching/weight-shifting training</td>
<td>Number of falls (-)</td>
</tr>
<tr>
<td></td>
<td>N&lt;sub&gt;Start&lt;/sub&gt;=61 N&lt;sub&gt;End&lt;/sub&gt;=42</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Dean et al. (2012)</td>
<td>RCT (7)</td>
<td>E: Exercise and task-related training C: Upper extremity strength training and cognitive tasks</td>
<td>Proportion of fallers (-) Rate of falls (-) 6-minute walk test (-) 10-meter Walk Test (-)</td>
</tr>
<tr>
<td></td>
<td>N=151</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Batchelor et al. (2012)</td>
<td>RCT (7)</td>
<td>E: Tailored multifactorial falls prevention C: Usual care</td>
<td>Fall rates (-) Proportion of fallers (-) Injurious falls (-) Falls risk (-) Participation (-) Activity (-) Leg Strength (-) Gait speed (-) Balance (-) Falls efficacy (-)</td>
</tr>
<tr>
<td></td>
<td>N&lt;sub&gt;Start&lt;/sub&gt;=156 N&lt;sub&gt;End&lt;/sub&gt;=132</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cheng et al. (2001)</td>
<td>RCT (6)</td>
<td>E: Symmetrical standing training and repetitive sit-to-stand training with a standing biofeedback trainer C: Conventional stroke rehabilitation</td>
<td>Number of falls (-)</td>
</tr>
<tr>
<td></td>
<td>N=54</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Tilson et al. (2012)</td>
<td>RCT (5)</td>
<td>E1: Early treadmill training with partial body-weight support (within 2 months of stroke) E2: Late treadmill training with partial body-weight support (6 months after stroke) E3: A home-based exercise program</td>
<td>Number of reported falls (-)</td>
</tr>
<tr>
<td></td>
<td>N=408</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

+ Indicates statistically significant differences between treatment groups
- Indicates non-statistically significant differences between treatment groups

Discussion

Overall, the studies included in this review failed to provide any benefits of interventions for preventing falls in individuals with lower limb impairments following a stroke. In a large RCT, various exercises...
combined with task-related training was not superior over upper extremity training for improving rate of falls and gait (Dean et al. 2012). Treadmill training with body weight support provided early after a stroke (within 2 months) provided no benefits of lowering the number of reported falls compared to when the intervention was delivered late after a stroke (after 6 months) (Tilson et al. 2012).

**Conclusions Regarding Falls Prevention Programs**

*There is level 1a evidence that exercise-based falls prevention programs may not reduce the rate of falls following stroke.*

**Exercise-based falls prevention programs may not reduce the rate of falls post-stroke.**

### 9.4 Gait Retraining

Restoration of gait is considered to be one of the primary goals of stroke rehabilitation. Mobility is often negatively impacted by stroke due to residual impairments and disabilities including impaired balance, spasticity and decreased motor control (Pohl et al. 2004). Hesse et al. (2003) notes that three months following a stroke, approximately 20% of stroke survivors remain primary wheelchair users, and walking is limited in another 60% (Stefan Hesse et al. 2003; Jørgensen et al. 1995; Wade et al. 1987). Adults with acute of subacute stroke ambulate only 40-50% of the distance that community dwelling adults without stroke are reported to walk (Pohl et al. 2004). Many techniques are currently in use to aid in the recovery of gait, however a systematic review by Hollands et al. (2012) highlights repetitive task-specific practice and/or auditory cueing as the most promising techniques for restoring gait in stroke survivors. In this section, we examine a variety of gait training techniques which includes, repetitive task-specific training (in general), treadmill training with and without body weight support, the application of virtual reality, in addition to the provision of feedback during rehabilitation.

#### 9.4.1 Repetitive Task Training

Proponents of task-specific training cite that intense training is not always necessary for positive outcomes in stroke patients, but instead suggest that therapy designed to be more task-specific within normal contact time (30 to 45 minutes per session) could be more efficacious (Page 2003). Hesse et al. (2003) notes that, “Task-specific therapy can enable hemiplegic patients to practice walking repetitively, in contrast to conventional treatment in which tone-inhibiting manoeuvres and gait-preparatory tasks during sitting and standing dominate”.

A Cochrane review by French et al. (2009) evaluated the effect of repetitive task training, on both upper and lower-extremity function. With respect to interventions aimed at improving mobility task-specific training was associated with improvements in walking distance, speed and performance in sit-to-stand. The authors concluded that task-specific training was associated with modest improvement in lower limb function. A systematic review by van de Port et al. (2007), including 14 RCTs. examined the benefit of repetitive task gait-oriented training programs. Overall, a significant treatment effect was found for the programs, with respect to outcome measures of gait speed and walking distance.

Task-oriented circuit class training is a specific form of task-specific therapy implemented in stroke patients. This type of training is usually defined as therapy that involves a tailored intervention program targeted at improving strength, balance and range of movement and includes walking practice. The therapy also involves groups rather than individuals physically moving between work stations set up at
different work stations. Circuit class training is most often provided in addition to individual physical therapy sessions (English et al., 2007). Looking beyond mobility outcomes, benefits associated with this type of training include peer support and social interaction as well as more efficient use of therapy staff.

In a Cochrane review (6 RCTs) looking at a circuit training and mobility, in contrast to control conditions, group circuit training increased gait speed, improved balance and shortened length of hospital stay (English & Hillier, 2010). Furthermore, in a meta-analysis by Wevers et al. (2009) a significant treatment effect of task-oriented circuit class training for several measures of gait were found. The effect sizes in favour of task-oriented circuit class training for walking distance were 0.43 (95% CI, 0.17 to 0.68; P<0.001), gait speed 0.35 (95% CI, 0.08 to 0.62; P=0.012), and a timed up-and-go test 0.26 (95% CI, 0.00 to 0.51; P=0.047). Nonsignificant summary effect sizes in favour of task-oriented circuit class training were found for the step test and balance control. The authors suggested that this form of training might be more beneficial when provided in the sub-acute, rather than chronic stage of stroke. There was also evidence that the training benefits were lost after the exercise sessions stopped.

Identifying training programs defined as repetitive task training can be problematic. While treadmill training is an example of this form of therapy, we have included this treatment under its own section. Similarly, studies specifically evaluating cardiorespiratory fitness training and strengthening programs have also been included in other sections. Table 9.4.1.1 includes a variety of interventions that we considered under the rubric of repetitive task training.

### Table 9.4.1.1 Summary of RCTs Examining Task-Specific Training

<table>
<thead>
<tr>
<th>Author, Year</th>
<th>Study Design (PEDro Score)</th>
<th>Sample Size (N)</th>
<th>Intervention</th>
<th>Main Outcome(s) Result</th>
</tr>
</thead>
</table>
| Blennerhassett & Dite (2004) | RCT (9) | N=30 | E: Mobility + Usual Care + Task-related practice C: Upper Limb + Usual Care + Task-related practice | • 6-minute Walk Test (+)  
• Step Test (+)  
• Timed Up-and-Go Test (+) |
| Tung et al. (2010) | RCT (8) | N=32 | E: General physical therapy + additional sit-to-stand training C: General physical therapy | • Directional control anteriorly (+)  
• Affected hip extensor strength (+)  
• Berg Balance Scale (-)  
• Extensor Muscle strength (-) |
| Salbach et al. (2004) | RCT (8) | N=91 | E: 10 functional tasks C: Upper extremity activities | • 6-minute Walk Test (+)  
• 5-meter Walk  
• Timed Up-and-Go Test (+) |
| Marigold et al. (2005) | RCT (8) | N=61 | E: Stretching and weight-shifting exercises C: Agility exercise | • Step Reaction Time (+)  
• Berg Balance Scale (-)  
• Timed Up-and-Go Step Reaction Time (+)  
• Nottingham Health Profile (-) |
| Verma et al. (2011) | RCT (8) | N=30 | E: Task-oriented circuit training C: Conventional lower extremity rehabilitation | • Functional Ambulation Category (+)  
• Rivermead Visual Gait Assessment (+)  
• Cadence (+)  
• Comfortable gait speed (+)  
• 6-minute Walk Test (+) |
van de Port et al. (2012)  
RCT (7)  
N=250  
E: Graded task specific circuit training program  
C: Usual outpatient physiotherapy  
• Mobility subscale of the Stroke Impact Scale (-)  
• 6-minute Walk Test (+)  
• 5 m comfortable walking speed test (+)  
• Modified Stairs Test (+)  
• Rivermead Mobility Index (-)  
• Nottingham extended activities of daily living (-)  
• Functional ambulation categories (-)  
• Timed-Up-and-Go Test (-)

Dean et al. (2000)  
RCT (7)  
N=12  
E: Sitting training protocol  
C: Sham sitting training protocol  
• 10-meter Walk Test (-)  
• Peak Vertical Force (-)  
• Sitting ability (-)

Yang et al. (2006)  
RCT (7)  
N=48  
E: Task-oriented progressive resistance strength training  
C: No treatment  
• Lower extremity muscle strength (-)  
• Cadence (-)  
• Stride length (-)  
• Timed up and go test (-)  
• Gait velocity (-)  
• Step test (-)  
• 6-minute walk test (-)

Yang et al. (2007)  
RCT (7)  
N=25  
E: Ball exercise program  
C: No rehabilitation training  
• Walking speed (+)  
• Cadence (+)  
• Stride time (+)  
• Stride length (+)  
• Temporal symmetry index (-)

Mudge et al. (2009)  
RCT (7)  
N=60  
E: Clinic-based rehabilitation delivered in a circuit class  
C: Comparable duration of group social and educational classes  
• 6-minute Walk Test(+)  
• Gait speed (+) (C>E)  
• Rivermead Mobility Index (+) (C>E)  
• Activities-Based Confidence Scale (-)  
• Physical Activity and Disability Scale (-)

Outermans et al. (2010)  
RCT (7)  
N=44  
E: High-intensity, task-oriented training program  
E: Conventional rehabilitation therapy  
• 10-meter Walk Test (+)  
• 6-minute Walk Test (+)  
• Berg Balance Scale (-)  
• Functional Reach test (-)

Dean et al. (2000)  
RCT (5)  
N=20  
E: Exercise circuit program for lower limbs  
C: Exercises circuit program for upper limbs  
• Sit-to-stand (+)  
• Number of repetitions (+)  
• Walking speed (+)  
• Endurance (+)  
• Force production (+)

Barreca et al. (2004)  
RCT (5)  
N=48  
E: Conventional rehabilitation + sit-to-stand training  
C: Conventional rehabilitation  
• Care Cooperative Chart Scores (-)  
• Satisfaction scores (-)

Shim et al. (2012)  
RCT (5)  
N=35  
E: Dual motor task training + physiotherapy  
C: Physiotherapy  
• Gait speed (+)  
• Cadence (+)  
• Paretic single limb support periods (+)  
• Paretic and non-paretic step (+)  
• Stride length (+)

- Indicates non-statistically significant differences between treatment groups  
+ Indicates statistically significant differences between treatment groups

**Discussion**

Findings suggests that delivering lower-limb task-related exercises improves lower limb mobility and endurance when compared against task-related practice that exercises the upper limbs (Blennerhassett & Dite 2004; Dean et al. 2000; Salbach et al. 2004). Conversely, sit-to-stand exercises improved hip
extensor strength but not the strength of the full impaired lower extremity (Tung et al. 2010). Furthermore, balance also failed to improve following the intervention (Tung et al. 2010), however the evidence for this is limited and larger trials are encouraged.

**Conclusions Regarding Task-Specific Training**

*There is level 1b and limited level 2 evidence that sit-to-stand training may not improve balance or strength of the impaired lower limb when compared to conventional therapy.*

*There is level 1a and limited level 2 evidence that resistive/strength task-oriented training may improve gait, cadence and lower limb mobility; however, it may not be beneficial for improving balance.*

**Lower extremity exercises involving resistive and strength training may improve lower limb mobility, gait and cadence however, their effect on balance is unclear.**

### 9.4.2 Treadmill Training With/Without Body-Weight Support

Treadmill training has been used, either alone or in combination with body-weight support, as a form of task-specific training. Treadmill training offers the opportunity for repetitive, practice of complex gait cycles, which can facilitate improvements in ambulatory and non-ambulatory patients.

A more recent innovation for retraining gait has been partial weight support combined with treadmill training. The body weight support (BWS) approach to motor recovery is appropriately summarized as “those who want to walk learn by walking,” (Stefan Hesse et al. 2003). As noted by both Hodgson et al. (1994) and Jordan (1991), based on animal models, various motor activity specifics such as stepping, may be induced by the brainstem and spinal cord with little cortical stimulus. Harkema et al. (1997) and Dobkin et al. (1995) both observed that sensory inputs associated with normal stepping could elicit locomotor outputs, even in those patients suffering from a complete thoracic spinal cord injury. Consequently, this has led several investigators to study body weight-supported treadmill training after stroke in an attempt to optimize locomotor-related sensory inputs to all neural regions that are involved in walking (Hassid et al. 1997; Hesse et al. 1995). This strategy is thought to increase functional independence and speed of walking. Hence, there appears to be a strong neurophysiological basis for this mode of gait retraining.

On a more practical level, BWS attempts to provide postural support and promote coordination of the lower extremities. The decreased weight bearing, theoretically, allows more physiological movement strategies by minimizing weight-bearing demands. Patient confidence is greater because of a reduced risk of falling while still engaging in the task. Body weight support can be gradually withdrawn as patients’ posture, balance and coordination improves.

Hesse et al. (2003) notes that, “treadmill with body weight support technique employs a modified parachute harness to substitute for balance deficiency. The rotating treadmill belt requires complex stepping movements. The harness is used to promote vertical body position; swinging in the harness is avoided. If the patient assumes a flexed body position, the point of suspension can be moved posteriorly so that the trunk is erect. When correctly positioned, the harness supports a proportion of body weight, allowing the patients to support the remaining weight adequately without knee collapse or excessive hip flexion during the single-stance period of the affected lower limb.”
Hesse et al. (2003) also noted that, “the appropriate patient for treadmill training with body weight support should be able to sit at the edge of the bed independently, but standing ability is not required ... initially, two (and often three) therapists are required to assist the patient’s movement on the belt, so that the patient practices stepping not only repetitively but also in a correct manner.”

Moseley et al. (2003) conducted a meta-analysis that compared treadmill training with/without BWS to other physiotherapy interventions as a means to improve gait speed, endurance and walking dependency. There was no statistically significant differences found for walking dependency and walking speed for people who were dependent in walking at the start of treatment for treadmill training with BWS compared to other physiotherapy intervention. It was noted that treadmill training with BWS appeared to have a non-significant benefit for people who were independent walkers at the start of treatment. Overall, differences in the training intensities and comparison interventions used by the independent studies included in the analysis made for very divergent findings.

An updated review of the Moseley et al. (2003) publication included 44 trials (randomized or quasi-randomized) and evaluated the effects of body weight support treadmill training in combination with other treatments or offered alone on walking ability after a stroke (Mehrholz et al. 2014). Treadmill training and body weight support for walking after stroke. The findings indicate that compared to conventional therapy or to treatments other than treadmill training with our without body weight support, the intervention was not significantly superior at improving gait but it may improve walking speed and endurance. Non-ambulatory stroke patients are not found to benefit as much as patients that are able to walk (Mehrholz et al. 2014). Treadmill training and body weight support for walking after stroke.

Research shows that gait training with BWS increases gait velocity but not the symmetrical walking pattern between the paretic and non-parectic limbs (Combs et al. 2012), suggesting that BSW treadmill training during rehabilitation is applicable for patients with a goal to walk faster. Furthermore, in a study by Hall et al. (2012) improved step length symmetry and increases in daily step counts following treadmill training with partial BWS were found to be associated with gains in self-selected walking speed.

Table 9.4.2.1 Summary Studies Evaluating of Treadmill Training Without BWS

<table>
<thead>
<tr>
<th>Author, Year Study Design (PEDro Score) Sample Size</th>
<th>Intervention</th>
<th>Main Outcome(s) Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Langhammer &amp; Stanghelle (2010) RCT (8) N=39</td>
<td>E1: Treadmill training E2: Outdoor walk</td>
<td>• 6-minute Walk Test (+) &lt;br&gt; • 10-meter Walking Speed (+) &lt;br&gt; • Bilateral Stride Length (+) &lt;br&gt; • Step width (+)</td>
</tr>
<tr>
<td>Globas et al. (2012) RCT (8) N=36</td>
<td>E: Progressive graded, high-intensity aerobic treadmill exercise C: Conventional physiotherapy</td>
<td>• Distance walked in 6-minute Walk Test (+) &lt;br&gt; • Berg Balance Scale (-) &lt;br&gt; • 5 Chair-rise (-) &lt;br&gt; • Rivermead Mobility Index (-)</td>
</tr>
<tr>
<td>Kuys et al. (2011) RCT (8) N=30</td>
<td>E: Exercise program of treadmill C: Usual physiotherapy</td>
<td>• Walking pattern (-) &lt;br&gt; • Angular kinematics (knee/hip/ankle flexion/extension) (-) &lt;br&gt; • Walking speed (-)</td>
</tr>
<tr>
<td>Study</td>
<td>Year</td>
<td>Design</td>
</tr>
<tr>
<td>-----------------------</td>
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</tr>
<tr>
<td>Liston et al. (2000)</td>
<td>RCT</td>
<td>18</td>
</tr>
<tr>
<td>Laufer et al. (2001)</td>
<td>RCT</td>
<td>25</td>
</tr>
<tr>
<td>Ada et al. (2003)</td>
<td>RCT</td>
<td>29</td>
</tr>
<tr>
<td>Macko et al. (2005)</td>
<td>RCT</td>
<td>61</td>
</tr>
<tr>
<td>Lau et al. (2011)</td>
<td>RCT</td>
<td>61</td>
</tr>
<tr>
<td>Bang et al. (2014)</td>
<td>RCT</td>
<td>12</td>
</tr>
<tr>
<td>Carda et al. (2013)</td>
<td>RCT</td>
<td>30</td>
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</table>
Table 9.4.2.2 Summary of RCTs Evaluating Treadmill Training with Body Weight Support

<table>
<thead>
<tr>
<th>Author, Year</th>
<th>Study Design (PEDro Score)</th>
<th>Sample Size (N)</th>
<th>Intervention</th>
<th>Main Outcome(s): Result</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Ada et al. (2010)</strong></td>
<td>RCT (8)</td>
<td>N=126</td>
<td>E: Treadmill walking + body weight support C: Overground walking</td>
<td>• Proportion of participants achieving independent walking within 6 mo (+)</td>
</tr>
<tr>
<td><strong>Kelley et al. (2013)</strong></td>
<td>RCT (8)</td>
<td>NStart=21, NEnd=20</td>
<td>E: Lokomat gait training + body weight supported treadmill C: Gait training</td>
<td>• Barthel Index(-)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>• 10-meter Walk Test (-)</td>
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<td></td>
<td>• 6-minute Walk Test (-)</td>
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<td></td>
<td></td>
<td>• Stroke Impact Scale (-)</td>
</tr>
<tr>
<td><strong>Eich et al. (2004)</strong></td>
<td>RCT (8)</td>
<td>N=50</td>
<td>E: Treadmill training with minimal weight bearing support + physiotherapy C: Routine physiotherapy</td>
<td>• Walking velocity (m/s) (+)</td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td>• Capacity (m) (+)</td>
</tr>
<tr>
<td>Study</td>
<td>Design</td>
<td>N Start/End</td>
<td>Intervention</td>
<td>Outcomes</td>
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<tr>
<td>MacKay-Lyons et al. (2013)</td>
<td>RCT (8)</td>
<td>50</td>
<td>E: 12-week body weight supported treadmill</td>
<td>• Berg Balance Scale (-)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>C: Usual care</td>
<td>• Chedoke-McMaster Stages of Recovery (-)</td>
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<td></td>
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<td></td>
<td></td>
<td>• PeakVO₂ (+)</td>
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<td></td>
<td>• 6-minute Walk Test (+)</td>
</tr>
<tr>
<td>Nilsson et al. (2001)</td>
<td>RCT (7)</td>
<td>73</td>
<td>E1: Walking training on a treadmill with body weight support (BWS)</td>
<td>• Functional Independence Measure (-)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>E2: Walking training according to Motor Relearning Program on the ground</td>
<td>• Walking Velocity (-)</td>
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<td>• Functional Ambulation Categories (-)</td>
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<td></td>
<td></td>
<td>• Fugl-Meyer Stroke Assessment (-)</td>
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<td></td>
<td>• Berg Balance Scale (-)</td>
</tr>
<tr>
<td>Sullivan et al. (2007)</td>
<td>RCT (7)</td>
<td>80</td>
<td>E1: Body-weight-supported treadmill training</td>
<td>• Self-selected Comfortable gait speed (+)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>E2: Limb-loaded resistive leg cycling</td>
<td>• Self-selected Fast gait speed (+)</td>
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<tr>
<td></td>
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<td></td>
<td>E3: LE muscle-specific progressive-resistive exercise and upper-extremity ergometry</td>
<td>• 6-minute walk Distance (-)</td>
</tr>
<tr>
<td>Yen et al. (2008)</td>
<td>RCT (7)</td>
<td>14</td>
<td>E: General physical therapy + body weight-supported treadmill training</td>
<td>• Walking Speed (+)</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td>C: General physical therapy</td>
<td>• Step length (+)</td>
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<td></td>
<td>• Berg Balance Scale (-)</td>
</tr>
<tr>
<td>Middleton et al. (2014)</td>
<td>RCT (7)</td>
<td>50-43</td>
<td>E: Body weighted supported treadmill training</td>
<td>• Step length differential (-)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>C: Intermixed overground gait activities</td>
<td>• 3-meter Walk Test (-)</td>
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<td>• 6-meter Walk Test (-)</td>
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<td>• Berg Balance Scale (-)</td>
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<td></td>
<td>• Dynamic Gait Index (-)</td>
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<td></td>
<td>• Activities Specific Balance Confidence Scale (-)</td>
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<td>• Single Limb Stance (-)</td>
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<td></td>
<td>• Timed Up-and-Go test (-)</td>
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<td></td>
<td>• Fugl-Meyer Scale Lower extremity subscale (-)</td>
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<td></td>
<td>• Stroke Impact Scale (-)</td>
</tr>
<tr>
<td>DePaul et al. (2015)</td>
<td>RCT (7)</td>
<td>71-58</td>
<td>E1: Motor-learning walking program</td>
<td>• Gait speed (-)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>E2: Body weight supported treadmill program</td>
<td>• 6-meter Walk Test (-)</td>
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<td></td>
<td>• Functional Balance Tests scores (-)</td>
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<td></td>
<td>• Functional Balance Test time (-)</td>
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<td></td>
<td>• Activities-specific Balance Confidence Scale (-)</td>
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<td></td>
<td>• Stroke Impact Scale (global recovery, activities of daily living, mobility, participation) (-)</td>
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<td></td>
<td>• Life Space Assessment (-)</td>
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<tr>
<td>Franceschini et al. (2009)</td>
<td>RCT (6)</td>
<td>97</td>
<td>E: Conventional rehabilitation plus gait training with body weight support on a treadmill</td>
<td>• Trunk Control test (-)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>C: Conventional treatment with overground gait training</td>
<td>• Barthel Index (-)</td>
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<td></td>
<td>• Functional Ambulation Categories (-)</td>
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<td></td>
<td></td>
<td>• 10-meter and 6-minute Walk Tests (-)</td>
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<td></td>
<td>• Walking Handicap Scale (-)</td>
</tr>
<tr>
<td>Suputtitada et al. (2004)</td>
<td>RCT (6)</td>
<td>48</td>
<td>E: Partial Body Weight Support Treadmill Training</td>
<td>• Berg Balance Scale (-)</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td>C: Conventional therapy</td>
<td>• Walking Velocity (-)</td>
</tr>
<tr>
<td>Hoyer et al. (2012)</td>
<td>RCT (6)</td>
<td>60</td>
<td>E: Treadmill training with body weight support</td>
<td>• Functional Ambulation Category (-)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>E2: Traditional overground walking</td>
<td>• 10-meter Walk Test (-)</td>
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<td>• 6-minute Walk Test (-)</td>
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<td>• EU Walking (-)</td>
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<td></td>
<td>• Functional Independence Measure (-)</td>
</tr>
<tr>
<td>Yang et al. (2010)</td>
<td>RCT (6)</td>
<td>18</td>
<td>E: 12 sessions of body-weight supported training</td>
<td>• Map size of the abductor hallucis (+)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>C: General exercise program</td>
<td>• Fugl-Meyer Assessment (+)</td>
</tr>
<tr>
<td>Study</td>
<td>Design</td>
<td>N</td>
<td>Intervention</td>
<td>Measures</td>
</tr>
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<td>-----------------------</td>
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</tr>
<tr>
<td>Duncan et al. (2011)</td>
<td>RCT</td>
<td>408</td>
<td>E1: Treadmill training with partial body-weight support (within 2 months of</td>
<td>• Proportion of patients with an improved level of functional walking (-)</td>
</tr>
<tr>
<td></td>
<td>(5)</td>
<td></td>
<td>stroke)</td>
<td>• Ability to walk independently at a speed of &gt;0.4 m/s (-) and &gt;0.8 m/s</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>E2: Treadmill training with partial body-weight support</td>
<td>(-)</td>
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<tr>
<td></td>
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<td>E3: A home-based exercise program</td>
<td>• Gait speed (-)</td>
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<td></td>
<td></td>
<td></td>
<td>• Fugl-Meyer Assessment (-)</td>
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<td></td>
<td></td>
<td></td>
<td>• Berg Balance Scale (-)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>• Activities of daily living and items on the stroke Impact Scale (-)</td>
</tr>
<tr>
<td>Da Cunha Filho et al. (2002)</td>
<td>RCT (5)</td>
<td>12</td>
<td>E: Regular rehabilitation with supported treadmill ambulation training</td>
<td>• Functional Ambulation Category Scale (-)</td>
</tr>
<tr>
<td></td>
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<td></td>
<td>C: Regular rehabilitation</td>
<td>• Gait Speed (-)</td>
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<td></td>
<td>• Walking Distance (-)</td>
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<td></td>
<td>• Gait energy expenditure (-)</td>
</tr>
<tr>
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<td></td>
<td></td>
<td></td>
<td>• Gait energy cost (-)</td>
</tr>
<tr>
<td>Moore et al. (2010)</td>
<td>RCT</td>
<td>20</td>
<td>E: Intensive locomotor training using a treadmill with body-weight support</td>
<td>• Fastest velocity (m/s) (+)</td>
</tr>
<tr>
<td></td>
<td>(4)</td>
<td></td>
<td>C: Conventional treatment</td>
<td>• Oxygen cost (mL/kg/km) (+) and peak treadmill speed) (+)</td>
</tr>
<tr>
<td>Kosak &amp; Reding (2000)</td>
<td>RCT</td>
<td>56</td>
<td>E: Partial body weight-supported treadmill training</td>
<td>• Overground walking endurance (-)</td>
</tr>
<tr>
<td></td>
<td>(4)</td>
<td></td>
<td>C: Aggressive bracing assisted walking</td>
<td>• Overground walking speed (-)</td>
</tr>
<tr>
<td>Kim et al. (2014)</td>
<td>RCT</td>
<td>36</td>
<td>E1: Progressive body weight supported treadmill forwards and backwards</td>
<td>• Affected Side Step Length (+)</td>
</tr>
<tr>
<td></td>
<td>(4)</td>
<td></td>
<td>walking training</td>
<td>• Affected Side Stance Phase (+)</td>
</tr>
<tr>
<td></td>
<td>NStart=36</td>
<td></td>
<td>E2: Progressive Body weight supported treadmill forwards walking training</td>
<td></td>
</tr>
<tr>
<td></td>
<td>NEnd=36</td>
<td></td>
<td>E3: Progressive Body weight supported treadmill backwards walking training</td>
<td></td>
</tr>
<tr>
<td>Takao et al. (2015)</td>
<td>RCT</td>
<td>18</td>
<td>E: Body weight supported treadmill training</td>
<td>• Gait speed (+)</td>
</tr>
<tr>
<td></td>
<td>(4)</td>
<td></td>
<td>C: Routine rehabilitation regimen</td>
<td></td>
</tr>
<tr>
<td></td>
<td>NStart=18</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>NEnd=18</td>
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</tbody>
</table>

- Indicates non-statistically significant differences between treatment groups
+ Indicates statistically significant differences between treatment groups

**Discussion**

The most common control condition was that of routine rehabilitation. Among the RCTs that used a two-group design with conventional rehabilitation as the control condition, several demonstrated significantly greater improvement with treadmill training (Ada et al. 2010; da Cunha et al. 2002; Eich et al. 2004; Franceschini et al. 2009; Moore et al. 2010; Nilsson et al. 2001; Werner et al. 2002; Yang et al. 2010). The MOBILISE trial recruited only non-ambulatory patients following an acute stroke reported that although the proportion of patients who achieved independent ambulation status was higher in the treadmill group, the difference was not statistically significant (Ada et al. 2010). The authors suggested that the reason that such a large number of patients achieved independent ambulation status was due to the intensity of the task-specific training. They reported that the distance patients in the control group walked in the first week of the trial was only 20% of that of patients in the experimental group. However other research has shown that differences in initial impairment did not affect functional walkability (walking speed, motor recovery, balance, functional status, and quality of life), following intervention (Duncan et al. 2011). Similarly, other studies have also demonstrated a lack of significant differences between the intervention group receiving body-weight supported treadmill training and the control group receiving conventional therapy with respect to gait, motor function, and balance (da...
Conclusions Regarding Treadmill Training

There is level 1a and level 2 evidence that treadmill training either in combination with conventional therapy or delivered alone, may improve gait velocity, stride length and lower limb functional mobility; however, it may not improve balance.

There is level 1a and level 2 evidence that partial body weight support treadmill training may not improve gait or balance outcomes compared to conventional or other gait training interventions.

Treadmill training without body weight support may improve lower limb impairments pertaining to gait velocity and function but not balance.

Body-weight supported treadmill training may not be superior to conventional therapy at improving gait, motor function, or balance.

9.4.3 Virtual Reality Training

Virtual reality (VR), also known as virtual environment, is a technology that allows individuals to experience and interact with three-dimensional environments. Virtual reality tools are classified as either immersive (the person is situated within a virtual environment via a piece of equipment that is worn, such as head-mounted display) or non-immersive (a two-dimensional environment delivered by conventional computer monitors or projector screens). Commercial gaming consoles (e.g., PlayStation EyeToy, Nintendo Wii) have been used in research to deliver VR training, however customized VR programs have also been created and tested in stroke rehabilitation.

Two Cochrane reviews have been published by Laver et al. (2011; 2012), examining the effect of VR interventions in stroke rehabilitation. Both reviews have included results from 19 RCTs (565 subjects). Pooled analysis of three independent studies (58 participants) reported no effect for improvements on gait speed (mean difference=0.07, 95% CI -0.09 to 0.23) (Laver et al. 2011). In a systematic review that specifically looking at non-immersive VR interventions as an adjunct or alternative to conventional rehabilitation therapy in stroke patients (Smith et al. 2012), when combined with conventional physiotherapy VR demonstrated to have significant improvements on balance, walking speed and function.

Table 9.4.3.1 Summary of RCTs Evaluating Virtual Reality Training

<table>
<thead>
<tr>
<th>Author, Year Study Design (PEDro Score) Sample Size</th>
<th>Intervention</th>
<th>Main Outcome(s) Results</th>
</tr>
</thead>
</table>
| Fritz et al. (2013) RCT (8) N=15                  | E: Nintendo WII E2: PlayStation 2 | • Fugl-Meyer Assessment (-)  
• Berg Balance Scale (-) 
• Dynamic Gait Index (-) 
• 6-Minute Walk Test (-) 
• 3-Meter Walk Test (-) 
• Stroke Impact Scale (-) 
• Timed Up & Go Test (-) |
<table>
<thead>
<tr>
<th>Study</th>
<th>Design</th>
<th>N Start</th>
<th>N End</th>
<th>E: Methodology</th>
<th>C: Methodology</th>
<th>Outcome Measures</th>
</tr>
</thead>
</table>
Timed Up-and-Go Test (+) 
Gait velocity (+) 
Cadence (+) |
Timed Up and Go Test (+) 
Gain speed (+) 
Cadence (+) 
Single limb support period (+) 
Double limb support period (+) 
Step length (+) 
Stride length (+) |
| Fritz et al. (2013)   | RCT (7)         | 30      | 30      | Game-play + physical therapy                                              | Game-play without physical therapy                                           | Fugl-Meyer Assessment (-) 
Berg Balance Scale (-) 
Dynamic Gait Index (-) 
6-Minute Walk Test (-) 
3-meter Walk Test (-) |
| Llorens, Gil-Gomez et al. (2015) | RCT (7) | 22      | 20      | Virtual reality-based tele-rehabilitation system                           | In-clinic                                                                     | Brunel Balance Assessment (+) 
Berg Balance Scale (-) 
Performance Oriented Mobility Assessment (-) |
Berg Balance Scale (-) 
10-meter Walk Test (-) |
| Caltagirone and Morone (2014) | RCT (7) | 50      | 30      | Balance training with Wii + physiotherapy                                   | Balance training without Wii + physiotherapy                                  | Functional Balance (+) 
Disability (+) 
Berg Balance Scale (+) 
10-minute Walk Test (+) 
Functional Ambulation Category (+) |
| Cho et al. (2013)     | RCT (7)         | 16      |         | Treadmill training program with real-world video recording                   | Treadmill training program without real-world video recording                 | Berg Balance Scale (+) 
Timed Up and Go Test (+) 
Gait velocity (+) 
Cadence (+) 
Paretic side step length (-) 
Single-limb support period (-) |
| Kang et al. (2012)    | RCT (7)         | 30      |         | Treadmill training with optic flow                                           | Control group                                                                  | Gait speed (m/sec) (+) 
Distance walked (m) (E>E2 and E>C) (+) |
| Kim et al. (2009)     | RCT (7)         | 24      |         | Virtual reality therapy + conventional physical therapy                     | Conventional physical therapy                                                 | Berg Balance Scale (+) 
Velocity (+) 
Modified Motor Assessment Scale (+) 
Cadence (+) 
Step time (+) 
Step length (+) 
Stride length (+) |
| Yang et al. (2008)    | RCT (7)         | 20      |         | Virtual reality-based treadmill training                                     | Treadmill training                                                            | Community Walking speed at post-intervention (+) 
Community walking time (+) 
Community Walking speed at follow-up (+) |
| Changho et al. (2015) | RCT (6)         |         |         | Virtual environment system ankle exercise                                    |                                                                                 | Modified Tardieu Scale (+) 
Timed Up-and-Go Test (+) |
<table>
<thead>
<tr>
<th>Study</th>
<th>Design</th>
<th>N_Start</th>
<th>N_End</th>
<th>Intervention 1</th>
<th>Intervention 2</th>
<th>Outcome Measures</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ucar et al. (2014)</td>
<td>RCT</td>
<td>22</td>
<td>22</td>
<td>Active robotic training</td>
<td>Conventional exercise</td>
<td>- 10-meter Walk Test immediately after intervention and at 8 weeks (+)</td>
</tr>
<tr>
<td>McEwen et al. (2014)</td>
<td>RCT</td>
<td>74</td>
<td>59</td>
<td>Virtual Reality exercises in standing position.</td>
<td>Virtual Reality games in a seated position.</td>
<td>- Chedoke McMaster Stroke Assessment Scale Leg domain (+)</td>
</tr>
<tr>
<td>Rajaratnam et al. (2013)</td>
<td>RCT</td>
<td>19</td>
<td>19</td>
<td>Conventional therapy + Balance trunk control training using Virtual Reality Microsoft Kinect or Nintendo Wii Fit</td>
<td>Conventional therapy</td>
<td>- Berg Balance Scale (-) - Timed Up-and-Go Test (-) - Centre of Pressure (-)</td>
</tr>
<tr>
<td>Mirelman et al. (2010)</td>
<td>RCT</td>
<td>18</td>
<td>18</td>
<td>Robotic gait training device with virtual reality assistance</td>
<td>Robotic device only</td>
<td>- Gait velocity (+) - Distance walked (+) - Number of steps taken in the community (+)</td>
</tr>
<tr>
<td>Yang et al. (2011)</td>
<td>RCT</td>
<td>14</td>
<td>14</td>
<td>Virtual reality treadmill training</td>
<td>Traditional training</td>
<td>- Centre of Pressure – related measures during quiet stance: mediolateral sway (+) - Symmetric index and sway excursion (+) - Level walking (-)</td>
</tr>
<tr>
<td>Kim, Cha et al. (2015)</td>
<td>RCT</td>
<td>20</td>
<td>18</td>
<td>Gait training + Constraint-induced movement therapy.</td>
<td>Gait training only</td>
<td>- Dynamic Balance (+)</td>
</tr>
<tr>
<td>Kim et al. (2012)</td>
<td>RCT</td>
<td>17</td>
<td>17</td>
<td>Virtual reality</td>
<td>Control group</td>
<td>- Postural control ability [postural assessment scale] (+) - Motor ability <a href="+">modified motor assessment scale</a></td>
</tr>
<tr>
<td>Jung et al. (2013)</td>
<td>RCT</td>
<td>17</td>
<td>10</td>
<td>ankle dorsiflexion therapy with augmented reality (AR)-based EMG-triggered functional electric stimulation on the tibialis anterior</td>
<td>EMG-triggered FES alone</td>
<td>- Medial gastrocnemius plantarflexion (+) - Lateral gastrocnemius plantarflexion and dorsiflexion (+) - Muscle strength during dorsiflexion and plantarflexion (+) - Ankle Range of Motion (-)</td>
</tr>
<tr>
<td>You et al. (2005)</td>
<td>RCT</td>
<td>10</td>
<td></td>
<td>Virtual reality</td>
<td>No treatment control group</td>
<td>- Functional Ambulation Categories (+) - Modified Motor Assessment Scale (+)</td>
</tr>
</tbody>
</table>

- Indicates non-statistically significant differences between treatment groups
+ Indicates statistically significant differences between treatment groups

**Discussion**

Virtual reality technology has been used in subacute and chronic stroke rehabilitation. In this review, 21 studies were collectively analyzed to evaluate the effect of virtual reality on lower limb function and balance. The studies delivered virtual reality either in combination with standard therapy or alone, and compared the effects either to standard therapy or to no therapy. While the majority of the studies...
exemplified high methodological quality, they were all low powered. There was high variability in the virtual reality therapy that was used in terms of intensity, type, and the equipment used. Despite the variability, there was no significant difference between using the Nintendo Wii and the PlayStation 2, as both equipment types functioned to improve gait and balance (Fritz et al. 2013). Much less variability was found in the outcome measures used. Balance was largely measured using the Balance Berg Scale (BBS) and the Timed-Up and Go Test (TUG). Based on these measures, balance was found to significantly improve following virtual reality therapy. The same effect was found for cadence, suggesting that virtual reality may be an effective adjunct therapy at improving lower limb impairments after a stroke. On the other hand, conflicting findings were found for gait velocity and gait outcomes.

One study showed that whether game play using a virtual reality system was supplemented with standard therapy or not, no significant difference was found regarding balance, gait, and lower limb function (Fritz et al. 2013). Conversely, supplementing virtual reality with constraint induced movement therapy resulted in an improvement in dynamic balance (Kim & Cha 2015). Whether virtual reality therapy was delivered either by a telerehabilitation system or in a clinic, no significant differences were found on oriented mobility, while the results on balance were conflicting (Llorens et al. 2015). Lastly, virtual reality therapy conducted in a standing position evoked greater improvements in leg function compared to when the exercises were conducted in a seated position (McEwen et al. 2014).

In a recent systematic review, Corbetta et al. (2015) evaluated the effects of virtual reality technology on lower limb function after a stroke. The review analyzed results from 15 trials, showing that when virtual reality therapy replaced standard rehabilitation, walking speed, balance and mobility were significantly improved (Corbetta et al. 2015). Conversely, when virtual reality therapy was delivered in addition to standard therapy, only mobility was found to be improved (Corbetta et al. 2015). These findings suggest that although virtual reality technology may provide some benefits when it supplements or replaces standard therapy, more research is needed to determine if these effects are clinically relevant. Furthermore, it is also important to consider the severity of the stroke as well as the time post-stroke to determine the ideal group of patients that can benefit the most from this intervention.

Conclusions Regarding Virtual Reality Training in Gait Training

There is level 1a and limited level 2 evidence that virtual reality combined with treadmill training may improve gait and balance post stroke.

There is level 1a and level 2 evidence that virtual reality-based interventions compared to conventional therapy may improve balance; however evidence is conflicting for gait outcomes.

Virtual reality may improve gait and balance when combined with treadmill training. When delivered alone, it may only improve balance.

9.4.4 Feedback
The provision of feedback-based training has been used as a method to help improve balance and mobility-related activities. Providing individuals with additional sensory information through the use of visual cues or auditory means may be an effective way to improve motor performance. The type of feedback provided varies to a large degree and includes but is not limited to auditory stimulation, action observation, and biofeedback methods. Research suggests that more focus needs to be given to the type/amount of attention therapists provide to patients in rehabilitation (Johnson et al. 2013), as attentional focus (feedback to patients on how they perform motor tasks) during gait rehabilitation has
been demonstrated to impact the patient’s performances and learning.

Stanton et al. (2011) conducted a systematic review (22 RCTs) that examined a variety of interventions in which feedback was provided from different sources (e.g., from the therapist, patient’s sensory system, EMG signals, etc.), as part of the rehabilitation practice. Collectively, feedback was associated with medium effect sizes for the outcome of short-term and long-term improvement in lower-limb activities (SMD=0.41; 95% CI 0.21 to 0.62 and 0.41, 95% CI 0.06 to 0.75, respectively). In a review by Zijlstra et al. (2010), which assessed the effectiveness of biofeedback among the frail elderly, post stroke patients, and older persons having undergone lower-limb surgery, application of biofeedback during balance training or during sit-to-stand transfers was found to be an effective means for improving such tasks post-stroke.

The results of trials that evaluated some form of feedback as part of a rehabilitation training program are summarized in Table 9.4.4.1.

Table 9.4.4.1 Summary of RCTs Evaluating Feedback

<table>
<thead>
<tr>
<th>Author, Year</th>
<th>Study Design (PEDro Score)</th>
<th>Sample Size (N)</th>
<th>Intervention</th>
<th>Main Outcome(s) Result</th>
</tr>
</thead>
</table>
| Barcala et al. (2013) | RCT (9) | N\text{Start}=20 N\text{End}=20 | E: Balance training with visual biofeedback using Wii Fit + Conventional physical therapy. C: Conventional physical therapy | • Stabilometry (-)  
• Berg Balance Scale (-)  
• Timed Up-and-Go Test (-)  
• Functional Independence Measure (-) |
| Khallaf et al. (2014) | RCT (8) | N\text{Start}=16 N\text{End}=16 | E: Intensive mobility training + walking program with biofeedback from pedography. C: Program of strengthening muscles and gait training with a solid ankle foot orthosis | • Maximum force values and time of contact (+) |
| Jung et al. (2015) | RCT (8) | N\text{Start}=22 N\text{End}=21 | E: Gait training with a with auditory feedback C: Gait training with a cane without auditory feedback | • Surface electromyography for the difference in muscle activation of the gluteus medius and vastus medialis oblique on the affected side versus unaffected side (+) |
| Dorsch et al. (2015) | RCT (7) | N\text{Start}=151 N\text{End}=125 | E1: Speed-only feedback group E2: Augmented feedback. | • Average daily time spent walking (-)  
• Walking Speed (-)  
• Functional Ambulation Category (-)  
• Stroke Impact Scale (-)  
• 3-minute Walking Distance (-) |
| Sungkarat et al. (2011) | RCT (7) | N=35 | E: Insole shoe wedge and sensors set-up C: Conventional programme | • Standing and gait symmetry (+)  
• Gait speed (+)  
• Step length asymmetry ratio (+)  
• Single support time asymmetry ratio (+)  
• Berg Balance Scale (+) |
| Kim et al. (2013) | RCT (6) | N\text{Start}=30 N\text{End}=27 | E1: Action observation training E2: Motor imagery training C: Physical training | • Timed Up-and-Go Test (+)  
• Cadence (+)  
• Single Limb Support of Affected Side (+) |
| Winchester et al. (1983) | RCT (6) | N=40 | E: Positional visual auditory feedback stimulation C: Physical therapy | • Ankle range of motion (-)  
• Knee extensor torque (+)  
• Spasticity of the involved knee (-) |
| Morris et al. (1992) | RCT (6) | | E: Electrogoniometric feedback C: Standard physical therapy | • Knee hyperextension (+)  
• Gait recovery (+) |
<table>
<thead>
<tr>
<th>Study</th>
<th>Design</th>
<th>N Start</th>
<th>N End</th>
<th>Condition A</th>
<th>Condition B</th>
<th>Outcome Measures</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dobkin et al. (2010)</td>
<td>RCT (6)</td>
<td>N=26</td>
<td></td>
<td>E: Feedback about self-selected fast walking speed</td>
<td>C: No reinforcement of speed after the walk</td>
<td>• Walking speed at discharge (velocity) (+) • Functional Ambulation Classification (-) • Distance walked (-)</td>
</tr>
<tr>
<td>Varoqui et al. (2011)</td>
<td>RCT (6)</td>
<td>N=179</td>
<td>N=24</td>
<td>E1: coordination biofeedback originating from the unaffected side</td>
<td>E2: coordination biofeedback originating from the affected side</td>
<td>C: Performance of a stand-up task</td>
</tr>
<tr>
<td>Chung et al. (2014)</td>
<td>RCT (5)</td>
<td>N=24</td>
<td></td>
<td>E1: coordination biofeedback originating from the unaffected side</td>
<td>E2: coordination biofeedback originating from the affected side</td>
<td>C: Performance of a stand-up task</td>
</tr>
<tr>
<td>Eun Cho et al. (2015)</td>
<td>RCT (5)</td>
<td>N=24</td>
<td>N=19</td>
<td>E1: Action Observation Gait training</td>
<td>E2: General Gait Training</td>
<td>C: Core stabilization exercise without real time feedback</td>
</tr>
<tr>
<td>Basmajian et al. (1975)</td>
<td>RCT (5)</td>
<td>N=20</td>
<td></td>
<td>E: 20 minutes of therapeutic exercise plus 20 minutes of biofeedback training</td>
<td>C: Core stabilization exercise without real time feedback</td>
<td>• Range of motion (+) • Strength of dorsiflexion (+)</td>
</tr>
<tr>
<td>Wong et al. (1997)</td>
<td>RCT (5)</td>
<td>N=60</td>
<td></td>
<td>E1: Standing training table + performance of a pushing and pulling load tasks using resistive movements of the upper limb</td>
<td>E2: Standing biofeedback training device</td>
<td>C: Core stabilization exercise without real time feedback</td>
</tr>
<tr>
<td>Schauer et al. (2003)</td>
<td>RCT (5)</td>
<td>N=23</td>
<td></td>
<td>E: Therapy sessions with musical motor feedback</td>
<td>C: Conventional gait therapy</td>
<td>• Gait velocity (+) • Stride length (+) • Gait symmetry (+) • Foot rollover (+) • Path length (+) • Gait cadence (+)</td>
</tr>
<tr>
<td>Kim &amp; Oh (2012)</td>
<td>RCT (5)</td>
<td>N=20</td>
<td></td>
<td>E: Walking comfortably at their own speed while listening to a metronome beat</td>
<td>C: Overground walking</td>
<td>All gait parameters:</td>
</tr>
<tr>
<td>Chae et al. (2011)</td>
<td>RCT (5)</td>
<td>N=21</td>
<td></td>
<td>E: Spinal stabilization exercise + Visual biofeedback</td>
<td>C: Conventional physiotherapy</td>
<td>• Velocity (-) • Cadence (-) • Step length (-) • Step Length Asymmetry Ratio (-) • Single Support Time Asymmetry Ratio (-) • Functional Ambulation Profile (-)</td>
</tr>
<tr>
<td>Kim &amp; Kim (2012)</td>
<td>RCT (4)</td>
<td>N=30</td>
<td></td>
<td>E: Action observation using video</td>
<td>C: Stretching program</td>
<td>• Step length (+) • Single support time (+) • Double support time (+) • Velocity (+) • Cadence (+)</td>
</tr>
<tr>
<td>Lee et al. (2013)</td>
<td>RCT (4)</td>
<td>N Start=22</td>
<td>N End=22</td>
<td>E: Visual feedback training</td>
<td>C: Conventional rehabilitation program</td>
<td>• Speed of Sway (+) • Velocity (+)</td>
</tr>
<tr>
<td>Study</td>
<td>Type</td>
<td>Comparator Group Descriptions</td>
<td>Outcome Measures</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>---------------</td>
<td>--------</td>
<td>-----------------------------------------------------------------------------------------------</td>
<td>----------------------------------------------------------------------------------</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Jung et al.</td>
<td>RCT (4)</td>
<td>E: 3D exercise group (Visual feedback)</td>
<td>• Berg Balance Score (+)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>C: Weight shifting exercise group</td>
<td>• 10-meter Walk Test (-)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ki et al.</td>
<td>RCT (3)</td>
<td>E: Gait training and neurodevelopmental treatment, and auditory feedback during gait training</td>
<td>• Timed Up-and-Go Test (-)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>C: Same gait training, without auditory feedback</td>
<td>• Stance (-)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• Single Limb Stance (-)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ceceli et al.</td>
<td>RCT (3)</td>
<td>E: Trained using a joint-positioning biofeedback device</td>
<td>• Degrees of recurvation (+)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Aruin et al.</td>
<td>RCT (2)</td>
<td>E: Gait training with a feedback device</td>
<td>• Recovery of step width (+)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Krewer et al.</td>
<td>PCT</td>
<td>E1: Galvanic vestibular stimulation</td>
<td>• Scale for Contraversive Pushing (-)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>E2: Driven-gait orthosis Lokomat</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>E3: Physiotherapy with visual feedback components.</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

- Indicates non-statistically significant differences between treatment groups
+ Indicates statistically significant differences between treatment groups

Discussion
There are a number of different types of devices and protocols that have been evaluated in the rehabilitative sector of stroke care. The type of feedback can be sensory specific such that it can either provide auditory, visual or somatosensory cues corresponding the motor output of the patient. Auditory feedback delivers audible sounds/tones during an exercise to correct or indicate a successful movement. In stroke rehabilitation, only a few studies have used this method to determine its effect on impaired lower extremity function. Studies demonstrate that gait parameters and muscle activity are significantly more improved following auditory feedback compared to when auditory feedback is absent (Jin-Seop & Duck-Won 2012; Jung et al. 2015; Morris et al. 1992; Schauer & Mauritz 2003). Sensory feedback and biofeedback with various gait training devices were also found to improve gait parameters however, the evidence is still limited and more studies are needed to confirm these findings. (Aruin et al. 2003; Basmajian et al. 1975; Ceceli et al. 1996; Dorsch et al. 2015; Khallaf et al. 2014; MK et al. 1997). Visual feedback or action observation is characterized by a visual output in response to a motor input. All studies in this review evaluated the use of different devices to provide auditory feedback and thus far, the evidence is conflicting and insufficient to draw meaningful conclusions regarding their effectiveness at improving balance, gait and lower limb function.

Conclusion Regarding Feedback

There is level 1a and level 2 that auditory feedback may improve gait and muscle activity.

There is limited and conflicting level 1a and level 2 evidence regarding the effect of visual feedback on balance and gait.

Auditory feedback may improve gait and muscle activity.
9.4.5 EMG / Biofeedback

Biofeedback therapy has been used as a means to improve gross motor function, which will lead to improvements in standing balance and gait, using either auditory or visual feedback. Although the treatment has been widely used for many years, and many systematic reviews published, questions still remain regarding its effectiveness. Moreland and colleagues concluded that EMG biofeedback was an effective adjunct to stroke physiotherapy in the lower limb but not in the upper limb (Moreland & Thomson 1994; Moreland et al. 1998), while Glanz et al. did not find evidence of a benefit (Glanz et al. 1996).

A Cochrane review evaluating EMG-biofeedback treatment, with either a sham or no treatment control, on motor recovery following stroke was recently published (Woodford & Price 2007). The results from 13 RCTs involving 269 subjects were included assessing recovery of both the lower and upper extremity. In terms of outcomes germane to the lower extremity, no benefit of treatment was found for any of the pooled outcomes including range of motion (knee, ankle), change in stride length, change in gait speed or change in gait quality scores.

Table 9.4.5.1 Summary of RCTs Evaluating EMG/Biofeedback Treatment in the Lower Extremity

<table>
<thead>
<tr>
<th>Author, Year</th>
<th>Study Design (PEDro Score)</th>
<th>Sample Size</th>
<th>Intervention</th>
<th>Main Outcome(s) Result</th>
</tr>
</thead>
</table>
E2: Conventional therapy that included task-specific training  
E3: Conventional therapy plus EMG biofeedback | • Ankle power (+)  
• Gait velocity (+)  
• Stride length (+)  
• Knee flexion (-) |
| Lee et al. (2015) RCT (6) | N<sub>start</sub>=25  
N<sub>end</sub>=20 | E: Neurofeedback (biofeedback provided with brain wave control stimulation)  
C: Pseudo-neurofeedback (sham neurofeedback training) | • Dual task performance test (+)  
• Gait velocity (+)  
• Cadence (+)  
• Plantar Foot pressure of entire foot and forefoot (+)  
• Brain wave activity Test (+) |
| Cozean et al. (1988) RCT (6) | N=36 | E1: Electromyographic Biofeedback  
E2: Functional electrically stimulation  
E3: Combined therapy with BFB and FES  
C: Control therapy | • Knee flexion (+) (E3 vs C)  
• Ankle dorsiflexion (+) (E3 vs C) |
| Burnside et al. (1982) RCT (6) | N=22 | E: Exercise program + EMG-biofeedback  
C: Exercise program + Sham EMG | • Strength of Dorsiflexion (+)  
• Active Range of Movement at the ankle (-)  
• Basmajian’s rating scale for gait evaluation (-)  
• Medical Research Council (-) |
| Bradley et al. (1998) RCT (6) | N=21 | E: Electromyography biofeedback training + Physiotherapy  
C: Physiotherapy | • Active movement (-)  
• Mobility (-)  
• Activities of daily living (-) |
| Intiso et al. (1994) RCT (6) | N=16 | E: Electromyography biofeedback (EMG BFB) +Physical therapy (without standard exercises)  
C: Physical therapy + Bobath method, with standard exercises | • Barthel Index (-)  
• Step length (-)  
• Velocity (-)  
• Ankle dorsiflexion in swing phase (+)  
• Basmajian rating scale for gait (-) |
| Mandel et al. (1990) RCT (4) | | E1: Received only EMG-BFB treatment  
E2: Received EMG-BFB 1<sup>st</sup> half of treatment | • Walking Speed: E1 vs C (+); E2 vs C (+) |
N=37 and then rhythmic positional BFB for the 2nd half.
C: No treatment

Mulder et al. (1986)
RCT (3)
N=12
E: EMG feedback in the re-learning of motor control to the
C: Conventional physical therapy procedure (NDT)
- Range of Motion (-)
- Gait (-)

Discussion
A variety of EMG-biofeedback interventions have been studied in the stroke population. Thus far, this review found conflicting findings regarding the effects of this intervention on lower limb function, specifically pertaining to gait kinematics. In a systematic review by Stanton et al. (2011), a total of 19 RCTs were included in the analysis scoring a mean of 5.7 on the PEDro scale for methodological quality. The results of the meta-analysis revealed a significant effect of biofeedback on lower limb activities at post-intervention. However, the study also has several limitations which may have led to an overestimate of the biofeedback effect. The outcomes measured varied between studies and the time since stroke was also not consistent as it ranged from acute to chronic. The small trials limited the power of the studies and the lack of blinding may have introduced bias in the collection/analysis of the data. The need for larger trials is therefore evident to determine if this intervention is beneficial at improving lower limb impairments.

Recent evidence has yielded more consistent results. Jonsdottir et al. (2010) reported improvements in ankle power, gait velocity and stride length in individuals who underwent conventional therapy plus EMG biofeedback compared to their conventional therapy counterparts. More recently, Lee et al. (2015) demonstrated increases in gait velocity, cadence and duel-task performance in the neurofeedback group compared to the shame neurofeedback control group. Further research is required to determine if EMG-biofeedback has a significant effect on lower limb stroke recovery.

Conclusions Regarding EMG/Biofeedback Treatment in Lower Extremity

There is conflicting level 1a and level 2 evidence regarding the effect of EMG/Biofeedback on lower limb function following stroke.

The evidence for the effectiveness of EMG-Biofeedback is conflicting and limited. Further research is required.

9.4.6 Bilateral Leg Training
Bilateral arm training has been used with some success in the rehabilitation of the upper extremity. As a result, a single group of researchers questioned whether the technique could also be used effectively in the lower extremity.

Table 9.4.6.1 Summary of Bilateral Leg Training

<table>
<thead>
<tr>
<th>Author, Year Country PEDro Score</th>
<th>Methods</th>
<th>Outcomes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Johannsen et al. (2010)</td>
<td>E: A custom-made device (BLETRAC) enabling various</td>
<td>• Fugl-Meyer Scale (-)</td>
</tr>
</tbody>
</table>
9. Mobility and the Lower Extremity

**RCT (7)**
N=24

<table>
<thead>
<tr>
<th>Study Design (PEDro Score)</th>
<th>Intervention</th>
<th>Main Outcome(s)</th>
</tr>
</thead>
</table>
| C: Device enabling bilateral arm movements (BATRAC), which served as the control condition | • 10-meter Walk Test (-)  
• Step Length (-) | + Indicates a statistically significant difference between treatment groups  
- Indicates a non-statistically significant difference between treatment groups |

**Discussion**

One RCT was used in this review to determine the efficacy of bilateral leg exercises to aid in lower limb recovery following a stroke. Johannsen et al. (2010) tested a custom made device enabling various lower limb bilateral movements against a device enabling bilateral upper limb movements serving as the control group. Results showed no significant difference in Fugl-Meyer Scale, 10-meter Walk Test nor Step Length between the lower limb and upper limb groups suggesting that bilateral leg training with a custom-made device does not improve lower limb motor function.

**Conclusions Regarding Bilateral Leg Training**

*There is level 1b evidence that that bilateral leg training with a custom-made device may not improve lower limb motor function.*

More research is needed to determine the effectiveness of bilateral leg training on lower limb motor function.

**9.4.7 Motor Imagery/ Mental Practice**

The use of motor imagery (MI) or mental practice (MP) as a means to enhance performance following stroke was adapted from the field of sports psychology. In athletes, this technique has been shown to improve athletic performance when used as an adjunct to standard training methods. The technique, as the name suggests, involves rehearsing a specific task or series of tasks, mentally. A series of small trials have adapted and evaluated the effects of mental practice as a treatment following stroke. Mental practice can be used to supplement conventional therapy and can be used at any stage of recovery. The use of MP following stroke has been studied predominantly in the recovery of upper extremity function (Module 10); however, some research has been done looking at the application of MP in the recovery of lower limb function. Systematic reviews exploring the efficacy of MP in stroke rehabilitation (upper and lower limb trials together) have been conducted (Braun et al. 2013; El-Shennawy & El-Wishy 2012). While there is some evidence for MP in improving functional recovery of chronic stroke patients (El-Shennawy & El-Wishy 2012), there is a lack of evidence for MP improving outcomes related to mobility (Braun et al. 2013). Overall, the authors of the reviews note that evidence is limited, results are equivocal, and it is unclear as to whether or not improvements are retained over time.

Table 9.4.7.1 lists studies examining mental practice incorporated or as an adjunct to lower limb rehabilitation.

**Table 9.4.7.1 Summary of RCTs Evaluating Mental Practice and Motor Imagery**

<table>
<thead>
<tr>
<th>Author, Year Study Design (PEDro Score)</th>
<th>Intervention</th>
<th>Main Outcome(s) Result</th>
</tr>
</thead>
</table>
| Braun et al. (2012) RCT (7) N=36        | E: Mental practice  
C: Conventional rehabilitation | • Self-perceived performance (-)  
• Rivermead Mobility Index (-)  
• Berg Balance Scale (-) |
9. Mobility and the Lower Extremity

Schuster et al. (2012)  
RCT (7)  
N=41  
E: Mental imagery + physiotherapy  
C: Listened to audio tapes  
• 10-meter Walk Test (-)  
• Time difference in performance (-)

Malouin et al. (2009)  
RCT (6)  
N=12  
E1: Mental practice + physical practice  
E2: Physical practice + cognitive training  
C: No training  
• Limb loading during both rising and sitting: E1 vs E2 (+); E1 vs C (+)

Hosseini et al. (2012)  
RCT (6)  
N=30  
E: Mental practice sessions + conventional therapy  
C: Conventional therapy  
• Timed Up-and-Go Test (+)  
• Berg Balance Scale (+)

Lee et al. (2015)  
RCT (6)  
NStart =36  
NEnd=36  
E: Proprioception training that consisted of tasks on a balance pad and motor imagery training  
C: Proprioception training only  
• Berg Balance Scale (+)  
• Timed Up-and-Go test (+)  
• Joint position sense error (+)  
• Affected/Unaffected side weight bearing ratio (+)

Cho et al. (2013)  
RCT (6)  
NStart =28  
NEnd=28  
E: Motor imagery  
C: Gait training  
• Fugl-Meyer Assessment (+)  
• Timed Up-and-Go Test (+)  
• 10-minute Walk Test (+)

Park et al. (2013)  
RCT (4)  
NStart =20  
NEnd=20  
E: Functional Electrical Stimulation + video  
C: Functional Electrical Stimulation without training video  
• Weight distribution (anterior-posterior) (+)  
• Weight distribution (right-left) (+)  
• Stability Index (+)  
• Gait velocity (+)

- Indicates non-statistically significant differences between treatment groups  
+ Indicates statistically significant differences between treatment groups

Discussion
Research on mental imagery however, is much more consistent. Not only does mental practice yield the same gait and balance outcomes as conventional rehabilitation (Braun et al. 2012), but when combined with physical training, mental practice improves both balance and gait (Hosseini et al. 2012; Malouin et al. 2009). Furthermore, mental imagery has also shown significant improvement in balance and gait performance when combined with proprioception training (Lee et al. 2015), gait training (Cho et al. 2013) and functional electrical stimulation (Park et al. 2013).

Conclusions Regarding Mental Practice

There is level 1a and limited level 2 evidence that mental practice/motor imagery may improve gait and balance outcomes.

Mental practice or motor imagery may improve gait and balance outcomes post-stroke.

9.4.8 Horse Riding Simulation/ Hippotherapy
Horse riding stimulation / hippotherapy has not been widely researched as a rehabilitative therapy for lower limb recovery post-stroke but has received recent attention. The rhythmic and repetitive movement of the horse stimulates all of the senses and has been reported that this is similar to the movement pattern of the pelvis when a person is walking (Cunningham 2009). As a result, hippotherapy has garnered attention as a rehabilitative method for lower limb stroke recovery.
Table 9.4.8.1 Summary of Studies Evaluating Hippotherapy

<table>
<thead>
<tr>
<th>Author, Year</th>
<th>Study Design (PEDro Score)</th>
<th>Intervention</th>
<th>Main Outcome(s) Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sung et al. (2013)</td>
<td>RCT (6)</td>
<td>E: Hippotherapy simulator</td>
<td>• Gait performance (-)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>C: Conventional rehabilitation</td>
<td>• Time in step length (-)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• Stance phase (-)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• Swing phase (-)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• Cadence (-)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• Single support and load response (+)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• Double support (-)</td>
</tr>
<tr>
<td>Lee et al. (2015)</td>
<td>RCT (6)</td>
<td>E: Hippotherapy</td>
<td>• Berg Balance Scale (+)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>C: Sham therapy</td>
<td>• Timed Up and Go test (+)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• Beck Depression Inventory (+)</td>
</tr>
<tr>
<td>Lee, Kim, Yong et al. (2014)</td>
<td>RCT (5)</td>
<td>E: Hippotherapy</td>
<td>• Step length asymmetry ratio (+)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>C: Treadmill training</td>
<td>• Berg Balance Scale (-)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• Gait velocity (-)</td>
</tr>
<tr>
<td>Baek et al. (2014)</td>
<td>RCT (4)</td>
<td>E: Horse riding simulation training that simulates three directional movements.</td>
<td>• Centre of pressure (COP) path length (+)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>C: Trunk exercises using Swiss balls.</td>
<td>• COP travel speed (+)</td>
</tr>
<tr>
<td>Beinotti et al. (2010)</td>
<td>PCT</td>
<td>E: Conventional therapy and horse therapy (hippotherapy)</td>
<td>• Functional Ambulation Category (-)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>C: Conventional treatment</td>
<td>• Fugl-Meyer Assessment Scale (+)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• Berg Balance Scale (-)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• Cadence (-)</td>
</tr>
<tr>
<td>Han et al. (2012)</td>
<td>PCT</td>
<td>E: Mechanical horseback riding therapy + conventional therapy</td>
<td>• Balance Part of Performance Oriented Mobility Assessment (B-POMA): sitting (-); standing (-); dynamic balance (+)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>C: Conventional therapy</td>
<td>• Berg Balance Scale (+)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• Functional Ambulation Scale (-)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• Gait Part of Performance Mobility Assessment (G-POMA) (-)</td>
</tr>
</tbody>
</table>

- Indicates non-statistically significant differences between treatment groups
+ Indicates statistically significant differences between treatment groups

Discussion

Limited evidence exists as to the efficacy of hippotherapy as a treatment for lower limb stroke recovery. Recent evidence suggests that hippotherapy does not improve gait outcomes compared to conventional rehabilitation (Sung et al. 2013) or treadmill training (Lee et al. 2014). However, there is evidence to suggest that hippotherapy does improve foot pressure (Sung et al. 2013) and centre of pressure length and speed (Baek & Kim 2014). Furthermore, there is conflicting evidence of the effect of hippotherapy on balance outcomes. Lee et al. (2014) reported no improvement in berg balance scale scores compared to treadmill training, whereas Lee et al. (2015) showed an increase in berg balance scale scores in hippotherapy treatment compared to a sham therapy. Additionally, two prospective controlled trials reported conflicting results for balance outcomes with Han et al. (2012) reporting an increase in balance scores and Beinotti et al. (2010) showing no significant difference between hippotherapy paired with conventional treatment and the control conventional treatment.
Conclusions Regarding Hippotherapy

There is level 1a and level 2 evidence that hippotherapy may not improve gait outcomes; however there may be an improvement on foot pressure. The evidence for balance is conflicting.

**Hippotherapy may not improve gait outcomes. More research is needed to determine the effect of hippotherapy on balance.**

### 9.4.9 Rhythmic Auditory Stimulation

Rhythmic auditory stimulation is a form of gait therapy that involves the sensory cuing of motor systems. The rhythmic auditory stimulus provides a time reference for motor gait response. The gait response and the auditory stimulus develop into a stable temporal relationship (Thaut et al. 1997). As a result, researchers are interested in the effects of rhythmic auditory stimulation on lower limb stroke recovery.

#### Table 9.4.9.1 Summary of RCTs Evaluating Rhythmic Auditory Stimulation

<table>
<thead>
<tr>
<th>Author, Year</th>
<th>Study Design (PEDro Score)</th>
<th>Intervention</th>
<th>Main Outcome(s) Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Suh et al. (2014)</td>
<td>RCT (9)</td>
<td>E: Rhythmic auditory stimulation C: Gait training without rhythmic auditory stimulation</td>
<td>• Overall stability index of the standing balance parameter (+) • Mediolateral index of the standing balance parameter (+) • Anteroposterior index (+)</td>
</tr>
<tr>
<td></td>
<td>N\text{Start}=16 N\text{End}=16</td>
<td>E: Rhythmic auditory stimulation training with intensive gait training C: Intensive gait training without RAS</td>
<td>• Gait velocity (+) • Cadence (+) • Stride length (+)</td>
</tr>
<tr>
<td>Cha et al. (2014)</td>
<td>RCT (7)</td>
<td>E: Program of rhythmic auditory stimulation C: Neurodevelopmental therapy (NDT)/Bobath-based training</td>
<td>• Gait velocity (+) • Stride length (+) • Cadence (+)</td>
</tr>
<tr>
<td></td>
<td>N=78</td>
<td>E: Program of RAS-muscle movement program C: Usual care</td>
<td>• Ankle extension (+) • Ankle flexion (-)</td>
</tr>
<tr>
<td>Jeong &amp; Kim. (2007)</td>
<td>RCT (5)</td>
<td>E: Gait training with the addition of rhythmic auditory stimulation C: Twice-daily gait training</td>
<td>• Velocity (+) • Stride length (+)</td>
</tr>
<tr>
<td></td>
<td>N=33</td>
<td>E: Gait training without rhythmic auditory stimulation C: Gait training without RAS</td>
<td></td>
</tr>
</tbody>
</table>

- Indicates non-statistically significant differences between treatment groups
+ Indicates statistically significant differences between treatment groups

#### Discussion

The effective of rhythmic auditory stimulation on lower limb stroke rehabilitation in current research is relatively consistent. Thaut et al. (2007) determined that a rehabilitation program consisting of rhythmic auditory stimulation is more effective in improving gait and balance compared to neurodevelopmental therapy. Various other studies have reported improvements in both gait and balance with rhythmic auditory stimulation compared to traditional gait therapy (Cha et al. 2014; Suh et al. 2014; Thaut et al. 1997). However, it is important to note that these studies contained relatively low sample sizes. There is limited evidence to suggest RAS improves ankle flexion and extension, however...
some evidence suggests an increase in range of motion for extension but not flexion (Jeong & Kim 2007).

**Conclusions Regarding Rhythmic Auditory Stimulation**

*There is level 1a and level 2 evidence that rhythmic auditory stimulation training may improve gait and balance outcomes; however there is limited evidence for its effect on ankle range of motion.*

*Rhythmic auditory stimulation training may improve gait and balance outcomes post-stroke.*

9.4.10 Mirror Therapy

Mirror therapy has been used to improve upper limb motor function in stroke patients (see Module 10) and has been suggested to improve postural stability when used to rehabilitate lower limb impairments. The therapy involves the use of a mirror to watch their own reflection when performing exercises, thus recognizing errors in their posture or movement.

**Table 9.4.10.1 Summary of RCTs Evaluating Mirror Therapy**

<table>
<thead>
<tr>
<th>Author, Year</th>
<th>Study Design (PEDro Score)</th>
<th>Intervention</th>
<th>Main Outcome(s) Result</th>
</tr>
</thead>
</table>
| Cha et al. (2015) | RCT (8) | E: Mirror therapy + rTMS  
C: Mirror therapy + Sham rTMS | • Balance Index (+)  
• Dynamic limits of stability (+) |
| Mohan et al. (2013) | RCT (7) | E: Mirror therapy  
C: Conventional therapy | • Fugl-Meyer Assessment (-)  
• Brunel Balance Assessment (-)  
• Functional Ambulation Category (-) |

**Discussion**

A study conducted by Chan et al. (2015) found that mirror therapy in combination with rTMS is effective in improving balance in post-stroke patients compared to the non-rTMS control group. However, research also suggests that mirror therapy alone is not sufficient for improving functional recovery, balance or gait when compared to conventional therapy (Mohan et al. 2013). These findings suggest that mirror therapy may be effective in lower limb stroke recovery in combination with other proven recovery methods.

**Conclusions Regarding Mirror Therapy**

*There is level 1b evidence that mirror therapy combined with repetitive transcranial magnetic stimulation may improve balance; however, when provided alone, level 1b evidence indicates no additional benefit for lower limb function compared to conventional therapy.*

*Mirror therapy in combination with rTMS improves balance; however, when delivered alone, mirror therapy does not provide additional benefits to gait and lower limb motor function relative to conventional therapy.*
9.4.11 Self-Management Programs
Self-management programs involve self-monitoring and modification of ones behaviour (Dinsmore et al., 2008). Self-management requires individuals to identify and solve problems, internal motivation and reflecting and improving on past experiences with the direction of others (Goverover et al. 2007). Self-management programs have not been extensively researched, but may have applications in stroke rehabilitation.

Table 9.4.1.1 Summary of RCTs Evaluating Self-Management Programs

<table>
<thead>
<tr>
<th>Author, Year</th>
<th>Study Design (PEDro Score)</th>
<th>Intervention</th>
<th>Main Outcome(s): Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lindvall &amp; Forsberg. (2014) RCT (7) N&lt;sub&gt;Start&lt;/sub&gt;=46 N&lt;sub&gt;End&lt;/sub&gt;=42</td>
<td>E: Body awareness therapy C: Conventional care</td>
<td>• Berg Balance Scale (-) • Timed Up-and-Go Test (-) • 6-minute walk test (-) • TUG &amp; Cognitive Test (-) • Activities-specific Balance Confidence Scale (-) • Short Form-36 (-) • Timed-Stands Test (-)</td>
<td></td>
</tr>
<tr>
<td>Liu &amp; Chan. (2014) RCT (7) N&lt;sub&gt;Start&lt;/sub&gt;=46 N&lt;sub&gt;End&lt;/sub&gt;=44</td>
<td>E: Self-regulation therapy C: Functional rehabilitation</td>
<td>• Functional Independence Measure – Motor (+) • Functional Independence Measure – Cognitive (-) • Fugl Meyer Assessment (-) • Colour Trials Test (-)</td>
<td></td>
</tr>
</tbody>
</table>

- Indicates non-statistically significant differences between treatment groups
+ Indicates statistically significant differences between treatment groups

Discussion
There is limited, although consistent, evidence suggesting self-management programs may not improve gait and balance measures post-stroke (Lindvall & Forsberg 2014; Liu & Chan 2014). Liu et al. (2014) did report evidence of increased motor functional independence in the self-regulation group compared to the control group. Overall, the limited results suggest that self-management programs may not be the optimal method for lower limb recovery following stroke.

Conclusion Regarding Self-Management Programs

*There is level 1a evidence that self-management programs may not improve gait and balance.*

**Self-management programs may not improve gait or balance post stroke.**

9.4.12 Caregiver Mediated Programs
A major component of stroke rehabilitation is exercise that continues beyond patient discharge. Caregiver mediated programs allow primary caregivers to assume responsibility for home-based exercise programs following patient discharge. There is limited research testing the efficacy of caregiver mediated programs.

Table 9.4.12.1 Summary of RCTs Caregiver Medicated Programs

<table>
<thead>
<tr>
<th>Author, Year</th>
<th>Study Design (PEDro Score)</th>
<th>Intervention</th>
<th>Main Outcome(s): Result</th>
</tr>
</thead>
</table>

9. Mobility and the Lower Extremity  www.ebrsr.com  pg. 45 of 177
Wang et al. (2015) (RCT) 8
N_{Start}=51
N_{End}=51

<table>
<thead>
<tr>
<th>E: Personalized caregiver-mediated home-based training</th>
<th>C: Traditional physiotherapy visits without intervention</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Stroke Impact Scale (+)</td>
<td></td>
</tr>
<tr>
<td>• Berg Balance Scale (+)</td>
<td></td>
</tr>
<tr>
<td>• 10-meter Walk Test (+)</td>
<td></td>
</tr>
<tr>
<td>• 6-minute Walk Test (+)</td>
<td></td>
</tr>
<tr>
<td>• Barthel Index (+)</td>
<td></td>
</tr>
<tr>
<td>• Caregiver Burden Scale (-)</td>
<td></td>
</tr>
</tbody>
</table>

- Indicates non-statistically significant differences between treatment groups
+ Indicates statistically significant differences between treatment groups

Discussion

Only one study was used in this review (Wang et al. 2015). Wang et al. (2015) tested various outcomes between personalized caregiver-mediated home-based (CHI) training and a control group that received physiotherapist visits without intervention. Results suggest that CHI training is significantly more effective in improving gait and balance post-stroke compared to the control group (Wang et al., 2015). Furthermore, the results suggest that there was no difference in the burden of the caregiver compared to the control group (Wang et al. 2015). Therefore, caregiver mediated programs may be an effective method to improve gait and balance post-stroke.

Conclusions Regarding Caregiver Mediated Programs

There is level 1b evidence that caregiver mediated programs may improve gait and balance outcomes.

Caregiver mediated programs may improve gait and balance outcomes post-stroke; however additional research is needed.

9.5 Strength Training

9.5.1 Weakness Post-Stroke

Weakness has been defined as inadequate capacity to generate normal levels of muscle force (Miller et al. 1998). Gray et al. (2012) revealed that patients experience decreases in muscle fibre length, and lean muscle mass, although the latter increases in the upper extremities. Neural input to the muscle are reduced resulting in weakness and a decrease in muscle fibre length which the fibres may adapt to if the muscle is not moved through the full range of motion (Gray et al. 2012). In contrast, Klein et al. (2013) did not find any significant differences in muscle volume or atrophy between the contralesional and ipsilesional limbs in relation to weakness but did report smaller levels of maximal voluntary contraction torque in the contralesional limb which was associated with deficits in twitch interpolation (activation) and electromyographic amplitude. Significant reductions in Insulin-like Growth Factor 1 (IGF1) and IGF Binding Protein 3 (IGFBP-3) have also been found to be potential biomarkers for decreases in muscle strength with each serum correlated with concentric extensor peak torque of the non-paretic limbs, and peak torque, work and power of the paretic limbs respectively (Silva-Couto Mde et al. 2014). Miller et al. have noted that weakness as a prominent concern in hemiplegic or hemiparetic stroke patients is sometimes overshadowed over concerns about treatment of spasticity and synergistic movements (Miller et al. 1998). Miller et al. (1998) also reported that Fenischel and Daroff (1964) had noted that because muscles with hyperactive stretch reflexes demonstrate atrophy, spastic muscles could become weak.
9.5.2 Relationship between Strength and Functional Activities Post Stroke

Correlational studies have examined the relationship between lower limb strength and functional capabilities post stroke (Bohannon 1986, 1987, 1988, 1989, 1992; Bohannon & Andrews 1990; Bohannon & Walsh 1992; Bohannon et al. 1991; Lindmark & Hamrin 1995; Miller et al. 1998; Sunderland et al. 1989). These studies have revealed positive, statistically significant correlations between the strength of specific muscle groups and a variety of functional attributes. For example, research has shown that ankle dorsiflexion strength of the affected leg following stroke is a statistically significant predictor of walking performance (Ng & Hui-Chan 2012). Furthermore, a nonlinear relationship has been found between walking performance and muscle strength in the lower extremities, suggestive of a threshold which muscle strength is sufficient to perform functional activity (walking speed) (Carvalho et al. 2013). Fayazi et al. (2014) also reported a significant correlation between lower extremity strength and multiple functional mobility measures but found no relationship between lower limb spasticity and mobility. However, Miller et al. (1998) noted that, “results should be viewed carefully given the uncertainties associated with the validity of strength assessment in these patients. Furthermore correlation studies do not infer causation...”. In one non-correlational study, muscle strength alone had been found to account for 29% of the variance on the 6-Metre Walk Test and this increased to 70% when confounders such as spasticity, balance and comorbidity were entered into a regression model (Moriello et al. 2011). The authors suggest that strength training, with particular emphasis on the hip flexors in the supine position, would be beneficial to walking ability (Moriello et al. 2011).

9.5.3 Strength Training

Muscle strengthening as an intervention is designed to improve the force-generation capacity of hemiplegic limbs post stroke and enhancing functional abilities. Forster and Young (1995) noted that, “current physiotherapy programmes do not include muscle strengthening as it has been argued that strength training increases spasticity (Bobath 1990)”. Since this statement was made, several studies have provided evidence that resistive training in the lower limb can produce strength gains for stroke patients (Engardt et al. 1995; Sharp & Brouwer 1997). Some research demonstrates that strength gains may not translate into improved functional performance (Weiss et al. 2000) and that training might be most effective if it is specific to the desired outcome (Ng & Shepherd 2000). A systematic review of resistance strength training, authored by Morris et al. (2004) included three RCTs (Bourbonnais et al. 2002; Giuliani et al. 1992; Inaba et al. 1973) as well as five non-experimental studies (Bütefisch et al. 1995; Engardt et al. 1995; Karimi 1996; Sharp & Brouwer 1997; Weiss et al. 2000). There was evidence that progressive resistance strength training increased muscle strength following stroke, without increasing spasticity, however the potential beneficial effects on functional outcome were uncertain. The variability of training methods and the intensities of the strength-training programs make general statements of conclusions difficult.

An additional systematic review by Ada et al. (2006), that included interventions for both upper and lower extremities, showed an overall treatment effect [0.33 standardized mean difference (SMD) (95% CI: 0.13 to 0.54, p=0.001)]. For the strengthening interventions. The overall effect on activity was 0.32 SMD (95% CI: 0.11 to 0.53, p=0.002). There was no significant treatment effect for the reduction of spasticity. The authors concluded that strengthening interventions should be a part of a stroke rehabilitation program.

Table 9.5.3 Summary of RCTs Evaluating Strength Training

<table>
<thead>
<tr>
<th>Author, Year Study Design (PEDro Score) Sample Size (N)</th>
<th>Intervention</th>
<th>Main Outcome(s) Result</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Study</th>
<th>Design</th>
<th>N Start/N End</th>
<th>Exercise (E)</th>
<th>Control (C)</th>
<th>Outcomes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mares et al. (2014)</td>
<td>RCT</td>
<td>52/44</td>
<td>E: Functional strength training for upper limb</td>
<td>C: Functional strength training for lower limb</td>
<td>• Arm Research Action Test (+)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>• Functional Ambulation Categories (-)</td>
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<td></td>
<td>• Modified Rivermead Mobility Index (-)</td>
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<td></td>
<td>• Timed Up-and-Go Test (-)</td>
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<td>• 9-Hole Peg Test (-)</td>
</tr>
<tr>
<td>Mead et al. (2007)</td>
<td>RCT</td>
<td>66</td>
<td>E: Strength and resistance exercise</td>
<td>C: Relaxation</td>
<td>• Functional Independent Measure (-)</td>
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<td></td>
<td>• Rivermead Mobility Index (-)</td>
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<td>• Sit-to-stand Test (-)</td>
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<tr>
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<td></td>
<td></td>
<td>• Elderly Mobility Score (-)</td>
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<td></td>
<td></td>
<td></td>
<td>• Timed Up-and-Go Test (-)</td>
</tr>
<tr>
<td>Clark &amp; Patten (2013)</td>
<td>RCT</td>
<td>35/33</td>
<td>E1: Eccentric resistance training + Gait training</td>
<td>E2: Concentric resistance training + Gait training</td>
<td>• Eccentric power gains (+)</td>
</tr>
<tr>
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<td></td>
<td>• Concentric power gains (+)</td>
</tr>
<tr>
<td></td>
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<td></td>
<td>• Paretic Rectus Femoris activation (+)</td>
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<td>• Paretic Vastus Medialis activation (+)</td>
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<td>• Self-selected speed (-)</td>
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<td></td>
<td>• Fastest walking speed (-)</td>
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<td>• Net change in agonist activation (-)</td>
</tr>
<tr>
<td>Lee et al. (2010)</td>
<td>RCT</td>
<td>48</td>
<td>E1: Progressive resistance training (PRT) + cycling</td>
<td>E2: Cycling + Sham PRT</td>
<td>• Lower limb muscle strength (+)</td>
</tr>
<tr>
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<td>• Peak power (+)</td>
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<td></td>
<td></td>
<td></td>
<td>• Muscle endurance (+)</td>
</tr>
<tr>
<td>Cooke et al. (2010)</td>
<td>RCT</td>
<td>109</td>
<td>E1: Conventional Physiotherapy (CPT) + CPT</td>
<td>C: Conventional physiotherapy</td>
<td>• Walking speed 0.8m/s (E1 vs C) (+); (E2 vs C) (-)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>• Knee flexion peak torque (E1 vs C) (+); (E2 vs C) (-)</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>• Knee extensor peak torque (-)</td>
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<td></td>
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<td></td>
<td></td>
<td></td>
<td>• Rivermead Mobility Index (-)</td>
</tr>
<tr>
<td>Ouellette et al. (2004)</td>
<td>RCT</td>
<td>42</td>
<td>E: Progressive resistance training</td>
<td>C: Upper extremity stretching</td>
<td>• Bilateral leg press strength (+)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>• Knee extensor strength (+)</td>
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<td></td>
<td>• Ankle plantarflexion strength (+)</td>
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<td>• Ankle dorsiflexor strength (paretic only) (+)</td>
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<td></td>
<td>• Late Life Function and Disability Instrument (LLFDI): Advanced Lower Extremity (+)</td>
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<td></td>
<td></td>
<td>• LLFDI: Basic Lower Extremity (-)</td>
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<td></td>
<td>• 6-minute Walk (-)</td>
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<td></td>
<td>• Maximal gait velocity (-)</td>
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<td>• Habitual gait velocity (-)</td>
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<td>• Stair climb time (-)</td>
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<td>• Repeated chair-rise time (-)</td>
</tr>
<tr>
<td>Kim et al. (2015)</td>
<td>RCT</td>
<td>37/30</td>
<td>E1: Affected side knee belt was fastened and one-leg standing training using the less-affected side knee</td>
<td>C: Both knee belts of the tilt table were fastened</td>
<td>• Strength of hip flexors (+)</td>
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<td>• Strength of hip extensor (+)</td>
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<td>• Strength of knee flexors (+)</td>
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<td>• Strength of knee extensors (+)</td>
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<td>• Strength of ankle dorsiflexors (+)</td>
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<td>• Strength of ankle plantarflexors (+)</td>
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<td>• Gait velocity (+)</td>
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<td>• Cadence (+)</td>
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<td>• Stride length (+)</td>
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<td></td>
<td>• Gait symmetry ratio (+)</td>
</tr>
<tr>
<td>Study</td>
<td>Design</td>
<td>N</td>
<td>Intervention</td>
<td>Measures</td>
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<tr>
<td>Son et al. (2014)</td>
<td>RCT (6)</td>
<td>28</td>
<td>E: Three sets of resistance exercise + conservative physical therapy</td>
<td>Double support period (+)</td>
<td></td>
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<tr>
<td></td>
<td></td>
<td></td>
<td>C: Conservative physical therapy</td>
<td>A-P and M-L sway distances (+)</td>
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<td></td>
<td></td>
<td>Berg Balance Scale (+)</td>
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<td></td>
<td></td>
<td>Timed Up-and-Go test (+)</td>
<td></td>
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<tr>
<td>Duncan et al. (1998)</td>
<td>RCT (6)</td>
<td>20</td>
<td>E: Home-based exercise program stressing strength, balance and endurance</td>
<td>Fugl-Meyer Score: lower extremity (+)</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>C: Usual care</td>
<td></td>
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<tr>
<td>Flansbjer et al. (2012)</td>
<td>RCT (6)</td>
<td>24</td>
<td>E: Progressive resistance training of the knee muscles</td>
<td>Dynamic knee extension (+)</td>
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<td>Dynamic knee flexion (+)</td>
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<td></td>
<td></td>
<td>Isokinetic knee extension (non-paretic leg only) (+)</td>
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<td></td>
<td>Timed Up &amp; Go Test (follow-up only) (+)</td>
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<td></td>
<td>6-Minute Walk Test (-)</td>
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<td></td>
<td>Fast gait speed (-)</td>
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<tr>
<td>Flansbjer et al. (2008)</td>
<td>RCT (6)</td>
<td>24</td>
<td>E: Progressive resistance training of the knee muscles</td>
<td>Isotonic knee flexion (+)</td>
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<td>Isotonic knee extension (+)</td>
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<td>Isokinetic knee extension (+)</td>
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<td></td>
<td>Timed Up &amp; Go Test (-)</td>
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<tr>
<td>Bale et al. (2008)</td>
<td>RCT (6)</td>
<td>18</td>
<td>E: Functional strength training</td>
<td>Habital gait speed (+)</td>
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<td>Maximum gait speed (-)</td>
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<td>Knee extension and flexion muscle strength (-)</td>
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<td>Maximum weight-bearing in standing (-)</td>
<td></td>
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<tr>
<td>Moreland et al. (2003)</td>
<td>RCT (6)</td>
<td>133</td>
<td>E: Lower-extremity progressive resistance exercises</td>
<td>Disability Inventory (-)</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>C: Lower extremity exercises without resistance</td>
<td>2-minute Walking Test (-)</td>
<td></td>
</tr>
<tr>
<td>Dean et al. (2000)</td>
<td>RCT (5)</td>
<td>12</td>
<td>E: Functional Strength Training for Lower Limb</td>
<td>Distance walked (+)</td>
<td></td>
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<tr>
<td></td>
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<td></td>
<td>C: Functional Strength Training for Upper Limb</td>
<td>Peak vertical ground reaction force through the affected foot (+)</td>
<td></td>
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<td>Number of repetitions of step test (+)</td>
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<td>Purdue Peg Test (-)</td>
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<td></td>
<td>Grip Strength (-)</td>
<td></td>
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<tr>
<td>Lee et al. (2013)</td>
<td>RCT (5)</td>
<td>28</td>
<td>E: Progressive Resistance training + Foot &amp; ankle compression</td>
<td>Step length (+)</td>
<td></td>
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<td></td>
<td></td>
<td></td>
<td>C: No exercise program</td>
<td>Stride length (+)</td>
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<td>Heel-to-heel support (+)</td>
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<td>Step time (+)</td>
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<td>Double limb support (+)</td>
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<td></td>
<td>Gait velocity (+)</td>
<td></td>
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<tr>
<td>Inaba et al. (1973)</td>
<td>RCT (4)</td>
<td>176</td>
<td>E1: Functional and selective stretching</td>
<td>Strength gains in mass extension: E3 vs E2 (+); E3 vs E1 (+)</td>
<td></td>
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<td></td>
<td></td>
<td></td>
<td>E2: Active exercise and functional training and selective stretching</td>
<td>Activities of Daily Living: E3 vs E1/E2 (+)</td>
<td></td>
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<tr>
<td></td>
<td></td>
<td></td>
<td>E3: Progressive training and selective stretching</td>
<td></td>
<td></td>
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<tr>
<td>Glasser (1986)</td>
<td>RCT (4)</td>
<td>20</td>
<td>E: Therapeutic exercise + isokinetic exercise</td>
<td>Functional Ambulation Profile (-)</td>
<td></td>
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<tr>
<td></td>
<td></td>
<td></td>
<td>C: Therapeutic exercise</td>
<td></td>
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<tr>
<td>Page et al. (2008)</td>
<td>RCT (4)</td>
<td>7</td>
<td>E1: A resistance-based, reciprocal, affected leg locomotor training protocol using the NuStep apparatus</td>
<td>Berg Balance Scale (-)</td>
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<td>Fugl-Meyer Assessment (-)</td>
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</tbody>
</table>
E2: A home exercise programme (HEP) consisting of self-supervised practice with fractionated joint movements of the lower limb

<table>
<thead>
<tr>
<th>Study</th>
<th>Intervention</th>
<th>Comparison</th>
<th>Summary</th>
</tr>
</thead>
</table>
| Lee & Kang (2013) | E: Muscle strengthening exercise + conventional therapy | C: Convention physical therapy | - Hip muscle strength (+)  
- Stair up and down time (+)  
- Gait velocity (+)  
- Timed Up-and-Go Test (+)  
- Hip muscle strength flex (+)  
- Hip muscle strength extension (+)  
- Gait velocity strength (+) |
| Park et al. (2014) | E: Incremental weight loading treadmill training | C: No-load treadmill training | - Centre of pressure for sway area (+)  
- Center of pressure for sway length (+) |

- Indicates non-statistically significant differences between treatment groups  
+ Indicates statistically significant differences between treatment groups

Discussion

Given that paresis or weakness is a common source of impairment and subsequent disability, strength training has been examined as a therapeutic approach. The central or upper motor neuron etiology of weakness makes stroke related weakness less amenable to strength training than other approaches such as deconditioning. An examination of all of the RCTs which evaluated strengthening programs (isokinetic or resistance training) reveals that there was variability in the length of time the treatment were provided which lasted from 3 to 12 weeks. Most subjects recruited were independent community ambulators. Heterogeneity of the types of interventions provided, their intensity and the outcomes assessed make it difficult to formulate conclusions as to the overall effectiveness of strength training treatment. Many studies failed to demonstrate a significant treatment effect, although the numbers of patients recruited were generally small. The studies with greater methodological rigour failed to demonstrate significant treatment effect.

A total of seven RCTs adopted a progressive or incremental training approach. However, due to the large amount of varying outcome measures used, the overall picture remains unclear concerning the efficacy of progressive training. Lee et al. (2010) reported that progressive resistance training (PRT) was significantly more effective than cycling in the improvement of muscle strength, peak power, and endurance. However, it is debatable as to whether there is an overlap between strength and endurance. In comparison to usual training, Flansbjer et al. (2008) reported a greater improvement in isokinetic knee muscle strength. These gains were maintained at a 4-year follow-up with the control group remaining stables thus excluding the presumption that the control group had simply demonstrated degradation of function (Flansbjer et al. 2012). Gait improved significantly in terms of stride/step length, velocity, time and support after PRT compared to no exercise therefore suggesting that PRT strengthened lower limb muscles and may have increased stimulation of the mechanoreceptors around the knee, ankle and hip joints (Lee et al. 2013). Significant gains in strength compared to a range of motion plus upper extremity stretching program were reported by Ouellette et al. (2004) but no significant differences in gait or function were reported. The authors note that although the experimental group did not report any changes in the frequency of performing life tasks, overall the group reported greater self-efficacy in performing such tasks. Further research into is required to investigate the use of PRT in motor recovery. In contrast, Moreland et al. (2003) did not report any significant differences between patients who received PRT and those who completed exercise without external resistance. The authors concede that only perceived moderate exertion was encouraged to
prevent discomfort and fatigue, and therefore potential withdrawal. As the control group completed the same exercises as the experimental group, further studies are required to clarify whether PRT or the practice of movement is the cause for functional improvement.

Clark and Patten (2013) compared eccentric and concentric resistance training of the lower limbs and despite the lack of significant differences in gait performance, both groups demonstrated modality-specific improvements although there were significant gains in strength and muscle activation favouring the eccentric training group. These findings may be explainable through the unique neural demands of eccentric contractions or even the increased intensity of contractions (Clark & Patten 2013). In combining resistance and gait training, more patients in the eccentric resistance group responded to treatment in exhibiting improvements in gait pattern and speed with Clark and Patten (2013) suggesting that bilateral gains in leg power production may have facilitated this enhancement.

Another common training approach in the recovery of lower motor impairment is functional strength training (FST). A multi-centre RCT conducted by Cooke et al. (2010) revealed that patients who received twice the intensity of conventional physiotherapy (CPT) exhibited significantly greater improvements in walking speed compared to a CPT control group and although a FST/CPT combination group also demonstrated greater improvements than the control group, they did not reach statistical significance. The authors suggest that the CPT included some functional training which may have diminished differences between groups. Bale et al. (2008) did not find any differences between FST and standard care in terms of strength and weight-bearing but did report a significant difference in habitual gait speed in favour of FST. In comparing FST for upper and lower limbs, Mares et al. (2014) and Dean et al. (2000) present conflicting results. Dean et al. (2000) reported significant improvement in patients receiving FST for lower limbs in gait and leg strength but Mares et al. (2014) did not reveal any significant differences between groups regarding gait or mobility. With the lack of between-group differences reported by Mares et al. (2014) notwithstanding, it could be suggested that comparing upper and lower limb training with specific measures for each may not be appropriate as favourable modality-specific results could be found in tandem.

**Conclusions Regarding Strength Training**

*There is Level 1a evidence that functional strength training may improve gait speed but may not knee extension and flexion strength.*

*There is Level 1a evidence that progressive resistance training may improve strength and knee extension but may not gait.*

*There is level 1b evidence that eccentric resistance training may result in greater muscle activation compared to concentric resistance training but may not improve gait speed.*

**Strength training may not improve gait speed or lower limb strength, while progressive resistance training may help with lower limb strength.**

**9.6 Cardiovascular Conditioning and Aerobic Exercises**

Aerobic exercise training has been shown to benefit the health of patients in several populations, including heart failure patients (Shephard 1991; Toth et al. 1997). Despite its acceptance in other populations, such training has not been incorporated into traditional stroke rehabilitation. Exclusion of
exercise training from stroke rehabilitation is partly due to concerns that increased exertion may cause another stroke or increase spasticity (Holt et al. 2001). However, “Low endurances may compound the increased energy cost of movement associated with residual hemiparesis and may contribute to poor rehabilitation outcomes,” (Duncan & Badke 1987).

Studies investigating the relationship between walking performance and aerobic capacity have yielded conflicting results. Courbon et al. (2006) noted a positive correlation between walking capacity (via the 6 minute walk test; 6MWT), and aerobic capacity and maximal power output (r =0.602 and r = 0.867, respectively). Kelly et al. (2003) also reported a correlation between performance on the 6MWT and measures of peak cardiorespiratory fitness (r =0.84) (Kelly et al., 2003). However, Eng et al. (2004) reported that neither the distance achieved on the 6MWT or self-selected gait speed were correlated with $VO_2$ max, while Pang et al. (2005) has reported a weak correlation (r=0.40).

There has been research conducted to examine the feasibility of cardiovascular conditioning and aerobic exercise for stroke patients. Overall, it appears that cardiovascular conditioning and aerobic exercise is not detrimental to stroke patients. In particular, stroke patients with mild/moderate motor impairments have been found to be successful at achieving the minimal exercise level recommendations of an adapted cardiac rehabilitation program (Marzolini et al. 2012).

Several studies have demonstrated that exercise training can be effective for stroke patients (David A. Brown & DeBacher 1987; Monga et al. 1988; Potempa et al. 1995). High aerobic intensity treadmill walking/exercise training has been shown to increase peak oxygen consumption (peak$VO_2$) (Gjellesvik et al. 2012; Macko et al. 1997; Rimmer et al. 2000), with the possibility of patients maintaining these improvements one year following the training (Gjellesvik et al. 2012). In addition aerobic exercise has been found to increase walking economy and capacity (Gjellesvik et al. 2012; Mehta et al. 2012), and to increase the workload of the plegic limb without increasing inappropriate muscle activity (Brown & Kautz 1998; Rimmer et al. 2000). In fact, termination of training was most often due to generalized fatigue rather than cardiopulmonary intolerance or hemiparetic leg fatigue (Macko et al. 1997). Holt et al. (2001) demonstrated on a single patient that aerobic exercise training on a static bicycle enabled a chronic stroke patient to increase his walking speed, endurance and walking symmetry, and concluded that an exercise bicycle is a relevant rehabilitation tool late after stroke in improving functional mobility. Furthermore, in a meta-analysis looking at cardiovascular conditioning initiated ≥ 6 months post stroke, cardiorespiratory training was found to result in moderate and statistically significant effect in improving total distance walked post treatment (Mehta et al. 2012).

In general, there have been several reviews conducted, looking at the evidence for aerobic exercise/cardiovascular training for improving health outcomes and quality of life in stroke survivors. In 2003, a systematic review by Meek et al. (2003) examined the efficacy of randomized or quasi randomized trials concerning cardiovascular exercise interventions. Outcomes of interest lay in two domains: (1) Impairment: gait speed, strength, endurance, balance, flexibility, tonus and exercise capacity; and (2) Disability: global dependency, functional independence. Extended activities of daily living, quality of life and death were also examined. From 16 identified articles, only three were included in their analyses (Duncan et al. 1998; Potempa et al. 1995; Teixeira-Salmela et al. 1999). Pooled estimates of treatment effect using standardised mean differences could be calculated for Fugl-Meyer Index scores, gait speed, Lawton Scale of Human Activities Profile, SF-36 and Nottingham Heath Profile. There were no statistically significant results between groups on any of the outcome measures, although, the authors noted that there was insufficient evidence to establish if cardiovascular exercise had a beneficial effect on disability, impairment, extended activities of daily living, quality of life and case fatality post stroke.
A Cochrane review examining the benefit of physical fitness training for stroke patients also concluded that definitive conclusions of efficacy could not be made due to the small body of literature, which included small sample sizes and heterogeneous treatments (Saunders et al. 2004). The primary objectives of this review were to examine the effects of physical training on reductions in death, dependency of disablement. Eleven published RCTs were included. There was no benefit of treatment on any of the primary outcomes assessed, however, only small numbers of studies (n=2 or n=3) could be included in the individual pooled analysis. Secondary endpoints included measures of mobility, physical fitness, physical functioning, quality of life and mood. In 2009, this review was updated and included results from 24 RCTs. The authors classified treatments as cardiorespiratory (n=11), strength (n=4) and mixed training interventions (n=9). Selected results are presented in Table 9.6.1. They concluded that cardiorespiratory walking training can increase walking speed and walking distance, while reducing the need for assistance, however, there was insufficient evidence for other types of interventions as being beneficial.

Table 9.6.1 The Results of the 2009 Cochrane Meta-analysis Evaluating the Effects of Physical Training

<table>
<thead>
<tr>
<th>Outcome Assessed</th>
<th>Intervention</th>
<th>Mean Difference 95% CI (* p&lt;0.05)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Peak oxygen uptake (mL/kg/min)</td>
<td>Cardiorespiratory training</td>
<td>0.60 (0.18, 1.02)</td>
</tr>
<tr>
<td>Functional Ambulation Categories</td>
<td>Cardiorespiratory training</td>
<td>0.73 (0.46, 0.98) *</td>
</tr>
<tr>
<td>Maximum walking speed (m/sec over 5-10 metres)</td>
<td>Cardiorespiratory training</td>
<td>6.47 (2.37, 10.57) *</td>
</tr>
<tr>
<td>Walking endurance (metres) over 6 minutes</td>
<td>Cardiorespiratory training</td>
<td>38.9 (14.3,63.5) *</td>
</tr>
<tr>
<td>Preferred gait speed (m/min)</td>
<td>Strength training</td>
<td>2.37 (-6.8,11.53)</td>
</tr>
<tr>
<td>Stair climbing (sec/step)</td>
<td>Strength training</td>
<td>0.04 (-0.47, 0.55)</td>
</tr>
<tr>
<td>Timed up and go (sec)</td>
<td>Mixed training</td>
<td>-1.16 (-2.93, 0.62)</td>
</tr>
</tbody>
</table>

Pang et al. (2006) conducted a systematic review of aerobic exercise following stroke, which included 7 RCTs, evaluating patients in the acute, sub-acute, and chronic stages of stroke. Standardized effect sizes for the main outcomes of peak VO2 and peak workload were calculated. Exercise intensity ranged from 50% to 80% heart rate reserve, while duration varied from 20-40 min for 3-5 days a week. Regardless of the stage of stroke recovery, there was a significant benefit of therapy. Improvements were noted in the parameters of peak VO2, peak workload, walking speed and endurance.

The American Heart Association has published exercise recommendations for stroke survivors (Gordon et al. 2004). The recommendations include a regime of aerobic exercises, strength training (including circuit training, weights and isometric exercises), flexibility (stretching) and coordination and balance activities (Gordon et al. 2004). The guidelines are aimed at preventing the recurrence of a subsequent stroke and the improvement of sensorimotor function. (Also see Chapter 8 Secondary Prevention; Section 8.6 Lifestyle Modification, for additional information concerning physical activity). Most recently, in 2013 a systematic review by Pang et al. (2013), was conducted in hopes of developing evidence-based exercise prescription recommendations for stroke patients. In total, 25 articles were included in the review with aerobic fitness (VO2) as the primary outcome of interest. Secondary outcomes of interest included cardiovascular health, functional performance, psychological health, and cognitive function. Aerobic exercise was found to have a significant beneficial effect for measures of VO2. There was some evidence for aerobic exercise having a benefit on functional performance (walking endurance and speed; SMD=0.22, p=0.003 and SMD=0.37, p=0.005, respectively), but evidence was inconclusive concerning cardiovascular health, psychological, and cognitive functioning. In conclusion, based upon the research evidence, the authors have recommend that stroke patients engage in aerobic
exercise of moderate to high intensity, 20-40min and 3-5 days per week, to obtain improvements in aerobic fitness, maximal walking speed and endurance (Pang et al. 2013).

Studies evaluating cardiovascular conditioning and its effect on improving lower limb outcomes are presented in table 9.6.2 below.

<table>
<thead>
<tr>
<th>Author, Year</th>
<th>Study Design (PEDro Score)</th>
<th>Intervention</th>
<th>Main Outcome(s)</th>
</tr>
</thead>
</table>
• Functional Ambulation Category (-) |
| | N_{Start}=30  
N_{End}=27 |  |  |
| **Kim et al.** (2014) | RCT (8) | E: Community walking training program  
C: Social walking intervention | • 10-m Walk test (+)  
• Community Walking test (+)  
• Stroke Impact Scale (+)  |
| | N_{Start}=26  
N_{End}=22 |  |  |
| **Duncan et al.** (2003) | RCT (8) | E: Structured, progressive, physiologically based exercise program in-home program  
C: Usual care | • Balance (+)  
• Endurance (+)  
• Mobility (+)  |
| | N=100 |  |  |
| **Salbach et al.** (2004) | RCT (8) | E: Functional tasks designed to strengthen the lower extremities  
C: Intervention focusing on upper extremity activities | • 6-minute Walk Test (+)  
• Comfortable walking speed (+)  
• Maximum walking speed (+)  
• Timed Up-and-Go Test (+)  |
| | N=91 |  |  |
E: Fitness and mobility program  
C: Seated upper extremity program | • Distance to 6min walk test (+)  
• Paretic leg muscle strength (+)  
• Berg Balance Scale (-)  |
| | N=20 |  |  |
| **Lennon et al.** (2008) | RCT (8) | E: 16 cycle ergometry sessions of aerobic-training intensity + stress-management classes  
C: Usual Care | • RPE rating (+)  |
| | N=48 |  |  |
| **Olney et al.** (2006) | RCT (7) | E: Supervised physical conditioning program  
C: Unsupervised physical conditioning program | • 6-minute Walking Speed (-)  
• Physiological Cost Index (-)  
• Lower extremity muscle strength (-)  |
| | N=72 |  |  |
| **Richards et al.** (2004) | RCT (7) | E: Specialized locomotor training using a tilt table, a Kinetron isokinetic device and treadmill training with full weight bearing  
C: Conventional therapy | • Fugl-Meyer Assessment (-)  
• Time needed to walk (-)  
• Timed Up and Go Test (-)  
• Barthel Index (-)  |
| | N=63 |  |  |
| **Pang et al.** (2005) | RCT (7) | E: Fitness and mobility program  
C: Seated upper extremity exercise program | • Distance on the 6-minute Walk Test (+)  
• Paretic Leg Muscle Strength (+)  
• Berg Balance Scale (-)  
• Physical Activities for Individuals with Physical Disabilities (metabolic equivalent h/d) (-)  |
| | N=63 |  |  |
| **Park et al.** (2014) | RCT (7) | E: Underwater treadmill gait program  
C: General rehabilitation program | • Dynamic balance (+)  |
| | N_{Start}=22  
N_{End}=22 |  |  |
<table>
<thead>
<tr>
<th>Study Authors</th>
<th>Year</th>
<th>Study Design</th>
<th>Sample Size</th>
<th>Intervention A</th>
<th>Intervention B</th>
</tr>
</thead>
<tbody>
<tr>
<td>Furnari et al.</td>
<td>2014</td>
<td>RCT (7)</td>
<td>N&lt;sub&gt;Start&lt;/sub&gt;=40 N&lt;sub&gt;End&lt;/sub&gt;=40</td>
<td>E: Hydrokinesytherapy (aquatic therapy)</td>
<td>C: Conventional physical therapy</td>
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<td></td>
<td>Speed (+)</td>
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<td>Cadence (+)</td>
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<td>Stance phase (+)</td>
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<td></td>
<td>Swing phase (+)</td>
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<td></td>
<td></td>
<td>Double support phase (+)</td>
<td></td>
</tr>
<tr>
<td>Bateman et al.</td>
<td>2001</td>
<td>RCT (7)</td>
<td>N=157</td>
<td>E: Cycle ergometer aerobic training</td>
<td>C: Relaxation training</td>
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<td></td>
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<td></td>
<td></td>
<td>Berg Balance Scale (-)</td>
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<td></td>
<td>10-meter Walking Speed (-)</td>
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<td>Functional Independence Measure (-)</td>
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<td>Barthel Index (-)</td>
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<td>Rivermead Mobility Index (-)</td>
<td></td>
</tr>
<tr>
<td>Globas et al.</td>
<td>2012</td>
<td>RCT (7)</td>
<td>N=38</td>
<td>E: Aerobic treadmill exercise</td>
<td>C: Usual care physiotherapy</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Berg Balance Scale (+)</td>
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<td>Rivermead Mobility Index (+)</td>
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<td>10-meter Walk Test (+)</td>
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<td></td>
<td></td>
<td>6-minute Walk Test (+)</td>
<td></td>
</tr>
<tr>
<td>Gordon et al.</td>
<td>2013</td>
<td>RCT (7)</td>
<td>N=128</td>
<td>E: A 12-week walking intervention</td>
<td>C: A light massage</td>
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<tr>
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<td></td>
<td>Physical Health Component Scores (+)</td>
<td></td>
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<td>6-minute Walk test (+)</td>
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<tr>
<td>Outermans et al.</td>
<td>2010</td>
<td>RCT (7)</td>
<td>N=44</td>
<td>E: A circuit-based training program that was of high intensity</td>
<td>C: A low-intensity circuit-based training program</td>
</tr>
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<td></td>
<td></td>
<td></td>
<td>Berg Balance Scale (-)</td>
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<tr>
<td>Toledano-Zarhi et al.</td>
<td>2011</td>
<td>RCT (6)</td>
<td>N=28</td>
<td>E: Supervised exercise training program including treadmill, hand-bike and cycling + home exercise booklet</td>
<td>C: Home exercise booklet</td>
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<td></td>
<td>6-minute Walk Test (+)</td>
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<tr>
<td>Chu et al.</td>
<td>2004</td>
<td>RCT (6)</td>
<td>N=12</td>
<td>E: An aquatic exercise program in chest-deep water</td>
<td>C: Upper extremity intervention program that required performance of arm and hand exercises while sitting</td>
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<td></td>
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<td>Gait speed (+)</td>
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<td>Muscle strength (+)</td>
<td></td>
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<tr>
<td>Macko et al.</td>
<td>2005</td>
<td>RCT (6)</td>
<td>N=61</td>
<td>E: Treadmill aerobic exercise program</td>
<td>C: Program of stretching and low-intensity walking</td>
</tr>
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<td></td>
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<td>6 minute Walk Test (+)</td>
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<td></td>
<td>Walking Impairment Questionnaire (+)</td>
<td></td>
</tr>
<tr>
<td>Mayo et al.</td>
<td>2013</td>
<td>RCT (6)</td>
<td>N=87</td>
<td>E1: Home-based exercise programs using a stationary cycle</td>
<td>E2: Home-based exercise program using a walking and exercise group</td>
</tr>
<tr>
<td></td>
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<td>6-minute Walk Test (-)</td>
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<tr>
<td>Seo et al.</td>
<td>2014</td>
<td>RCT (6)</td>
<td>N&lt;sub&gt;Start&lt;/sub&gt;=30 N&lt;sub&gt;End&lt;/sub&gt;=30</td>
<td>E: Gait training exercises by ascending and descending wooden stairs with support</td>
<td>C: Gait training exercises by walking 10m on a hard, flat and in-door surface with assistance</td>
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<td>Area ellipse of Romberg (+)</td>
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<td>Length/area of Romberg (+)</td>
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<tr>
<td>Katz-Leurer et al.</td>
<td>2003</td>
<td>RCT (5)</td>
<td>N=92</td>
<td>E: 8 week programme of aerobic training using a leg cycle ergometer</td>
<td>C: Regular therapy</td>
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<td></td>
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<td>Stair climbing (+)</td>
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<td>FIM (-)</td>
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<td>Walking distance (-)</td>
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<td></td>
<td></td>
<td>Walking speed (-)</td>
<td></td>
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<tr>
<td>Jeonhyeng et al.</td>
<td>2014</td>
<td>RCT (5)</td>
<td>N&lt;sub&gt;Start&lt;/sub&gt;=40 N&lt;sub&gt;End&lt;/sub&gt;=40</td>
<td>E: General physical therapy + walking exercise on stairs with flat surfaces</td>
<td>C: Reciprocating walking training on a flat indoor surface</td>
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<td>Weight-bearing footprint (+)</td>
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<td>Anterior length in the limit of stability (+)</td>
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<td>Posterior length in the limit of stability (+)</td>
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<td></td>
<td>Surface area ellipse of Romberg (+)</td>
<td></td>
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<tr>
<td>Song et al.</td>
<td>2015</td>
<td></td>
<td></td>
<td>E: Sliding Training</td>
<td>C: Sliding Training</td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td>10-m Walk Test (+)</td>
<td></td>
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</tbody>
</table>
RCT (5)
\(N_{\text{Start}}=40\)
\(N_{\text{End}}=40\)
C: Ergometer Bicycle Training
- Anterior and posterior ranges of the length of sway (+)

**Song et al.** (2015)
RCT (4)
\(N_{\text{Start}}=40\)
\(N_{\text{End}}=40\)
E: Complex exercise program that consisted of resistance and aerobic exercises
C: General exercise program for same duration
- Four square step test (-)
- Figure-of-8-Walking Test (-)

**Jin et al.** (2012)
RCT (4)
\(N=133\)
E: Exercise training
C: Low intensity overground walking training
- 6-minute walk distance (+)
- Knee muscle strength (+)
- Rivermead Mobility Index (-)
- Berg Balance (-)
- Modified Ashworth Scale (-)

**Letombe et al.** (2010)
RCT (3)
\(N=18\)
E: Physical exercises, including one-legged cycling
C: Conventional inpatient rehabilitation
- Barthel Index (-)
- Katz ADL scale scores (-)

**Taricco et al.** (2014)
PCT
\(N_{\text{Start}}=229\)
\(N_{\text{End}}=199\)
E: Adapted physical activity + Therapeutic Patient Education
C: Usual Care
- 6-minute Walk Test (+)
- Berg Balance Scale (+)
- Short Physical Performance Battery (+)
- Physical Composite Scale of the Short Form Health Survey (SF-12) (+)
- Modified Barthel Index (-)

**Rimmer et al.** (2000)
PCT
\(N=35\)
E: 12-week outpatient exercise program focusing on cardiovascular conditioning, strength and flexibility training
C: Health promotion intervention
- Strength (+)
- Lower limb flexibility (+)
- Body composition (body weight and BMI) (+)
- Waist-to-hip ratio (-)

- Indicates non-statistically significant differences between treatment groups
+ Indicates statistically significant differences between treatment groups

### Discussion
Various exercise programs have been used in acute, subacute and chronic stroke rehabilitation. In this review, 28 studies were collectively analyzed to evaluate the effect of exercise programs on lower limb gait, balance and strength. The studies mainly subjected participants to lower body exercise programs either in combination with standard therapy or alone, and compared the effects either to standard therapy or upper body therapy.

Cardiovascular training for stroke patients has been shown to improve peak aerobic capacity as well maximal oxygen consumptions in stroke patients (Chu et al. 2004; Duncan et al. 2003; Macko et al. 2005; Pang et al. 2005; Potempa et al. 1995). In addition, improvement in gait and sensorimotor function has also been observed after cardiovascular training (Duncan et al. 2003; Potempa et al. 1995). However, the sustainability of improved functional abilities noted immediately after treatment is not yet established (Katz-Leurer et al. 2003). Both supervised and unsupervised exercise programs were associated with benefit in a recent study (Olney et al. 2006). Only 47% of patients included in the study by Bateman et al. (2001) had suffered from stroke, therefore, their results may not be generalizable. They found that there was no additional gain in functional independence when an aerobic exercise program was added to standard rehabilitation, despite an increase in physical fitness.

Findings suggest that stroke patients who undergo structured, progressive, physiological based exercise programs show significance improvements in gait outcomes (Duncan et al. 2003; Globas et al. 2012; Gordon et al. 2013; Jin et al. 2012; Kautz et al. 2005; Kim et al. 2014; Macko et al. 2005; Pang et al. 2005; Salbach et al. 2004; Toledano-Zarhi et al. 2011). However, there are conflicting results on the effect of...
exercise programs on balance improvement. While some have reported improved balance scores during a fitness and mobility program (Duncan et al. 2003; Globas et al. 2012), others have reported no significant difference between exercise programs and control groups (Kautz et al. 2005; Pang et al. 2005). Further research is required to determine the effect of exercise programs on balance performance. Current literature suggests that fitness and mobility programs increase paretic leg muscle strength (Jin et al. 2012; Kautz et al. 2005; Pang et al. 2005; Salbach et al. 2004) and that lower extremity aquatic exercise programs may improve gait performance (Chu et al. 2004; Furnari et al. 2014; Park et al. 2014).

Various attributes of exercise programs may have an effect on gait improvements on individuals who have suffered a stroke. Duncan et al. (2003) Limited evidence suggests that an in-home exercise program (Duncan et al. 2003) and lower extremity cardiovascular exercise (Kautz et al. 2005; Pang et al. 2005) may improve gait. Some evidence suggests that the use of cycle ergometer aerobic training interventions (Bateman et al. 2001), as well as complex exercise programs (Song & Kim 2015) may not improve gait outcome measures. There is conflicting evidence with some suggesting that supervised aerobic exercise programs have no effect on gait (Olney et al. 2006) whereas others have shown a significant difference between supervised an unsupervised exercise programs (Toledano-Zarhi et al. 2011).

Other factors of aerobic exercise that have been shown to have an influence on outcome measures suggesting that community exercise may improve mobility, strength, flexibility and body composition (Kim et al. 2014; Rimmer et al. 2000) and walking exercises on stairs compared to flat surfaces may improve balance (Jeonhyeng & Kyochul 2014).

**Conclusion Regarding Cardiovascular Training**

*There is level 1a evidence that cardiovascular fitness, aquatic therapy, and mobility training programs may improve gait. There is level 1b evidence that home-based cardiovascular exercise programs may also improve gait outcomes.*

*There is level 1b and level 2 evidence that cycling training interventions may not improve gait.*

*There is conflicting level 1a evidence regarding supervised exercise training programs compared to unsupervised programs on gait.*

*There is level 1b and limited level 2 evidence that community or outpatient exercise programs may improve mobility, lower limb strength and flexibility.*

*There is level 1b evidence that high-intensity circuit training may not improve balance when compared to low-intensity circuit training.*

*There is limited level 2 evidence that walking exercises on stairs compared to flat surfaces may improve balance post-stroke.*

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**Cardiovascular training in the form of fitness and mobility programs, aquatic therapy, and community/outpatient exercise programs as well as supervised programs may improve gait. Further research is required to identify the effectiveness of cycling programs, and home-based exercise programs on mobility and balance.**
9.7 Assistive Devices for the Lower Extremity

9.7.1 Wheelchair
Patients who suffer a stroke, particularly when associated with hemiplegia, often require use of a wheelchair. The wheelchair must be of the self-propelling type with large wheels at the back and swinging detachable foot rests (Blower 1988). A wheelchair is normally propelled by using the unaffected hand on the large wheel and the unaffected foot on the floor (Blower 1988). Blower (1988) noted that while patients view the temporary use of a wheelchair positively there is a lack of consensus between clinicians about the benefits of wheelchair use in stroke rehabilitation (Ashburn & Lynch 1988; Blower 1988; Engstrom 1995), particularly early in the acute phase of stroke.

The main advantage for early use of wheelchairs is related to support for the hemiplegic sides and greater limited functional improvement and independence. The popular treatment regimen described by Bobath discourages early self-propulsion in a wheelchair because it is believed to cause increases in tone on the hemiplegic side, poor posture and may have an adverse impact on long-term recovery (Ashburn & Lynch 1988; Bobath 1990). These postulated negative impacts include increasing spasticity, encouraging one-sidedness and reducing motivation to walk (Blower 1988). Although the use of wheelchairs following stroke is widespread, we identified only a single RCT, which evaluated any form of intervention.

Table 9.7.1.1 Summary of RCTs Evaluating the Efficacy of Wheelchair Mobilization

<table>
<thead>
<tr>
<th>Author, Year Study Design (PEDro Score)</th>
<th>Intervention</th>
<th>Main Outcome(s) Result</th>
</tr>
</thead>
</table>
| Barrett et al. (2001) RCT (7) N=40     | E: Encouragement to self-propel; provided with a wheelchair and daily instruction C: Discouraged from self-propulsion; received additional measures to discourage self-propelling | • Barthel ADL (-)  
• Nottingham Extended ADL scale (-)  
• The shortened-General Health Questionnaire (-) |

- Indicates non-statistically significant differences between treatment groups  
+ Indicates statistically significant differences between treatment groups

Discussion
Although research regarding wheelchair use for post-stroke patients is quite limited it may give some insight into the efficacy of wheelchair mobilization as an aid in stroke recovery. Only one RCT was used in this review and the results suggest that the use of a self-propelled wheelchair post-stroke provides no additional benefits to activities of daily living or functional mobility compared to stroke patients who were discouraged from self-propelled wheelchair use (Barrett et al. 2001). Further research is required to determine the efficacy of self-propelled wheelchair use post-stroke.

Conclusion Regarding Wheelchair Mobility

There is level 1b evidence that encouraging hemiplegic individuals to propel their own wheelchair may not improve ADLs.

Additional research is required to investigate the impact of wheelchairs for improving mobilization post stroke.
9.7.2 Canes
Canes and walkers are frequently employed in the rehabilitation of stroke patients. Kuan et al. (1999) have noted that walking aids have long been used to assist hemiplegic patients to achieve independent ambulation. The major functions of walking aids are (1) to increase stability, (2) improve muscle action and (3) reduce weight-bearing loads through targeted anatomical structures (Kuan et al. 1999). Canes serve to increase base of support and improve ambulation for those with impaired balance.

Table 9.7.2 Summary of RCTs Evaluating the Evidence Regarding Canes and Walking Aids

<table>
<thead>
<tr>
<th>Author, Year</th>
<th>Country</th>
<th>PEDro Score</th>
<th>Intervention</th>
<th>Main Outcome(s)</th>
<th>Results</th>
</tr>
</thead>
</table>
| Jeong et al. (2015) |            | RCT (7)    | E1: Single-point cane  
E2: Quad cane  
E3: Hemi-walker | • 6-minute Walk Test: (+)  
• 10-meter Walk test (+) |
| Laufer et al. (2002) |            | RCT (5)    | E1: Two force plates with no cane  
E2: Two force places with a one-point cane  
E3: Two force plates with a 4-point (quad) cane | • Postural Sway: E3 vs E1/E2 (+)  
• Asymmetrical weight-bearing stance (-) |

- Indicates non-statistically significant differences between treatment groups  
+ Indicates statistically significant differences between treatment groups

Discussion
Research regarding assisted walking devices for post-stroke patients is quite limited as an aid in stroke recovery. One RCT divided post-stroke patients into two groups; poor balance and good balance based on the berg balance scale and had the participants use a single point cane, a quad cane or a hemi-walker (Jeong et al. 2015). The results showed that patients in the good balance group showed greater functional mobility, gait and aerobic capacity when using the single point cane (Jeong et al. 2015). Postural sway was also significantly more improved when patients used a quad cane compared to when a one-point cane or no cane was used (Laufer et al. 2002).

Conclusions Regarding Canes and Walking Aids

There is level 1b and level 2 evidence that quad canes or walkers are significantly better than a one-point cane or no cane for improving gait and balance.

Quad canes and walkers improve gait and balance more than when using a one-point cane or when no cane is provided.

9.7.3 Ankle Foot Orthoses
It is common practice to use splints in the hemiplegic lower extremity in an attempt to improve gait quality. The upper motor neuron injury results in gait deviation, including knee and hip extension and ankle plantarflexion, during stance phase. In order to facilitate the swing phase of gait, an ankle foot orthosis (AFO) is often used to compensate for excessive ankle plantarflexion and a lack of knee flexion. The brace (usually plastic) is worn on the lower leg and foot to support the ankle, hold the foot and ankle in the correct position, and correct foot-drop. The prime indication for prescription of the solid ankle orthoses for patients with hemiplegia is to control strong tendencies. Although the use of AFOs is
widespread, there is a dearth of evidence with respect to the timing of intervention or design type. Decisions are usually based on clinical experience.

### Table 9.7.3.1 Summary of RCTs Evaluating Ankle Foot Orthosis

<table>
<thead>
<tr>
<th>Author, Year</th>
<th>Study Design (PEDro Score)</th>
<th>Intervention</th>
<th>Main Outcome(s) Results</th>
</tr>
</thead>
</table>
| Forrester et al. (2014) | RCT (6) NStart=39 NEnd=34 | E: Robot training using dorsi-or plantarflexion of ankle with an ankle robot supporting the paretic leg, C: Usual physical therapy was also provided | • Gait velocity (-)  
• Ankle range of motion in dorsiflexion range (+)  
• Absolute step length ratios (-)  
• Angular velocity (+)  |
| Ding et al. (2015)      | RCT (6) NStart=103 NEnd=103 | E1: Botulinum toxin A and conventional rehabilitation along with an ankle foot brace, E2: Botulinum toxin A and conventional rehabilitation, C: Conventional rehabilitation | • Clinic spasticity influx (+)  
• Fugl-Meyer Assessment (+)  
• Berg Balance Scale (+)  |
| Wang et al. (2007)      | RCT (6) N=58             | E: With AFO, C: Without AFO                                                 | • % weight bearing difference (+)  
• movement velocity (deg/sec) (+)  
• % maximal excursion (+)  
• Speed (+)  
• Step length (+)  
• Stride length (+)  
• Base width (+)  |
| de Wit et al. (2004)    | RCT (5) N=20             | E: With AFO, C: Without AFO                                                 | • Walking speed (+)  
• Timed Up-and-Go Test (+)  |
| Pohl & Mehrholz (2006)  | RCT (5) N=20             | E: Wearing AFO for varying sequences, C: Wearing only footwear             | • Stance duration at 90% body-weight (vertical ground reaction forces) (+)  
• Deceleration forces (horizontal ground reaction forces) (+)  
• Double stance duration (+)  |
| Erel et al. (2011)      | RCT (5) N=32             | E: Dynamic ankle-foot orthosis, C: No dynamic ankle-foot orthosis            | • Timed up: stairs (+)  
• Gait velocity (+)  |
| De Seze et al. (2011)   | RCT (5) N=28             | E1: A standard AFO, E2: Chignon ankle-foot orthosis                         | • Mean gain ratio of walking speed (+)  |
| Kosak et al. (2000)     | RCT (4) N=56             | E: Partial body weight-supported treadmill training, C: Aggressive bracing assisted walking | • Gait speed (-)  
• Gait distance (-)  |
• Plantar flexion (+)  
• Swing phase (+)  
• Maximal eversion (+)  
• Maximal inversion angle (+)  
Coronal plane: E2 vs. C  
• Maximal inversion angle (+)  
Transverse plane: E1 vs. C and E2 vs. C |
Adduction angle (+)

- Maximal step length: E1 vs C (+)
- Gait speed: E1 vs E2 (-)
- Stride length: E1 vs E2 (-)
- Step length: E1 vs E2 (-)
- Time to complete and maximal step length: E1 vs E2 (-)

E1: Custom-made articulated ankle-foot orthosis
E2: A prefabricated articulated AFO (P-AFO)
C: No AFO

- Functional ambulation category: E1 vs. C (+), E2 vs. C (+), E3 vs. C (+), E4 vs. C (+)

Table 9.7.3.1 Summary of Ankle Foot Orthoses with Tibial Denervation

<table>
<thead>
<tr>
<th>Author, Year</th>
<th>Study Design (PEDro Score)</th>
<th>Sample Size</th>
<th>Intervention</th>
<th>Main Outcome(s)</th>
<th>Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>Beckerman et al. (1996)</td>
<td>RCT (8)</td>
<td>N=60</td>
<td>E1: Thermocoagulation (TH) of the tibial nerve with a custom made ankle foot orthosis (AFO) in five degrees of dorsiflexion</td>
<td>Sickness Impact Profile category “ambulation”</td>
<td>(-) Walking speed (-)</td>
</tr>
<tr>
<td>Beckerman et al. (1996)</td>
<td>RCT (7)</td>
<td>N=60</td>
<td>E1: Thermocoagulation (TH) of peripheral nerves with a custom made ankle foot orthosis (AFO) in five degrees of dorsiflexion</td>
<td>Achilles tendon reflexes (+)</td>
<td>Ankle clonus than groups 2 and 4 (both PTH) (+)</td>
</tr>
</tbody>
</table>

Discussion

A common practice in improving gait in hemiplegic stroke patients is the use of ankle foot orthotics. Research suggests that the use of AFO may improve gait and range of motion in patients post-stroke (de Wit et al. 2004; Ding et al. 2015; Pohl & Mehrholz 2006; Wang et al. 2007). Furthermore, there is limited evidence to suggest that there is no significant difference between AFO assisted walking and partial body weight supported walking with both being equally effective in increasing walking endurance and velocity (Kosak & Reding 2000). In addition to AFO, posterior tibial nerve denervation can be used as an additional method of treatment in stroke patients. Limited evidence suggests that posterior tibial nerve denervation, in combination with traditional AFO may improve ankle reflexes but may not improve gait (Beckerman et al. 1996).

Conclusions Regarding Splinting of Lower Extremity in Stroke

There is level 1a and level 2 evidence that wearing an AFO may improve gait and range of motion; however, there is limited evidence for its effectiveness on balance.
There is limited level 2 evidence showing no significant difference between brace-assisted walking and partial body weight-supported treadmill training for the improvement of gait outcomes.

There is level 1a evidence that an AFO when combined with posterior tibial nerve denervation, may not improve gait but may improve foot reflexes post-stroke.

Ankle foot orthoses (AFOs) may improve gait and range of motion; however not when combined with posterior tibial nerve denervation. More research is needed to determine if AFOs are beneficial for improving balance.

9.7.4 Electromechanical-assisted Training Devices
Currently, effort has been invested at developing electromechanical-assisted training devices for gait training. These devices can be used with or without body weight support and are classified as either an end effector device (i.e., have patient’s feet placed on foot plates and trajectories stimulate the stance and swing phases during gait training) or an exoskeleton device (i.e., patients are outfitted with programmable drives or passive elements, which move the hips and knees during gait phases). The most commonly studied end-effector device is the Gait Trainer, with the Lokomat and AutoAmbulator being the two most popular exoskeleton devices (Jan Mehrholz & Pohl 2012). The main advantage of these devices over conventional gait training is that they reduce the need for intensive therapist involvement. Furthermore, there has been recent studies focusing on small modular robots designed for single joint use such as the ankle (Forrester et al. 2013).

A Cochrane review including the results from 8 trials (414 participants) concluded that electromechanical-assisted training devices were associated with an increased odds of becoming an independent ambulator (OR: 3.06, 95% CI 1.85 to 5.06) and increased walking capacity, but were not associated with increases in gait velocity (Mehrholz et al. 2007). The authors noted that their results should be interpreted with caution since the duration, intensity and frequency of treatments differed among studies and the use of an additional therapy (electrical stimulation) in some of the included trials may have resulted in an inflated treatment effect. In 2013, this Cochrane review was updated (Mehrholz et al. 2013), for justification of large equipment and human resources costs to implement electromechanical-assisted training devices. Including results from 23 trials involving 999 participants, authors concluded that electromechanical-assisted training devices in combination with physiotherapy increased was associated with an increases odds ratio of becoming an independent walker (OR: 2.39%, 95% CI 1.67-3.43) but did not significantly increase walking velocity or capacity.

Ada et al. (2010) reviewed 6 RCTs that examined the benefit of either treadmill training or electromechanical gait trainers which included a body-weight support component, in non-ambulatory persons in the subacute (< 3 months) period of stroke. The results from the meta-analysis indicated that treatment was associated with an increase in the percentage of patients who had achieved independent ambulation status at 4 weeks and 6 months. Patients were also able to walk faster and farther compared to those who received conventional overground walking therapy. The authors speculated that gait trainers afforded the opportunity for more task-related practice compared with same given amount of conventional training. In a systematic review comparing the effects of end-effector vs. exoskeleton devices as part of gait training after stroke (Mehrholz & Pohl 2012), authors found evidence for walking recovery after stroke being dependent on the type of training device. In general, studies using an end-effector device contained significantly fewer patients who walked independently (had more severe initial impairment), compared to studies using exoskeleton devices. Despite participants having greater
initial severe impairment, end-effector device studies achieved higher rates of independent walking at the end of the study period in contrast to studies involving exoskeleton devices (Mehrholz & Pohl 2012).

In addition to robot-assisted treadmill devices, there have been several RCTs assessing robots that assist stroke patients with ankle and mobility impairment. These devices are designed to improve ankle function following stroke by improving or maintaining passive range of motion in the ankle. Please note, that in the following Table, we have included the results of five studies (evaluating non-robotic devices) which are also included as part of the body-weight supported treadmill training section (Dias et al. 2007; Peurala et al. 2005; Pohl et al. 2007; Tong et al. 2006; Werner et al. 2002).

Table 9.7.4.1 summarizes RCTs that evaluate robotic devices for the rehabilitation of lower limb impairments. The time post-stroke (TPS) information was provide and divided in 3 stages of stroke recovery: acute (<3 months), subacute (3-6 months), and chronic (>6 months).

### Table 9.7.4.1 Summary of RCTs Evaluating Robotic Devices & Electromechanical-Assisted Training Devices

<table>
<thead>
<tr>
<th>Author, Year</th>
<th>Study Design (PEDro Score)</th>
<th>Sample Size</th>
<th>TPS</th>
<th>Intervention</th>
<th>Main Outcome(s) Result</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Gait Trainer / Robotic Gait Trainer</strong></td>
<td>E: Repetitive practice on a gait trainer, C: Individual physiotherapy</td>
<td>E: Gait-assisted robot gait training, C: Overground conventional gait training</td>
<td>E: Robotic group, C: Control group</td>
<td>E1: Locomotor therapy on a gait trainer, E2: Treadmill therapy with body weight support</td>
<td>Functional Ambulation Category (+), Rivermead Mobility Index (+), Barthel Index (+)</td>
</tr>
<tr>
<td>Ochi et al. (2015)</td>
<td>RCT (8) N=26 TPS=acute</td>
<td>E: Gait-assisted robot gait training, C: Overground conventional gait training</td>
<td>E: Robotic group, C: Control group</td>
<td>E1: Gait training using an electrical gait trainer with partial body weight support, E2: Gait training using an electromechanical</td>
<td>10-metre Walk Test (·), 6-minute Walk Test (-), Modified Motor Assessment Scale (-)</td>
</tr>
<tr>
<td>Morone et al. (2011)</td>
<td>RCT (8) N=48 TPS=acute</td>
<td>E: Robotic group, C: Control group</td>
<td>E1: Gait training using an electrical gait trainer with partial body weight support, E2: Gait training using an electromechanical</td>
<td>E1: Gait training using an electrical gait trainer with partial body weight support, E2: Gait training using an electromechanical</td>
<td>10-metre Walk Test (-), 6-minute Walk Test (·), Modified Motor Assessment Scale (-)</td>
</tr>
<tr>
<td>Stein et al. (2014)</td>
<td>RCT (7) N=30 TPS=acute</td>
<td>E: Robotic treatment received 1 hour of individualized physical therapy</td>
<td>E1: Gait training using an electrical gait trainer with partial body weight support, E2: Gait training using an electromechanical</td>
<td>E1: Gait training using an electrical gait trainer with partial body weight support, E2: Gait training using an electromechanical</td>
<td>10-metre Walk Test (·), 6-minute Walk Test (-), Modified Motor Assessment Scale (-)</td>
</tr>
<tr>
<td>Study</td>
<td>Intervention</td>
<td>Control</td>
<td>Outcome Measures</td>
<td></td>
<td></td>
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<td></td>
</tr>
<tr>
<td><strong>TPS=acute</strong></td>
<td>gait trainer with functional electric stimulation</td>
<td>C: Conventional gait training</td>
<td>• 5-metre Walk Test (+)</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Ng et al. (2008)</strong></td>
<td>Addition of 4 subjects to study authored by Tong et al. (2006)</td>
<td></td>
<td>• Motricity Index leg scores (-)</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Dias et al. (2007)</strong></td>
<td>E: Gait trainer</td>
<td>C: Control group</td>
<td>• Motricity Index (-) • Toulouse Motor Scale (-) • Modified Ashworth Spasticity Scale (-) • Berg Balance Scale (-) • Rivermead Mobility Index (-) • Fugl-Meyer Stroke Scale (-) • Barthel Index (-) • Time Up-and-Go Test (-)</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Peurala et al. (2009)</strong></td>
<td>E1: Gait trainer exercise with BWS</td>
<td>E2: Training over ground with 1 or 2 physiotherapists</td>
<td>C: Conventional treatment</td>
<td>• Walking ability: E1 vs C (+); E2 vs C (+) • Mean accomplished walking distance (-)</td>
<td></td>
</tr>
<tr>
<td><strong>Hesse et al. (2012)</strong></td>
<td>E: Gait robot offering repetitive practice</td>
<td>C: Task-specific repetitive approach to physiotherapy</td>
<td></td>
<td>• Functional Ambulation Category scores, Gait velocity (+) • Rivermead Mobility Index (+) • Motricity Index scores (+)</td>
<td></td>
</tr>
<tr>
<td><strong>Waldman et al. (2013)</strong></td>
<td>E: Robot program: active stretching and movement training of the affected ankle</td>
<td>C: Exercise program; written and verbal instructions on how to perform passive calf stretches and active movement exercises of the impaired ankle</td>
<td></td>
<td>• 6-minute Walk Test (-) • Modified Ashworth Scale (-) • Stroke Rehabilitation Assessment of Movement (-) • Berg Balance Scale (-)</td>
<td></td>
</tr>
<tr>
<td><strong>Fisher et al. (2011)</strong></td>
<td>E: Robot-assisted gait training using the Autoambulator</td>
<td>C: Goal-oriented Physiotherapy</td>
<td></td>
<td>• 8-metre Walk Test (-) • 3-minute Walk Test (-) • Tinnetti Balance Assessment (-)</td>
<td></td>
</tr>
<tr>
<td><strong>Rydwik et al. (2006)</strong></td>
<td>E: Program including active and passive range of motion of the ankle with a portable device</td>
<td>C: No Intervention</td>
<td></td>
<td>• Range of motion (-) • Muscle strength (-) • Spasticity (-) • Gait variables (-) • Balance (-) • ADL (-)</td>
<td></td>
</tr>
<tr>
<td><strong>Watanabe et al. (2014)</strong></td>
<td>E: Hybrid Assistive Limb training</td>
<td>C: Gait training</td>
<td></td>
<td>• Functional Ambulation Category (+) • Maximum Walking speed (-) • Cadence (-) • Stride (-) • Fugl-Meyer Assessment of the Lower-Extremity (-) • 6-minute walk test (-) • Timed Up-and-Go Test (-)</td>
<td></td>
</tr>
<tr>
<td><strong>Dundar et al. (2014)</strong></td>
<td>E: Robotic training combined with conventional physiotherapy</td>
<td>C: Conventional physiotherapy</td>
<td></td>
<td>• Berg Balance Scale (-) • Modified Ashworth Scale (-) • Functional Ambulation Category (-)</td>
<td></td>
</tr>
<tr>
<td>TPS=acute</td>
<td>Lokomat</td>
<td>Other Devices</td>
<td></td>
<td></td>
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<td>-----------</td>
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<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
| **Husemann et al.** (2007)  
RCT (7)  
N=30  
TPS=acute | E: Conventional therapy + treadmill training with the Lokomat robotic device  
C: Conventional physical therapy |  
- Functional Ambulation Category (-)  
- 10-metre Walk Test (-) |
| **Mayr et al.** (2007)  
RCT (6)  
N=16  
TPS=acute | E: Lokomat training + Conventional training  
C: Conventional training |  
- Rivermead Motor Assessment Scale (-)  
- 10-metre Walk Test (-)  
- 6-minute Walk Test (-)  
- Medical Research Council Scale (-)  
- Ashworth Scale (-) |
| **Schwartz et al.** (2009)  
RCT (6)  
N=67  
TPS=acute | E: Physical therapy + additional therapy using the Lokomat training device  
C: Similar amount of physical therapy |  
- Functional Ambulatory Capacity Scale (+)  
- NIHSS Scores (+)  
- Stroke Activity Scale Scores (-)  
- Timed Walk tests (-) |
| **van Nunen** (2015)  
RCT (6)  
N<sub>Start</sub>=30  
N<sub>End</sub>=30  
TPS=acute | E: Robot-assisted treadmill training administered with Lokomat  
C: Conventional overground therapy |  
- 10-metre timed walk test (-)  
- Berg Balance Scale (-)  
- Motricity Index (-) |
| **Westlake & Patten** (2009)  
RCT (6)  
N=16  
TPS=chronic | E: Lokomat training  
C: Manual-body-weight support treadmill training |  
- Self-selected overground walking speed (-)  
- Paretic step length ratio (-) |
| **Chang et al.** (2012)  
RCT (6)  
N=48  
TPS=acute | E: Robot-assisted gait training using the Lokomat  
C: Conventional physical therapy |  
- Peak VO₂ (+)  
- Cardiovascular or ventilatory response (+)  
- Fugl-Meyer Assessment lower extremity (-)  
- Motricity Index (-)  
- Functional Ambulation Categories (-) |
| **Ucar et al.** (2014)  
RCT (6)  
N<sub>Start</sub>=22  
N<sub>End</sub>=22  
TPS=chronic | E: Lokomat training  
C: Conventional exercise for the same duration |  
- 10-metre Walk Test (+)  
- Timed Up-and-Go Test (+) |
| **Hidler et al.** (2009)  
RCT (5)  
N=63  
TPS=subacute | E: Lokomat training  
C: Conventional gait training |  
- Self-selected overground walking speed (+)  
- Self-selected overground walking distance (+)  
- Balance (-)  
- Mobility and function (-)  
- Cadence and symmetry (-)  
- Level of disability (-)  
- Quality of life measures (-) |
| **Krewer et al.** (2013)  
PCT  
N<sub>Start</sub>=25  
N<sub>End</sub>=24  
TPS=chronic | E1: Galvanic vestibular stimulation.  
E2: Driven-gait orthosis Lokomat.  
C: Physiotherapy with visual feedback components. |  
- Scale for Contraversive Pushing (-) |
| **Freivogel et al.** (2009)  
RCT Crossover (7)  
N=16 | E: Locomotor training with an electromechanical gait device (LokoHelp)  
C: Task-oriented gait training |  
- Walking ability (-)  
- Gait velocity (-)  
- Rivermead Mobility Index (-) |
<table>
<thead>
<tr>
<th>TPS=acute</th>
<th>E: 12 training sessions at similar speeds, with guided symmetrical locomotor assistance using a robotic orthosis</th>
<th>Gait speed (+)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hornby et al. (2008)</td>
<td>C: 12 training sessions using manual facilitation from a single therapist using an assist-as-needed paradigm</td>
<td></td>
</tr>
<tr>
<td>RCT (6)</td>
<td>N=48</td>
<td></td>
</tr>
<tr>
<td>TPS=chronic</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Forrester et al. (2014)</td>
<td>E: Robotic training using dorsiflexion of the ankle with an ankle robot supporting the paretic leg to control movements in video games</td>
<td>Gait velocity (-)</td>
</tr>
<tr>
<td>RCT (6)</td>
<td>N\textsubscript{Start}=39</td>
<td>Ankle range of motion (-)</td>
</tr>
<tr>
<td>N\textsubscript{Exp}=34</td>
<td>Mean paretic to non-paretic step-time ratio (+)</td>
<td></td>
</tr>
<tr>
<td>TPS=acute</td>
<td>Mean angular velocity (+)</td>
<td></td>
</tr>
<tr>
<td>Monticone et al. (2013)</td>
<td>E: Exercises while wearing a “Regent Suit”</td>
<td>Gait speed (+)</td>
</tr>
<tr>
<td>RCT (7)</td>
<td>C: Same exercises without the suit.</td>
<td>Cadence (+)</td>
</tr>
<tr>
<td>N\textsubscript{Start}=60</td>
<td>Paretic step length (+)</td>
<td></td>
</tr>
<tr>
<td>N\textsubscript{Exp}=50</td>
<td>Healthy step length (+)</td>
<td></td>
</tr>
<tr>
<td>TPS=acute</td>
<td>Berg Balance Scale (+)</td>
<td></td>
</tr>
<tr>
<td>Tea-Woo Kim et al. (2014)</td>
<td>E: Sideways gait training on a treadmill with eye patches on their eyes</td>
<td>Walking speed (+)</td>
</tr>
<tr>
<td>RCT (5)</td>
<td>C: Sideways gait training on a treadmill without eye patches</td>
<td>Step length of the affected and unaffected limbs (+)</td>
</tr>
<tr>
<td>N\textsubscript{Start}=24</td>
<td>Stride length of the affected and unaffected side(+)</td>
<td></td>
</tr>
<tr>
<td>N\textsubscript{Exp}=24</td>
<td>TPS=chronic</td>
<td></td>
</tr>
<tr>
<td>Choi et al. (2013)</td>
<td>E: Application of taping + therapeutic exercise</td>
<td>Straight line walking test (-)</td>
</tr>
<tr>
<td>RCT (4)</td>
<td>C: No application of taping + therapeutic exercise</td>
<td>Berg Balance Scale (+)</td>
</tr>
<tr>
<td>N\textsubscript{Start}=30</td>
<td>10-metre Walk Test (+)</td>
<td></td>
</tr>
<tr>
<td>N\textsubscript{Exp}=30</td>
<td>TPS=NA</td>
<td></td>
</tr>
</tbody>
</table>

- Indicates non-statistically significant differences between treatment groups
+ Indicates statistically significant differences between treatment groups

**Discussion**

A variety of robotic devices have been used to help improve lower limb function after stroke. Several authors have reported improved gait following the use of the Gait trainer in acute stroke patients (Ochi et al. 2015; Morone et al. 2011; Werner et al. 2002; Tong et al. 2006; Peurala et al. 2009; Hesse et al. 2012). Conversely, Peurala et al. (2005) and Watanabe et al. (2014) found no additional benefit of using the Gait trainer on gait speed. In the chronic stroke population, the Gait trainer was not found to be significantly different than conventional therapy at improving gait or balance (Fisher et al. 2011; Rydwik et al. 2006; Dias et al. 2007). Similar findings were found in patients in the subacute stage of recovery (Waldman et al. 2013; Dundar et al. 2014).

The Lokoman was studied in stages of stroke recovery, and was not found to be significantly different than conventional therapy regarding its effectiveness at improving lower limb motor function, gait, or balance in the acute stroke population (Chang et al. 2012; van Nunen et al. 2015; Schwartz et al. 2009; Mayr et al. 2007; Husemann et al. 2007). One study reported improved gait and balance following the use for the device in chronic stroke individuals (Ucar et al. 2014), while Westlake and Patten (2009) found no added benefit on walking speed after using the Gait trainer.
Conclusions Regarding Electromechanical-Assisted and Other Devices

There is level 1a and level 2 evidence that the Gait Trainer device may improve gait in the acute phase but not in the subacute or chronic phase of stroke recovery.

There is level 1a and level 2 evidence that the Lokomat may not improve gait and balance in the acute phase of stroke recovery. The evidence is unclear and limited regarding the use of this device in the chronic and subacute stroke phases.

The Gait trainer may improve gait but only when used in the acute phase of stroke. The Lokomat may not be beneficial at improving gait or balance in the acute phase of stroke recovery; however, more research is needed to determine if patients in the chronic or subacute phase can benefit from using this device.

9.8 Electrical Stimulation

Electrical stimulation has been used as a method to improve spasticity, muscle tone, sensory deficits and pain reduction, which may lead to improvements in functional recovery. The application of an electrical current to the skin stimulates lower motor nerves and muscle fibres resulting in improved contractility. Electrical stimulation is typically administered via two methods, functional electrical stimulation (FES) and transcutaneous electrical nerve stimulation (TENS).

A Cochrane review examined these two forms of electrical stimulation as a treatment for functional motor recovery following stroke (Pomeroy et al., 2006). Twenty-four trials (2,077 subjects) were identified that included subjects with both upper and lower limb hemiparesis. The authors concluded that there was some benefit associated with treatment. The authors suggested that future research that paid particular attention to issues of timing and dose was required before definitive conclusions could be reached.

9.8.1 Transcutaneous Electrical Nerve Stimulation (TENS)

TENS is a form of treatment that delivers electrical stimulation using a current intensity that it is beneath motor threshold; the sensation has been described as feeling like “pins-and-needles.” Although TENS has been used most frequently as a means to reduce pain, it may also promote recovery of movement or functional ability following stroke. Similar to acupuncture or FES, TENS is one method of achieving increased afferent stimulation (Sonde et al., 1998). TENS is also used to treat focal spasticity.

Nine studies, of which six were RCTs, examined the efficacy of TENS on motor recovery. In five studies the effect of TENS on functioning was investigated in both the upper and lower extremity (Johansson et al. 2001; Peurala et al. 2002; Potisk et al. 1995; Rorsman & Johansson 2006; Tekeoglu et al. 1998). Tekeörgülü et al. (1998) hypothesized that repeated application of TENS might decrease clinical spasticity and improve motor function of the paretic extremity in the hemiparetic patient. The results from RCTs examining TENS treatment are summarized in Table 9.8.1.1.

<table>
<thead>
<tr>
<th>Author, Year</th>
<th>Study Design (PEDro Score)</th>
<th>Intervention</th>
<th>Main Outcome(s) Result</th>
</tr>
</thead>
</table>

Table 9.8.1.1 Summary of RCTs Evaluating Transcutaneous Electrical Nerve Stimulation (TENS)
<table>
<thead>
<tr>
<th>Sample Size</th>
<th>Treatment Details</th>
<th>Outcomes</th>
</tr>
</thead>
</table>
| **Tekeoğlu et al. (1998)**  
RCT (9)  
N=60 | E: Basic neurophysiological rehab treatment + Active TENS  
E: Basic neurophysiological rehabilitation | • Barthel Index (+) |
| **Johansson et al. (2001)**  
RCT (8)  
N=150 | E1: Acupuncture  
E2: TENS  
C: Control | • Rivermead Mobility Index (-)  
• Walking Ability (-)  
• Barthel Index (-)  
• Nottingham Health Profile (-) |
| **Chan et al. (2015)**  
RCT (8)  
NStart=37  
NEnd=37 | E1: TENS + Task related trunk training  
E2: Placebo-TENS + TRTT  
C: Placebo | • Dynamic Sitting Balance: E1/E2 vs C (+)  
• Coordination: E1 vs. E2 (+); E1 vs. C (+)  
• Trunk Impairment Scale: E1 vs E2 (+) |
| **Picelli et al. (2014)**  
RCT (8)  
NStart=30  
NEnd=30 | E1: Therapeutic ultrasound (US) to the affected leg calf muscles  
E2: TENS  
E3: 200 units of botulinum toxin type A to the gastrocnemius muscle belly on the affected side | • MAS (+) significantly differed between all groups at T2 and T3  
• MAS at T2 and T3: E3 vs E1 (+)  
• Ankle passive range of motion at T2 and T3: E3 vs E1 (+) and E3 vs E2 (+)  
• MAS at all times: E1 vs E2 (-)  
• Ankle PROM: E1 vs E2 (-) |
| **Park et al. (2014)**  
RCT (7)  
NStart=34  
NEnd=29 | E: TENS exercise plus therapeutic exercise  
C: Placebo TENS plus therapeutic exercise | • Modified Ashworth Scale (+) |
| **Ng & Hui-Chan (2009)**  
RCT (7)  
N=109 | E1: TENS  
E2: TENS + exercise  
E3: Placebo stimulation + exercise  
C: No active treatment | • 6-minute Walk Test (+)  
• Timed Up-and-Go Test (+) |
| **Yan et al. (2009)**  
RCT (6)  
N=62 | E1: TENS  
E2: Placebo stimulation  
C: Standard rehabilitation | • Plantarflexor spasticity (+)  
• Ankle dorsiflexion muscle strength (+) |
| **Tyson et al. (2013)**  
RCT (6)  
N=29 | E: Active TENS  
C: Sham TENS | • Muscle strength (dynamometer balance) (-)  
• 10-meter walk test) (-) |
| **Ng & Hui-Chan (2007)**  
RCT (6)  
N=88 | E1: TENS  
E2: TENS + PT  
E3: Sham TENS  
C: No treatment control | • Ankle dorsiflexion torque (+)  
• Ankle plantarflexion (+)  
• Plantarflexor spasticity (+)  
• Gait velocity (+) |
| **Tekeoğlu et al. (1998)**  
RCT (6)  
N=60 | E: Rehabilitation + TENS  
C: Rehabilitation | • Barthel Index improvement (+) |
| **Hussain et al. (2013)**  
RCT (6)  
NStart=50  
NEnd=30 | E: Bobath and TENS  
C: Bobath therapy | • Ankle-joint dorsiflexion range of motion (+)  
• Strength of ankle dorsiflexor muscles (+)  
• 10-meter Walking Test (+)  
• Hand-held goniometer for ankle dorsiflexion (+)  
• Manual muscle strength testing scale for strength of ankle dorsiflexors (+)  
• Brunnstrom stage for motor function of lower limb (+) |
| **Cho et al. (2013)**  
RCT (5)  
NStart=50 | E: TENS  
C: Placebo-TENS | • Modified Ashworth Scale (+)  
• Eyes open and eyes closed for postural sway length (+) |
- Indicates non-statistically significant differences between treatment groups
+ Indicates statistically significant differences between treatment groups

Discussion
Transcutaneous electrical nerve stimulation (TENS) is widely used for the treatment of pain, however there is evidence that TENS is not limited to pain reduction but may also be used in promoting lower limb movement recovery following a stroke. TENS may improve gait, spasticity, balance, range of motion and muscle strength (Chan et al. 2015; Cho et al. 2013; Hussain & Mohammad 2013; Ng & Hui-Chan 2007, 2009; Park et al. 2014; Tekeoglu et al. 1998; Yan & Hui-Chan 2009). It is important to note that one study found no difference between active TENS treatment and sham TENS treatment (Tyson et al. 2013) suggesting that a placebo may be sufficient in treating lower limb recovery following a stroke. Furthermore there is limited evidence that TENS also improves performance of activities of daily living (Tekeoglu et al. 1998).

Conclusions Regarding TENS treatment in the lower extremity

**There is level 1a and limited level 2 evidence that transcutaneous electrical nerve stimulation may improve gait, spasticity, balance, and ankle joint dorsiflexion range of motion and muscle strength.**

Transcutaneous electrical nerve stimulation may improve gait, spasticity, balance, muscle strength, and ankle dorsiflexion range of motion.

9.8.2 Functional Electrical Stimulation

Functional electrical stimulation (FES) in the lower extremity has been used to enhance ankle dorsiflexion during the swing phase of gait (Kim et al. 2012). Weak ankle dorsiflexion with plantarflexion hyper tonicity results in a drop foot, which is typically corrected by an ankle foot orthosis (AFO). FES of the common peroneal nerve during the swing phase of gait would appear to be a suitable alternative. Although not widely used or universally available, there is growing evidence that treatment with FES for highly motivated patients, able to walk independently or with minimal assistance, can improve dropped foot which in turn improves gait. Improvements in gait speed, cadence, and stride length have resulted from this treatment (Kim et al. 2012). Both implantable and surface electrodes may be used. A meta-analysis by Glanz et al. (1996) including four RCTs (Bowman et al. 1979; Levin & Hui-Chan 1992; Merletti et al. 1978; Winchester et al. 1983), reported a favourable treatment effect associated with FES compared to a no treatment control. The effect size associated with a statistically significant change in paretic muscle force of contraction was 0.63 (95% CI 0.29, 0.98), although the clinical significance of this outcome was unclear. There were no other common outcomes among the four included studies.

A systematic review (Kottink et al. 2004) has also evaluated the effect of FES treatment on gait recovery. This review included eight studies, only one of which was an RCT, evaluating both implanted and transcutaneous stimulators (Table 9.8.2.1). The primary outcomes in this review were self-selected walking speed and the physiological cost index (PCI). Pooled estimates of treatment effect only included point estimates from three studies. The result suggested that FES treatment was associated with a 38% (95% CI, 22% - 54%) improvement in walking speed. Only two studies were included in the evaluation of improvement of PCI and the results were inconclusive.

| Table 9.8.2.1 Studies Included in the Systematic Review by Kottink et al. (2004) |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  | 
A systematic review by Robbins et al. (2006) evaluated the effect of TENS and FES on gait speed and included the results from 8 studies, 4 of which were RCTs. FES was associated with a significant treatment effect although the effect size was larger in studies, which used multichannel FES compared to single-channel FES.

A Cochrane review examined the use of all forms of electrostimulation (ES) in the recovery of functional ability following stroke. This review assessed the efficacy of functional electrical stimulation (both as a form of neuromuscular retraining and as a form of neuroprosthesis/orthosis), transcutaneous electrical nerve stimulation, EMG and electroacupuncture (Pomeroy & Tallis 2000). Twenty-four RCTs evaluating the efficacy of treatment on both the upper and lower extremities were included. Only three outcomes yielded a benefit of treatment that reached statistical significance: i) ES improved motor impairment active joint range of movement in the lower limb, compared to no stimulation; ii) improved co-contraction of agonist and antagonist muscles for the comparison of ES compared with placebo and improved Fugl-Meyer scores for the comparison of ES vs. conventional therapy. The authors concluded that further research is required to confirm a benefit of treatment.

Individual studies that evaluated the effects of FES on lower extremity are found in Table 9.8.2.2 below.

### Table 9.8.2.2 Summary of RCTs Evaluating Electrical Stimulation

<table>
<thead>
<tr>
<th>Author, Year</th>
<th>Study Design (PEDro Score)</th>
<th>Intervention</th>
<th>Outcome</th>
</tr>
</thead>
<tbody>
<tr>
<td>Spachh et al. (2014) RCT (8) N_start=30 N_end=28</td>
<td>E: Physiotherapy-based gait training combined with activation of the nociceptive withdrawal reflex by FES of the arch of the foot C: Physiotherapy-based gait training alone.</td>
<td>Gait velocity: E vs C (+) Gait cycle duration: at 6mo post E vs. C (+) Stance duration: at 6mo post E vs. C (+) Stance time symmetry ratio: E vs. C (+) Functional Ambulation Category: at 6mo post E vs. C (+)</td>
<td></td>
</tr>
<tr>
<td>Morone et al. (2012) RCT (8) N=20</td>
<td>E: FES WalkAide + Conventional physiotherapy C: Conventional physiotherapy</td>
<td>Ten-meter Walking Speed Test (+) Functional Ambulation Classification (+) Barthel Index (-) Rivermead Mobility Index (-)</td>
<td></td>
</tr>
<tr>
<td>Ambrosini et al. (2011) RCT (8) N=35</td>
<td>E: FES-induced cycling training C: Placebo FES cycling</td>
<td>Gait speed (-)</td>
<td></td>
</tr>
<tr>
<td>Suh &amp; Han (2014) RCT (8) N_start=42 N_end=42</td>
<td>E: Interferential Current Therapy group (stimulation of the gastrocnemius in conjunction with an air-pump massage) C: Placebo-ICT group.</td>
<td>Functional Reach Test (+) Berg Balance Scale (+)</td>
<td></td>
</tr>
<tr>
<td>Bae et al. (2014)</td>
<td>E: Robot-assisted gait training combined</td>
<td>Maximal knee flexion at post intervention (+)</td>
<td></td>
</tr>
<tr>
<td>Study</td>
<td>Design</td>
<td>N Start</td>
<td>N End</td>
</tr>
<tr>
<td>-------</td>
<td>--------</td>
<td>---------</td>
<td>-------</td>
</tr>
<tr>
<td>Daly et al. (2006)</td>
<td>RCT (8)</td>
<td>N=20</td>
<td>N=20</td>
</tr>
<tr>
<td>Daly et al. (2011)</td>
<td>RCT (7)</td>
<td>N=54</td>
<td>N=54</td>
</tr>
<tr>
<td>Tan et al. (2014)</td>
<td>RCT (7)</td>
<td>N=55</td>
<td>N=37</td>
</tr>
<tr>
<td>You et al. (2014)</td>
<td>RCT (7)</td>
<td>N=42</td>
<td>N=37</td>
</tr>
<tr>
<td>Kottink et al. (2010)</td>
<td>RCT (7)</td>
<td>N=29</td>
<td>N=29</td>
</tr>
<tr>
<td>Yavuzer et al. (2007)</td>
<td>RCT (7)</td>
<td>N=30</td>
<td>N=30</td>
</tr>
<tr>
<td>Knutson et al. (2013)</td>
<td>RCT (6)</td>
<td>N=24</td>
<td>N=24</td>
</tr>
<tr>
<td>Janssen et al. (2008)</td>
<td>RCT (6)</td>
<td>N=12</td>
<td>N=12</td>
</tr>
<tr>
<td>Yan et al. (2005)</td>
<td>RCT (6)</td>
<td>N=46</td>
<td>N=46</td>
</tr>
<tr>
<td>Salisbury et al. (2013)</td>
<td>RCT (6)</td>
<td>N=16</td>
<td>N=14</td>
</tr>
<tr>
<td>Study Reference</td>
<td>Design</td>
<td>Randomized N</td>
<td>Type of Intervention</td>
</tr>
<tr>
<td>---------------------------------</td>
<td>--------</td>
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<td>---------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Cozean et al. (1988)</td>
<td>RCT</td>
<td>N=36</td>
<td>E1: Electromyography Biofeedback (BFB) E2: Functional electrically stimulation (FES) E3: Combined therapy with BFB and FES. C: Standard physical therapy regimen</td>
</tr>
<tr>
<td>Chung et al. (2015)</td>
<td>RCT</td>
<td>NStart=10 NEnd=10</td>
<td>E: Brain-computer interference-based functional electrical stimulation (BCI-FES) (i.e. received ankle dorsiflexion training with FES as per the BCI-based program) C: Ankle dorsiflexion training with FES</td>
</tr>
<tr>
<td>Yavuzer et al. (2006)</td>
<td>RCT</td>
<td>N=25</td>
<td>E: Neuromuscular electric stimulation (NMES) treatment of the tibialis anterior muscle + traditional therapy program C: Traditional therapy program</td>
</tr>
<tr>
<td>Bethoux et al. (2014)</td>
<td>RCT</td>
<td>NStart=495 NEnd=399</td>
<td>E: WalkAide functional electrical stimulation (FES) system (WA) C: Ankle foot orthosis (AFO) brace</td>
</tr>
<tr>
<td>Kim, Choi et al. (2014)</td>
<td>RCT</td>
<td>NStart=30 NEnd=30</td>
<td>E: Proprioceptive neuromuscular facilitation combination patterns and kinesio taping C: Neurodevelopmental treatment</td>
</tr>
<tr>
<td>Kojovic et al. (2009)</td>
<td>RCT</td>
<td>N=13</td>
<td>E: Functional electrical stimulation during walking with a four channel stimulator targeting 4 muscle groups C: No FES</td>
</tr>
<tr>
<td>Kluding et al. (2013)</td>
<td>RCT</td>
<td>N=197</td>
<td>E: Surface FES C: Standard AFO</td>
</tr>
<tr>
<td>Kottnik et al. (2007)</td>
<td>RCT</td>
<td>N=29</td>
<td>E: Implantable 2-channel peroneal nerve stimulator for correction of their drop foot C: Conventional walking device, consisting of an ankle-foot orthosis, orthopedic shoes, or no device</td>
</tr>
<tr>
<td>MacDonnel et al. (1994)</td>
<td>RCT</td>
<td>N=35</td>
<td>E: Cyclic electrical stimulation with an exercise and physical therapy program C: Self-exercise program independently with an exercise and physical therapy program</td>
</tr>
<tr>
<td>Sheffler et al. (2013)</td>
<td>RCT</td>
<td>NStart=110 NEnd=84</td>
<td>E: Peroneal Nerve Stimulation C: Usual care group.</td>
</tr>
<tr>
<td>Ribeiro et al. (2013)</td>
<td>RCT</td>
<td>N=50</td>
<td>E: Proprioceptive neuromuscular facilitation training</td>
</tr>
</tbody>
</table>
- Indicates non-statistically significant differences between treatment groups
+ Indicates statistically significant differences between treatment groups

### Discussion

Generalizations of the effectiveness of the treatment are difficult to make due to variations in the type of stimulation (single-channel vs. multichannel units), intensity of treatment, patient acceptability and compliance, additional treatments provided (i.e. routine physiotherapy, AFOs) as well as the timing and choice of outcome measurement.

Peroneal nerve stimulation has been shown to improve gait speed (Kottink et al. 2007) and balance (Kim et al. 2012). Multiple studies (Daly et al. 2004; Macdonell et al. 1994; Morone et al. 2012) have also reported that FES, when combined with physiotherapy, was superior to physiotherapy alone in improving certain elements of ambulation. Burridge et al. (1997) found that FES combined with physiotherapy, significantly improved gait speed while reducing energy costs compared to those receiving physiotherapy alone; however, the benefit was only evident when the stimulator was being used and there was no carryover effect. Daly et al. (2006; 2011) evaluated the effect of intramuscular functional neuromuscular stimulation when combined with overground walking training and body-weight supported treadmill training and reported that patients in the experimental group improved more on a number of gait assessments. Knutson et al. (2013) investigated contra-laterally controlled versus cyclic neuromuscular stimulation combined with gait training by a physiotherapist. The authors did not report any differences between groups, although when the data from both groups were combined, improvements in the Fugl-Meyer score were reported (Knutson et al. 2013); there was no sham FES control group.
FES in combination with other therapies has shown mixed results. Cozean et al. (1988) found that FES combined with biofeedback produced better results than standard physical therapy or FES or biofeedback alone. Kim et al. (2012) reported that individuals receiving FES-assisted treadmill training, when combined with augmented reality, had greater improvement in gait than those receiving FES or no-FES treadmill training.

Ankle foot orthoses are commonly used in the treatment of drop foot, with or without FES. Three studies have examined the benefit of using the Odstock Dropped Foot Stimulator (ODFS) (Burridge et al., 1997; Taylor et al., 1999; Sheffler et al., 2006). Sheffler et al. (2006) reported that a traditional AFO was most effective in improving walking performance compared with either no device or the ODFS. The authors speculated that patients likely needed a longer period of time to become accustomed to the ODFS in order to realize a benefit of treatment. Everaert et al. (2013) investigated the WalkAide ankle foot stimulator compared to an AFO in a cross-over RCT and found that over 12 weeks there were no significant difference in walking speed between devices and that individuals in both groups produced equivalent functional gains. In a larger study comparing FES to an AFO, Kluding et al. (2013) concluded that while improvements were observed in both groups on multiple gait outcomes, there was no significant difference between the two. Although, Swigchem et al. (2012) reported that individuals using FES had greater obstacle success rates than when they used an AFO and that these rates were highest among those with the poorest muscle strength.

Two trials have evaluated the effectiveness of FES-induced cycle training. One trial recruited patients within 6 months of stroke and reported a benefit of treatment, while Janssen et al. (2008) included patients with chronic stroke and reported no benefit (Ambrosini et al. 2011; Janssen et al. 2008). The sample sizes of both studies were small.

**Conclusion for Functional Electrical Stimulation in Lower Extremity**

*There is level 1a and level 2 evidence that FES may improve gait, balance, and range of motion.*

*There is level 1b evidence that interferential current therapy may improve balance.*

*There is level 1b and limited level 2 evidence that peroneal nerve stimulation may improve gait and quality of life post-stroke.*

*There is level 1a evidence that neuromuscular electrical stimulation may not improve gait.*

**Functional electrical stimulation, peroneal nerve stimulation, and interferential current stimulation may improve gait; however, neuromuscular electrical stimulation was not found to have the same beneficial effect.**

### 9.8.3 Repetitive Peripheral Magnetic Stimulation

Repetitive peripheral magnetic stimulation (rPMS) has not been widely researched as a rehabilitative therapy for lower limb recovery post-stroke. As a result, a single group of researchers questioned whether the technique could be used effectively in the stroke population (see Table 9.8.3.1).

**Table 9.8.3.1 Summary of RCT(s) Repetitive Peripheral Magnetic Stimulation (rPMS)**

<table>
<thead>
<tr>
<th>Author, Year Study Design (PEDro Score)</th>
<th>PEDro Score</th>
<th>Outcome</th>
</tr>
</thead>
</table>

9. Mobility and the Lower Extremity  
www.ebrsr.com
Sample Size

<table>
<thead>
<tr>
<th>Study</th>
<th>Sample Size</th>
<th>Intervention</th>
<th>Comparison</th>
</tr>
</thead>
<tbody>
<tr>
<td>Beaulieu et al. (2015)</td>
<td>RCT (7)</td>
<td>E: Repetitive Peripheral Magnetic Stimulation</td>
<td>C1: Sham, C2: Healthy Control</td>
</tr>
<tr>
<td></td>
<td>N&lt;sub&gt;Start&lt;/sub&gt;=32</td>
<td>Plantar flexor resistance to stretch: E vs. C2 (+)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>N&lt;sub&gt;End&lt;/sub&gt;=32</td>
<td>Active dorsiflexion range of motion (DF ROM): E vs. C1 (+)</td>
<td></td>
</tr>
</tbody>
</table>

- Indicates non-statistically significant differences between treatment groups
+ Indicates statistically significant differences between treatment groups

Discussion

Repetitive peripheral magnetic stimulation (rPMS) for lower limb recovery following a stroke is a limited research topic. However, one study (Beaulieu et al. 2015) compared rPMS to two different control conditions, one a sham stimulation and the other a healthy control participant. Results showed a significant decrease in resistance to stretch of the plantar flexors between the rPMS and healthy control. Furthermore, the rPMS group showed significant improvement in active range of motion compared to the sham group. These results suggest that rPMS may improve foot musculature strength and ankle range of motion.

Conclusion Regarding Repetitive Peripheral Magnetic Stimulation

*There is level 1b evidence that rPMS may improve foot muscle strength and ankle range of motion.*

Repetitive peripheral magnetic stimulation may improve foot muscle strength and ankle range of motion.

9.9 Medications Used in Motor Recovery Following Stroke

Medications to improve either motor function or recovery post stroke have been investigated in a series of small clinical trials and retrospectively, through a large, longitudinal study. The Post-Stroke Rehabilitation Outcomes Project (PSROP) was a large, prospective, multicenter study of stroke rehabilitation that included data from a total of 1291 patients, located in six hospital-based rehabilitation centers within the United States and one in New Zealand. In one of these studies, medication usage was tracked (Zorowitz et al. 2005). The charts of each patient admitted to a US institution (n=1,161) were reviewed for MD orders for: methylphenidate, modafinil, levadopa, amantadine or bromocriptine. Eighty percent of patients did not receive any of the aforementioned medications. Twenty-three (2%) of patients received one of these medications for 3 days or fewer. The remaining patients received meds for four or greater days. Overall, hospital LOS was longer among patients who received neurostimulants for ≥4 days compared with those who either received them for ≤3 days or who did not receive neurostimulants at all (25.7 vs. 15 vs. 17.1 days; p<0.0001). A greater proportion of patients with severe stroke who did not receive neurostimulants returned home compared with patients who received at least one day of neurostimulation (233/326 vs. 65/164, p=0.013). The only conclusions that the authors could draw from this study was that further studies, with larger sample sizes were required.

A systematic review evaluated the benefit of drugs influencing neurotransmitters on motor recovery following stroke (Berends et al. 2009). Six studies evaluating a broad range of drugs were included (i.e., antidepressants, amphetamine/methylphenidate and levadopa). The outcomes assessed included the BI and the FIM. Methylphenidate, tarazadone and nortriptyline were associated with improved motor
function. Recognizing that the studies differed from each other in many respects, Berends et al. (2009) concluded that there was insufficient evidence to recommend their use.

### 9.9.1 Noradrenergic Agents

This class of drug includes amphetamines, methylphenidate and L-DOPS.

**Amphetamines**

Amphetamines increase the release of noradrenaline and dopamine in the brain and act as potent stimulants. They have been shown to accelerate motor recovery following motor cortex lesions in the rat model (Feeney et al. 1982), especially when combined with task-specific training. Amphetamines have also been shown to enhance plastic changes in motor learning in both animals and humans (Lee & Ma 1995; Soetens et al. 1995). There is evidence that norepinephrine appears to be the most important neurotransmitter for amphetamine-induced recovery (Martinsson et al. 2007). A few RCTs have investigated the efficacy of this promising drug; however, most have failed to account for the confounding effects of depression. Amphetamines are also associated with clinically significant side effects such as insomnia, anorexia and elevated heart rate (Long & Young 2003).

A recent Cochrane review authored by Martinsson et al. (2007) concluded that there was no evidence to suggest that amphetamine use was associated with a reduction in death or dependence. In fact, there was an indication of an increased risk of death associated with amphetamine use, although the author attributes this, in part, to imbalances in baseline characteristics between the groups. However, based on the results from six RCTs, there was improvement in motor function, as assessed by the Fugl-Meyer scale (weighted mean difference −6.14, 95% CI −10.4 to −1.90). The authors concluded that further research is required. The results from RCTs evaluating the efficacy of amphetamines are presented in Table 9.9.1.1.

Sprigg and Bath (2009) also reported that there was no evidence of enhanced motor recovery following treatment with amphetamine, in a review that included the results from 11 trials (329 subjects); they also raised questions about safety.

The results of the RCTs examining the effects of amphetamine on motor recovery are summarized below.

<table>
<thead>
<tr>
<th>Author, Year</th>
<th>PEDro Score</th>
<th>Intervention</th>
<th>Outcome</th>
</tr>
</thead>
</table>
| **Sonde & Lokk (2007)** | RCT (9) N=30 | E1: 20mg amphetamine + L-dopa placebo + physiotherapy  
E2: 10mg amphetamine + 50mg L-dopa + physiotherapy  
E3: Amphetamine placebo + 100mg L-dopa + physiotherapy  
E4: Amphetamine placebo + L-dopa placebo + physiotherapy | • Barthel Index (−)  
• Fugl Meyer (−) |
| **Sonde et al. (2001)** | RCT (9) N=39 | E: 10mg Amphetamine (10 doses total)  
C: Placebo | • Barthel Index (−)  
• Fugl-Meyer (−) |
| **Treig et al. (2003)** | E: 10mg Amphetamine (10 doses total) + | Rivermead Motor Assessment: Leg and Trunk |
RCT (9)  
N=24  
physiotherapy  
C: Placebo + physiotherapy  
subscale (-)  
• Barthel Index (-)

**Martinsson et al. (2003)**  
RCT (7)  
N=30  
E: 10mg Amphetamine (10 doses total) + physiotherapy  
C: Placebo + physiotherapy  
• Fugl-Meyer (-)

**Martinsson et al. (2003)**  
RCT (7)  
N=45  
E: Amphetamine + 30-45min/d of physiotherapy  
C: Placebo + physiotherapy  
2/d  
E2: Amphetamine + 15 min/d of physiotherapy  
5/d  
• National Institute of Health Stroke Scale (-)  
• Lindmark Motor Assessment Chart (-)  
• Activities Index (-)

**Crisostomo et al. (1988)**  
RCT (7)  
N=8  
E: Amphetamine (2.5, 5 or 10mg)  
C: Placebo  
• Lindmark Motor Assessment Chart (1-7d) (+)  
• Lindmark Motor Assessment Chart (1-3mo) (-)  
• Activities Index (-)  
• 10-Metre Walk Test (-)

**Walker-Baston (1995)**  
RCT (7)  
N=10  
E: Single 10mg Amphetamine + physiotherapy  
C: Placebo + physiotherapy  
• Fugl-Meyer (+)

- Indicates non-statistically significant differences between treatment groups  
+ Indicates statistically significant differences between treatment groups

**Discussion**

Eight good quality studies examined the effects of amphetamine on motor recovery following stroke. Overall, there did not appear to be a significant treatment effect, despite positive animal studies and a physiologically-based mechanism of action. There was significant heterogeneity among studies which could have affected the interpretation of results: i) the doses of drug ranged from 2.5mg to 30 mg, ii) the total number of doses of drug ranged from 1 to 11 iii) treatment duration varied, iv) patients with mild, moderate-severe paresis and all levels of stroke severity were included; v) timing of intervention and assessment of outcome varied from several days to several weeks post stroke.

Seven of the eight studies investigated the use of amphetamines in combination with physiotherapy, of which five did not reveal any significant differences between patients prescribed amphetamines and patients given a placebo. Of these seven studies, four used the Fugl-Meyer Assessment (FMA) to assess motor recovery. Both Crisostomo et al. (1988) and Walker-Baston et al. (1995) reported significant gains in favour of amphetamines on the FMA compared to a placebo with the latter study observing positive outcomes at 1 year follow-up. However, both these studies did not stratify the results based on the upper and lower extremity subscales of the FMA. Interestingly, Sonde and Lokk (2007), Sonde et al. (2001) and Gladstone et al. (2006) stratified their results based on upper and lower extremities and reported no significant gains on lower extremity functioning after treatment of amphetamines. This discrepancy highlights the need for specific outcome measures and that “total” scores may not be sufficient when investigating motor recovery. All three studies state that dosages may have been too small, with Sonde and Lokk (2007) and Gladstone et al. (2006) also suggesting that the intensity of physiotherapy may not have been sufficient to induce significant changes.

Treig et al. (2003) also investigated the use of combining amphetamine treatment with physiotherapy but did not use the FMA. Like Sonde and Lokk (2007) and Sonde et al. (2001), Treig et al. (2003) observed functioning pertaining to activities of daily living (ADLs) as measured by the Barthel Index and did not find any significant gains. Further, no differences between the experimental and control group were reported on the Rivermead Motor Assessment. Treig et al. (2003) note that the physiotherapy provided in their study followed the neurodevelopmental approach aimed at restoring movement control in which exercises are mostly performed in sitting or lying positions. The lack of functional maneuvers practiced by the patients may be a potential reason for a lack of improvement in this field.
However, as other studies have suggested, it may be that amphetamines are simply not efficacious in motor recovery of the lower limbs.

Martinsson et al. (2003) assessed the efficacy of amphetamine treatment only without a physiotherapy protocol although patients did receive physiotherapy, occupational therapy or speech therapy during the study period. A significant improvement was noted during assessments at days 1, 2, 3, 5 and 7 compared to the placebo group but this effect tapered and was non-significant at 1 and 3 month follow-ups. A potential explanation for this may be due to the daily administration of amphetamines causing a depletion in neurotransmitters thereby inducing a tolerance effect (Louise Martinsson et al. 2003). Walker-Batson et al. (1995) noted they addressed this concern by administering doses every 4 days instead of daily and still reported significant improvements thus suggesting that a reduction in dosage frequency could still prove efficacious.

The following graph illustrates the results of an RCT by Treig et al. (2003) that investigated the effects of a combination of dexamphetamine and physical therapy on stroke patients.

**Conclusions Regarding Noradrenergic Agents**

*There is level 1a evidence that amphetamines may not improve lower limb function.*

**Amphetamines may not improve lower limb functional impairments.**

**Methylphenidate**

Methylphenidate increases endogenous noradrenaline and dopamine by blocking catecholaminereuptake thereby affecting noradrenergic and dopaminergic modulation (Lokk et al. 2011). The use of this drug (Ritalin) for motor recovery following stroke has been examined in two RCTs.

**Table 9.9.1.2 Summary of RCTs Evaluating the Effect of Methylphenidate on Motor Recovery**

<table>
<thead>
<tr>
<th>Author, Year PEDro Score</th>
<th>Intervention</th>
<th>Main Outcome(s) Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lokk et al. (2011) RCT (8) N=100</td>
<td>E1: Methylphenidate E2: Levodopa E3: Methylphenidate + Levodopa C: Placebo</td>
<td>• Barthel Index (mean change) (+) • Barthel Index (3 &amp; 6mos follow-up) (-) • Fugl-Meyer Assessment (mean change) (+) • Fugl-Meyer Assessment (3 &amp; 6mos follow-up) (-) • NIHSS Scores (3 &amp; 6mos follow-up) (-) • NIHSS Scores (mean change) (-)</td>
</tr>
<tr>
<td>Grade et al. (1998) RCT (7) N=21</td>
<td>E: Course of methylphenidate (max daily dose 30mg) C: Placebo in addition to routine therapy</td>
<td>• Functional Independence Measure (+) • Fugl-Meyer Assessment (-) • Fugl-Meyer Assessment (&lt;80 at baseline) (-)</td>
</tr>
</tbody>
</table>

- Indicates non-statistically significant differences between treatment groups
+ Indicates statistically significant differences between treatment groups

**Discussion**

Two RCTs investigated the use of Methylphenidate in lower extremity recovery with largely mixed results. Lokk et al. (2011) reported significant improvements in mean change from baseline to 6 month follow-up with greater gains reported in the Levodopa group, although the Methylphenidate + Levodopa group achieved comparable gains. However, raw scores at 3 and 6 month follow-ups did not differ significantly between all four groups. Similarly, Grade et al. (1998) reported a significant improvement in
gains on the Functional Independence Measure (FIM) from baseline to post-treatment but no between-group difference in improvement on the Fugl-Meyer Assessment (FMA). A ceiling effect was observed on the FMA and so patients with a score less than 80 were analysed separately. Greater gains compared to the placebo group were noted within this subgroup but these did not reach statistical significance. It could be suggested then that Methylphenidate may be more efficacious in patients with greater motor deficits than those of a milder disposition. As Methylphenidate stimulates the releases of dopamine, patients may have experienced an increase in motivation, mood and mental status thereby resulting in an increase in participation (Grade et al. 1998). It should be noted that both Lokk et al. (2011) and Grade et al. (1998) did not stratify the lower and upper extremity assessment scores of the FIM and FMA thus it is unclear as to the extent of improvement, or lack thereof, in lower motor recovery specifically.

Conclusions Regarding Methylphenidate in Motor Recovery

There is level 1a evidence that methylphenidate not improve motor function following stroke.

Methylphenidate may improve motor recovery; however, the evidence is currently limited.

L-3,4-Dihydroxyphenylserine (L-DOPS)

L-Threodops is a central norepinephrine (NE) precursor, which is decarboxylated to NE by 1-aromatic amino acid decarboxylase. Nishino et al. (2001) reported that chronic neurologically stable stroke patients treated with L-DOPS significantly improved (p<0.005) in Fugl-Meyer Score (FMS) compared with L-DOPS untreated patients over 2 days.

Table 9.9.1.3 Summary of Controlled Trial(s) Evaluating L-DOPS in Stroke Motor Recovery

<table>
<thead>
<tr>
<th>Author, Year Study Design (PEDro) Sample Size</th>
<th>Intervention</th>
<th>Main Outcome(s) Results</th>
</tr>
</thead>
</table>
| Miyai et al. (2000) PCT N=13                | E: PT + OT + 200 mg L-threodops (L-DOPS) C: PT | • FIM Total (+)  
• FIM Mobility (+)  
• Ambulation endurance (+)  
• Fugl-Meyer Lower Extremity (-)  
• Fugl-Meyer Balance (-)  
• Gait speed (-) |

- Indicates non-statistically significant differences between treatment groups  
+ Indicates statistically significant differences between treatment groups

Discussion

A PCT by Miyai et al. (2000) revealed significant improvements in functional ability and ambulation endurance after L-DOPS treatment and physiotherapy compared to physiotherapy alone. Although patients significantly improved on the FIM Mobility subscale compared to the control condition, there were no significant between-group differences in gait speed, nor on the Fugl-Meyer Lower Extremity and Balance subscales. This disparity within the findings may be the result of differing sensitivity and specificity of the outcome measures. Nishino et al. (2001) note that a significant increase in cerebral blood flow (CBF) to the ipsilesional hemisphere was observed, however lower extremity functioning according to the Fugl-Meyer Scale showed no significant improvement and there were no significant correlations between CBF, performance on the Fugl-Meyer Scale, and 10-metre gait speed. Gait speed
significant improved, suggesting that L-DOPS may be successful in the recovery of ambulation although the mechanism for locomotor recovery is unclear (Nishino et al. 2001).

**Conclusions Regarding L-DOPS**

*There is limited level 2 evidence that L-DOPS may improve functional outcomes post-stroke.*

More research is needed to determine the effectiveness of L-DOPS on lower limb motor function.

**9.9.2 Dopaminergic Agents**

Dopamine is a neurotransmitter that increases or reduces the activity of neurons. It has a variety of influences on brain function, including playing a role in regulating attention, cognition, movement, pleasure, and hormonal processes.

It has been suggested that dopamine is essential for motor learning and may therefore play a role in recovery following stroke. There is also an age-related decline in dopamine receptors, transporters and metabolism that may impair motor recovery following stroke, especially among older individuals (Rösser et al. 2008).

There have been two RCTs that have examined the effect of dopaminergic agents on motor recovery following stroke.

**Levodopa**

Previous literature has suggested that the dopamine system is an important aspect of motor learning therefore pharmacological interventions may be useful adjuvant in motor rehabilitation (Rösser et al. 2008). Levodopa is a dopamine precursor which, once it crosses the blood-brain barrier, is metabolised to dopamine and converted to norepinephrine as dopamine cannot cross the blood-brain barrier (Scheidtmann et al. 2001). Levodopa is therefore used to increase dopamine levels. Research conducted by Floel et al. (2005) revealed that a single dose of Levodopa enhanced motor memory encoding in the primary motor cortex of the ipsilesional hemisphere relative to a placebo, but this particular study consisted of a small sample and focused on movements of the thumb only. However, the use of Levodopa appears to be promising. Only one RCT was identified for the recovery of lower extremity motor function, as outlined in Table 9.9.2.1.

**Table 9.9.2.1 Summary of RCT(s) Levodopa in Lower Extremity Recovery Post Stroke**

<table>
<thead>
<tr>
<th>Author, Year Study Design (PEDro Score) Sample Size</th>
<th>Intervention</th>
<th>Main Outcome(s) Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Scheidtmann et al. (2001) RCT (8) N=47</td>
<td>E: Levodopa + decarboxylase inhibitor C: Placebo</td>
<td>Rivermead Motor Assessment (+)</td>
</tr>
</tbody>
</table>

- Indicates non-statistically significant differences between treatment groups
+ Indicates statistically significant differences between treatment groups

**Discussion**
The findings from Scheidtmann et al. (2001) suggest that the use of Levodopa combined with a decarboxylase inhibitor is a safe and effective treatment for lower limb motor recovery. The authors note however that many patients with stroke located in the right hemisphere had to be excluded due to severe aphasia and so it is unclear whether stroke location would affect recovery. Scheidtmann et al. (2001) did not observe the mechanism of recovery but postulate, based on previous research with different pharmacological treatments, that an enhancement in neuroplasticity, an increase in neural sprouting and synaptogenesis, or simply an increase in mood and motivation may have contributed to these results. Further research examining the mechanism behind motor recovery after treatment is required in order to fully understand the effects of Levodopa on neuroplasticity.

**Conclusions Regarding Levodopa in Stroke Recovery**

*There is level 1b evidence that Levodopa may improve motor recovery.*

*More research is needed to determine the effect of Levodopa on lower limb improvement following stroke.*

**Ropinirole**

Ropinirole is a non-ergoline dopamine agonist, which mimics the effect of natural dopamine in the body and produces dopamine-like effects. Dopaminergic agonists cross the blood-brain barrier and have central effects of neurological and endocrine types. Agonists that can have influence over the central nervous system have been found to have mixed results with regards to having a favourable effect on motor ability post stroke (Cramer et al. 2009). Ropinirole, a dopaminergic agonist, has been used in the treatment of Parkinson’s disease (Brooks et al. 1998) and restless leg syndrome (Kushida 2006). Only one study has investigated the use of Ropinirole on lower extremity functioning post stroke as detailed in Table 9.9.2.1.

**Table 9.9.2.1 Summary of RCT(s) Evaluating Dopaminergic Agents in Lower Limb Recovery**

<table>
<thead>
<tr>
<th>Author, Year Study Design (PEDro Score) Sample Size (N)</th>
<th>Intervention</th>
<th>Main Outcome(s) Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cramer et al. (2009) RCT (7) N=33</td>
<td>E: Immediate-release ropinirole (drug dose: 0.25 to 4 mg once daily) C: Placebo</td>
<td>• Gait velocity (-) • Gait endurance (-) • Fugl Meyer Assessment (-) • Stroke Impact Scale (-) • Barthel Index (-) • Hamilton Depression Scale (-)</td>
</tr>
</tbody>
</table>

- Indicates non-statistically significant differences between treatment groups
+ Indicates statistically significant differences between treatment groups

**Discussion**

Cramer et al. (2009) compared Ropinirole with a placebo in the improvement of lower extremity motor function following stroke but no differences were found. These findings may support theory that an increase in dopamine does not improve motor function. This may be the result of varying basal dopaminergic levels due to the individual and specific features of the stroke experienced by the patients (Cramer et al. 2009). The authors suggest that the intensity of the treatment may have been too mild with all experimental group patients not achieving the desired 3mg dosage by the study end of 9 weeks.
Moreover, an expectation effect may have occurred with 13 of 14 patients in the experimental correctly guessing their treatment assignment compared to eight of 15 in the placebo group. Further research into the use of Ropinirole with the above methodological considerations addressed is needed.

**Conclusions Regarding Ropinirole in Motor Recovery**

*There is level 1b evidence that ropinirole may not be superior to placebo at increasing gait, functional recovery and activities of daily living post-stroke.*

More research is needed to determine the effectiveness of Ropinirole in lower limb motor recovery.

### 9.9.3 Serotonergic Agents

Selective serotonin-reuptake inhibitors selectively block serotonin-reuptake rather than blocking both serotonin and norepinephrine reuptake. Although they are most commonly used to treat depression following stroke, their potential benefit for improving motor function has also been examined in a small number of studies. A meta-analysis by Mead et al. (2013) on 56 randomized and non-randomized trials concluded that SSRIs may reduce dependence, lessen disability and neurological impairment, and improve depression and anxiety post stroke; although, risks including seizures, bleeding and hyponatremia should be considered. Mead et al. (2013) state that large, high quality trials are necessary to elucidate the true treatment benefits from SSRIs.

**Citalopram**

Citalopram (Celexa) is a selective serotonin reuptake inhibitor, which has been used to treat depression. However, previous studies with rats have demonstrated that modification of serotonergic neurotransmission also enhanced dexterity. One study has investigated this effect of the off-label use of this drug in humans post stroke with promising results concerning hand dexterity (Zittel et al. 2008). It remains unclear whether the potential benefit of citaopram is brought about through modulation of motor cortex excitability or its anti-depressive effects. However, literature regarding the use of Citalopram in motor function is extremely limited. Only one RCT was indentified in the use of Citalopram in the treatment of motor recovery as detailed in Table 9.9.3.1.

| Table 9.9.3.1 Summary of RCT(s) Evaluating Citalopram in Lower Limb Recovery |
|-------------------------------|------------------|----------------|
| Author, Year                  | Study Design (PEDro) | Sample Size | Intervention | Main Outcome(s) | Result |
| Acler et al. (2009)           | RCT (6) N=20      |             | E: 10 mg/day of citalopram C: Placebo + physiotherapy | • NIHSS (+) | Barthel Index (-) |

- Indicates non-statistically significant differences between treatment groups
+ Indicates statistically significant differences between treatment groups

**Discussion**

There is currently a lack of evidence for the use of Citalopram as a treatment for lower motor recovery. Acler et al. (2009) revealed significantly greater gains on the Barthel Index (BI) and the National Institutes of Health Stroke Scale (NIHSS) for patients in the experimental group compared to a placebo. Furthermore, it was reported that there was significantly greater intracortical inhibition in the motor cortex in the contralesional hemisphere compared to patients in the placebo group. In addition, both...
groups demonstrated a significant increase in excitability within the ipsilesional motor cortex. Previous research using brain stimulation has suggested that a rebalance of cortical excitability is associated with greater functional gains (Lin et al. 2015; Wang et al. 2012). Although these findings seem to be promising, it should be noted that Acler et al. (2009) did not specifically focus on lower extremity recovery, rather, focusing on general functioning according to the BI and NIHSS. Therefore these results may not be generalizable to patients requiring treatment for lower limb dysfunction. Future research would be advised to directly observe the effects of Citalopram on lower extremity functioning, gait, balance and strength.

**Conclusions Regarding Citalopram**

*There is level 1b evidence that citalopram may improve neurological function but not functional recovery following stroke.*

*More studies are needed to investigate the effectiveness of Citalopram at improving lower limb motor function.*

**Fluoxetine**

Fluoxetine, like citalopram, is also a SSRI. Four RCTs have examined the use of this agent in motor recovery following stroke. The largest of the four (Chollet et al. 2011) recruited patients specifically who were not depressed and within 10 days following stroke, while the remainder included patients at a later stage of recovery and at least a portion of the patients were depressed at entry.

**Table 9.9.3.2 Summary of RCTs Evaluating Fluoxetine in Lower Limb Recovery**

<table>
<thead>
<tr>
<th>Author, Year</th>
<th>Study Design (PEDro Score)</th>
<th>Sample Size</th>
<th>Intervention</th>
<th>Main Outcome(s) Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chollet et al. (2011)</td>
<td>RCT (9)</td>
<td>N=118</td>
<td>E: Fluoxetine (20 mg/day for 90 days) + Physiotherapy C: Placebo + Physiotherapy</td>
<td>Fugl-Meyer Motor Scale (Lower Limb) (+)</td>
</tr>
<tr>
<td>Fruhwald et al. (2003)</td>
<td>RCT (9)</td>
<td>N=54</td>
<td>E: Fluoxetine C: Placebo</td>
<td>Barthel Index (-) \ Scandinavian Stroke Scale (-) \ Rankin Scale (-)</td>
</tr>
<tr>
<td>Robinson et al. (2000)</td>
<td>RCT (8)</td>
<td>N=104</td>
<td>E: Nortriptyline (max 100 mg/d) E: Fluoxetine (max 40 mg/d) C: Placebo</td>
<td>Functional Independence Measure (+)</td>
</tr>
<tr>
<td>Mikami et al. (2011)</td>
<td>RCT (8)</td>
<td>N=83</td>
<td>E1: Fluoxetine E2: Nortriptyline C: Placebo</td>
<td>Functional Independence Measure (-) \ Modified Rankin Scale (+)</td>
</tr>
<tr>
<td>Dam et al. (1996)</td>
<td>RCT (5)</td>
<td>N=52</td>
<td>E1: Maprotiline (150 mg/d) E2: Fluoxetine (20 mg/d) C: Placebo</td>
<td>Barthel Index: E1 vs E2 (+); E1 vs C (-); E2 vs C (-) \ Gait score: E1 vs E2 (+); E1 vs C (-); E2 vs C (-)</td>
</tr>
</tbody>
</table>

- Indicates non-statistically significant differences between treatment groups
+ Indicates statistically significant differences between treatment groups

**Discussion**
The use of serotonin reuptake inhibitors in the recovery of lower extremity function has been revealed mixed results. Chollet et al. (2011) reported significantly greater improvement on the Fugl-Meyer Motor Scale (FMMS) Lower Limb subscale and Modified Rankin Scale (mRS) among patients receiving Fluoxetine at post-treatment. A potential explanation for these results could be that the main function of the serotonergic system is to facilitate motor output which would allow for greater efficiency, especially when combined with physical training (Chollet et al. 2011). In contrast, Fruehwald et al. (2003) did not report any significant differences between Fluoxetine and a placebo. However, this may have been due to the fact the authors did not assess lower limb recovery specifically as the primary outcome of the study was depression, although the Scandinavian Stroke Scale does contain an assessment of gait. The lack of specific lower limb assessment notwithstanding, Fruehwald et al. (2003) revealed that Fluoxetine did not assist in functional recovery compared to a placebo.

In comparison with Nortriptyline, a Tricyclic antidepressant, Robinson et al. (2000) reported greater improvements on the FIM in patients who received Nortriptyline than those who received Fluoxetine or a placebo. However, one could argue that the reported FIM scores may not be specific to lower extremity only and so generalisability of the results may not be accurate. Further analyses of this dataset by Mikami et al. (2011) revealed that patients receiving antidepressant treatment, regardless of type (Nortriptyline or Fluoxetine), outperformed patients given a placebo on the mRS at 1-year follow-up, which includes an assessment into walking ability. Mikami et al. (2011) note that previous literature has suggested that both tricyclic antidepressants and SSRIs inhibit microglial production of proinflammatory cytokines thereby resulting in neurogenesis and synaptic plasticity. The authors propose that both types of antidepressant may be of benefit to stroke patients independent of presence of depression. The authors propose that both types of antidepressant may be of benefit to stroke patients independent of presence of depression.

Further research is required to fully assess the use of serotonergic agents such as Fluoxetine with greater emphasis and focus on lower extremity functioning such as gait, balance, and strength.

**Conclusions Regarding Fluoxetine**

- There is level 1a evidence from high-quality, high-powered studies that fluoxetine may improve motor recovery, ADL functioning may not be enhanced.

**Fluoxetine may improve motor recovery following stroke; however, further research is necessary.**

### 9.9.4 Other Drugs

**Almitrine + Raubasine (Duxil)**

Duxil is a medication, which maintains oxygen availability following ischemic stroke by increasing partial pressure of oxygen in the arterial blood supply. Hemoglobin oxygen saturation is also increased. While these effects are most often associated with cognitive benefit, a single study was identified which assessed the effects of Duxil on functional outcome. Only one RCT examining Duxil was identified and is detailed in Table 9.9.4.1

**Table 9.9.4.1 Summary for RCT(s) Evaluating Almitrine and Raubasine**

<table>
<thead>
<tr>
<th>Author, Year</th>
<th>Study Design (PEDro Score)</th>
<th>Methods</th>
<th>Outcomes</th>
</tr>
</thead>
</table>

9. Mobility and the Lower Extremity  
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Li et al. (2004)
RCT (7)
N=83
E: Almitrine + Raubasine
C: Placebo (2 tablets)

- Indicates non-statistically significant differences between treatment groups
+ Indicates statistically significant differences between treatment groups

Discussion
There were promising findings from the study conducted by Li et al. (2004) as patients receiving Duxil exhibited significantly greater and quicker improvements in functioning and activities of daily living compared to a placebo. Although the mechanism for these improvements are not discussed by the authors, Li et al. (2004) note that severity of neurological deficit was not severe in the majority of patients and that function can recover without intervention therefore implying that Duxil may have assisted natural recovery rather than being the sole facilitator. Further there was no significant difference between the two groups concerning adverse events. However, future research using lower limb specific outcome measures is required.

Conclusions Regarding Almitrine in Combination with Raubasine

There is level 1b evidence that Almitrine in combination with Raubasine may improve functional outcomes post stroke.

Almitrine in combination with Raubasine may improve functional outcomes following stroke; however more research is needed.

Piracetam
Piracetam is a γ-aminobutyrate derivative which has been marketed as a "nootropic" agent (a drug that exerts an effect on metabolic activity in the human brain) and has recently been used in the treatment of ischemic stroke. It is considered to be a neuroprotective drug which has the potential to improve cognition and motor recovery post stroke. The exact mechanism of action of piracetam is not known, but the drug is thought to increase regional cerebral blood flow and decrease glucose metabolism, facilitating the release of acetylcholine and excitatory amino acids. The effects are thought to be mediated through effects on the cell membrane (De Deyn et al. 1997; Kessler et al. 2000). Piracetam is not currently available for use in Canada.

A Cochrane review conducted and updated by Ricci et al. (2006) reported that piracetam administered acutely following stroke was associated with a slight (not statistically significant) increase in death at one month although the authors suggested that baseline imbalances in one of the three studies pooled may have biased these results. The review included three trials involving 1002 people, with the PASS trial making up 93% of the data. The odds ratios (and 95% CI) associated with death at one month, dependency at 12 weeks and death or dependency at 12 weeks were 1.32 (0.96, 1.82), 0.90 (0.67, 1.20) and 1.01 (0.77, 1.32), respectively. Drug administration was continued from 2 to 12 weeks following stroke. Although there was limited data, no difference was evident for functional outcome and dependency of the treatment group compared with the control group.

Table 9.9.4.2 Summary of RCTs Evaluating Piracetam

<table>
<thead>
<tr>
<th>Author, Year</th>
<th>Study Design (PEDro Score)</th>
<th>Study Sample</th>
<th>Intervention</th>
<th>Main Outcome(s) Results</th>
</tr>
</thead>
</table>

9. Mobility and the Lower Extremity
**Platt et al. (1993)**  
RCT (8)  
N=56  
E: Piracetam  
C: Placebo  
- Motor function according to a graduated scale of ECT (+)

**De Deyn et al. (1997)**  
RCT (8)  
N=927  
PASS  
E: Piracetam, 2g initially, then 12g/d for 4wks and 4.8g for 8wks.  
C: Placebo.  
- Barthel Index (-)  
- Orgogozo Scale (-)

**Enderby et al. (1994)**  
RCT (6)  
N=137  
E: Piracetam, 8g/d  
C: Placebo  
- Barthel Index (-)

- Indicates non-statistically significant differences between treatment groups  
+ Indicates statistically significant differences between treatment groups

**Discussion**

Of the three studies that examined the effect of Piracetam on functional recovery, two reported that Piracetam may not be efficacious in treating motor or functional deficits. Specifically, both Enderby et al. (1994) and De Deyn et al. reported that functional outcome did not differ significantly between experimental and placebo groups. However, De Deyn et al. (1997) uncovered a significant difference after 12 weeks of treatment favouring the experimental group but only among those who received treatment within 6 hours of stroke onset. Time post stroke may then be a key variable in the efficacy of Piracetam as patients treated beyond 6 hours did not demonstrate improvement in performance of functioning and activities of daily living, as did Enderby et al.’s (1994) sample who averaged 36.2 days post onset. Furthermore, De Deyn et al. (1997) revealed a lack of significant differences between groups regarding neurological improvement but noted that the sample recruited into the study had experienced a mild severity of stroke according to the Glasgow Coma Scale. It is plausible that the patients had experienced a ceiling effect. Despite these unfavorable outcomes, Platt et al. (1993) reported a significant improvement in lower motor function according to a graduated based on the results of single photon emission computer tomography (SPECT), specifically the paretic leg, and significantly greater improvement compared to a placebo. Further, 23 of 27 patients demonstrated functional improvement of leg motor movements compared to only 1 of 29 patients in the placebo condition. Imaging techniques such as SPECT may be useful but movements such as gait and stability deficits such as balance and posture may not be accurately measured by imaging. With assessments of ADLs and neurological notwithstanding, there is currently a lack of published research using outcome measures that focus specifically on lower extremity function. Further research is required.

**Conclusions Regarding Piracetam**

*There is level 1a evidence that Piracetam may improve lower extremity motor function but not neurological status or ADL performance following stroke.*

*Piracetam may improve motor function but not ADL performance and neurological status following stroke.*

**9.10 Spasticity and Contractures in Lower Extremities**

Spasticity is common in stroke patients although it does not always require treatment. Treatments are likely to be most effective in the subset of stroke patients with severe spasticity. Gresham et al. (1995) notes that, “Contractures that restrict movement of the involved joint or are painful will impede
rehabilitation and may limit the patient’s potential for recovery. Paretic limbs with muscle spasticity are at especially high risk of developing contracture. Prevention is the key to effective management,” (Gresham et al. 1995).

Spastic equinovarus foot positioning is a frequent complication following stroke, caused by spasticity of the gastrocnemius, tibialis posterior and tibialis anterior muscles. Treatment options include orthotic devices (splints), physical therapy, botulinum toxin, neurolysis with alcohol or phenol, as well as surgery (Deltombe et al. 2004). Presently there has been only a single study examining the treatment of contractures, while there is a growing literature examining the treatment of spasticity post-stroke.

9.10.1 Prevention of Contracture

Contracture of the ankle is a common sequela of hemiparetic stroke and occurs as a consequence of immobility, through a loss of length and extensibility of the calf muscles. The result may be reduced ankle dorsiflexion and difficulties with such activities as walking or descending stairs (Robinson et al. 2008). While techniques such as standing on a tilt table are in common use, they are time intensive strategies and have not been well-studied.

Table 9.10.1 summarizes one RCT that evaluates the effect of a splint for the prevention of ankle contracture.

<table>
<thead>
<tr>
<th>Author, Year</th>
<th>PEDro Score</th>
<th>Sample Size</th>
<th>Intervention</th>
<th>Outcomes</th>
</tr>
</thead>
</table>
| Robinson et al. (2008) | RCT (8) | N=30 | E: Splint with the affected ankle at plantar grade  
C: Standing on a tilt table with the ankle at maximum dorsiflexion | Passive ankle dorsiflexion (-) |

- Indicates non-statistically significant differences between treatment groups
+ Indicates statistically significant differences between treatment groups

Discussion

Based on the findings above, which were designed as an equivalency trial and designed without a true control group, it appears that intervention with either a tilt table or a night splint can be used to prevent contractures. The benefits of wearing a splint are that the treatment takes place during the overnight hours and can be sustained over long periods of time. In addition, a splint is portable and easy to use. When using a tilt table, maximum dorsiflexion can be achieved; therefore the treatment can be provided for shorter periods (Robinson et al. 2008). However, the lack of a control group that did not receive an intervention means it is unclear whether improvements were the result of treatment or due to an external factor.

Conclusions Regarding the Use of Splints to Prevent Ankle Contracture

There is level 1b evidence that both a tilt table and night splint may prevent ankle contracture in the early period following stroke.

**Splints and tilt tables are both effective in the prevention of ankle contracture.**
9.10.2 Injection of Botulinum Toxin (BTx)

Botulinum toxin (BTx) is a neurotoxin, which weakens muscles by blocking the release of acetylcholine at the neuromuscular junction. The benefits of BTx injections are generally realized within 3 to 7 days following injection and are dose-dependent. The effects have been studied extensively in the upper extremity and last approximately 2 to 4 months (Bakheit et al. 2000; Brashear et al. 2002; Francisco et al. 2002; Simpson et al. 1996; Smith et al. 2000). Two main types of BTx are available: Type A (Botox® and Xeomin®) and Type B (Dysport®). BTx guidelines suggest a dose no larger than 600U to prevent adverse effects and antibody development.

Incobotulinum toxin (Xeomin®) which is free of complexing proteins has been studied for the upper limb spasticity with good effect. A single study has shown good effect on reducing spasticity in the lower limb as well (Santamato et al. 2013). Although BTx has been shown to reduce spasticity following stroke, it remains unclear whether this results in functional improvements. The advantages of BTx include no ostensible effect on the sensory system and the ability to selectively target certain muscle groups.

Lower limb spasticity, manifested most commonly as equinovarus foot deformity, is a condition characterized by the development of reduced ankle dorsiflexion, often accompanied with forefoot inversion. Typically, there is difficulty in the swing phase of the stride such that the forefoot strikes the ground first instead of the heel. The deformity also produces an inadequate base of support, which is associated with balance and gait impairments. Muscles, which may be involved, include the tibialis anterior, tibialis posterior, long toe flexors, medial and lateral gastrocnemius, soleus and extensor hallucis longus. There have been four reports of BTx used to improve stiff knee gait following stroke (Boudarham et al. 2013; Caty et al. 2008; Robertson et al. 2009; Tok et al. 2012).

A recent systematic review and meta-analysis included the results from 8 trials, 5 randomized controlled trials and 3 single-group intervention studies examining the ability of BTx to increase gait velocity (Foley et al. 2010). Data representing 228 subjects were available for pooled analysis. Treatment with BTx was associated with a small improvement in gait velocity (Hedge’s g =0.193 ± 0.081 metres/sec; 95% CI: 0.033 to 0.353, p<0.018) representing an increase, on average, of 0.044 metres/sec.

Table 9.10.2.1 Summary of RCTs Evaluating the Effectiveness of BTx

<table>
<thead>
<tr>
<th>Author, Year</th>
<th>PEDro Score</th>
<th>Sample Size</th>
<th>Intervention</th>
<th>Outcomes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Kaji et al. (2010) RCT (9)</td>
<td>9</td>
<td>N=120</td>
<td>E: BTx (300U) C: Placebo</td>
<td>Modified Ashworth Scale: Weeks 4,6,8 (+); 10,12 (-) Clinical Global Improvement (-) Gait speed (-)</td>
</tr>
<tr>
<td>Bollens et al. (2013) RCT (8)</td>
<td>8</td>
<td>N=16</td>
<td>E1: Tibial Nerve Neurotomy to soleus nerve, tibialis posterior, and flexor hallucis longus E2: BTx in the same muscles as other group</td>
<td>Modified Ashworth Scale: tardieu soleus (+), soleus (+), triceps (-) Stroke Impairment Assessment Scale (+) Passive Range of Motion (-) 10-Metre Walk Test (-) Medical Research Council (-)</td>
</tr>
<tr>
<td>Pittock et al. (2003) RCT (8)</td>
<td>8</td>
<td>N=234</td>
<td>E: BTx (3 dosing levels) C: Placebo</td>
<td>Modified Ashworth Scale (+) 2-Minute Walk Test (-) Stepping rate (-) Step length (-)</td>
</tr>
<tr>
<td>Picelli et al. (2014) RCT (8)</td>
<td>8</td>
<td>N=30</td>
<td>E1: Therapeutic Ultrasound E2: Transcutaneous Electrical Nerve Stimulation E3: BTx</td>
<td>Modified Ashworth Scale: E1 vs E3 (+) Ankle Passive Range of Motion: E3 vs E2 (+)</td>
</tr>
<tr>
<td>Study</td>
<td>Design</td>
<td>N</td>
<td>E1</td>
<td>E2</td>
</tr>
<tr>
<td>-----------------------------</td>
<td>--------</td>
<td>----</td>
<td>----</td>
<td>------------------------</td>
</tr>
<tr>
<td>Kirazli et al. (1998)</td>
<td>RCT (8)</td>
<td>20</td>
<td>E1: BTx (400U)</td>
<td>E2: Phenol</td>
</tr>
<tr>
<td>Dunne et al. (2012)</td>
<td>RCT (7)</td>
<td>85</td>
<td>E: BTx (200/300U)</td>
<td>C: Placebo</td>
</tr>
<tr>
<td>Fietzek et al. (2014)</td>
<td>RCT (7)</td>
<td>52</td>
<td>E1: 2 BTx injections into 4 calf muscles</td>
<td>C: Saline injection followed by BTx injection</td>
</tr>
<tr>
<td>Burbaud et al. (1996)</td>
<td>RCT (7)</td>
<td>23</td>
<td>E: BTx</td>
<td>C: Placebo</td>
</tr>
<tr>
<td>Childers et al. (1996)</td>
<td>RCT (7)</td>
<td>21</td>
<td>E1: BTx at mid belly of the gastrocnemius</td>
<td>E2: BTx at the proximal portion of muscle located distal to the popliteal fossa</td>
</tr>
<tr>
<td>Ward et al. (2014)</td>
<td>RCT (7)</td>
<td>274</td>
<td>E: BTx + Standard care</td>
<td>C: Placebo + Standard care</td>
</tr>
<tr>
<td>Karadag-Saygi et al. (2010)</td>
<td>RCT (7)</td>
<td>20</td>
<td>E: BTx (75-100U) + Taping (kinesiotaping method)</td>
<td>C: BTx (75-100U) + Sham taping</td>
</tr>
<tr>
<td>Bayram et al. (2006)</td>
<td>RCT (6)</td>
<td>12</td>
<td>E1: Low-dose BTx + Functional Electrical Stimulation</td>
<td>C: High-dose BTx + Sham Functional Electrical Stimulation</td>
</tr>
<tr>
<td>Mancini et al. (2005)</td>
<td>RCT (6)</td>
<td>45</td>
<td>E1: BTx low dose</td>
<td>E2: BTx medium dose</td>
</tr>
<tr>
<td>Carda et al. (2011)</td>
<td>RCT (6)</td>
<td>69</td>
<td>E1: BTx (100U) at plantar flexors + Taping</td>
<td>E2: BTx (100U) at plantar flexors + Casting</td>
</tr>
<tr>
<td>Pimentel et al. (2014)</td>
<td>RCT (6)</td>
<td>21</td>
<td>E1: BTx (300U) in the midbelly and both heads of the gastrocnemius</td>
<td>E2: BTx (100U) distributed in the same locations as in the previous group</td>
</tr>
<tr>
<td>Roche et al. (2015)</td>
<td>RCT (6)</td>
<td>35</td>
<td>E: BTx + Standardized self-rehabilitation programme</td>
<td>C: BTx</td>
</tr>
<tr>
<td>Study</td>
<td>Design</td>
<td>N</td>
<td>E: Treatment Details</td>
<td>C: Treatment Details</td>
</tr>
<tr>
<td>-----------------------</td>
<td>---------</td>
<td>----</td>
<td>--------------------------------------------------------------------------------------</td>
<td>----------------------</td>
</tr>
<tr>
<td>Tao et al. (2015)</td>
<td>RCT (6)</td>
<td>23</td>
<td>BTx (200U) in gastrocnemius and posterior tibial muscle</td>
<td>Placebo in the same muscles</td>
</tr>
<tr>
<td>Ding et al. (2015)</td>
<td>RCT (6)</td>
<td>103</td>
<td>BTx + Conventional rehabilitation + Ankle foot brace</td>
<td>Conventional rehabilitation</td>
</tr>
<tr>
<td>On et al. (1999)</td>
<td>RCT (5)</td>
<td>20</td>
<td>BTx (400U)</td>
<td>Phenol</td>
</tr>
<tr>
<td>Reiter et al. (1998)</td>
<td>RCT (5)</td>
<td>18</td>
<td>BTx (190-320U) into 3-5 calf muscles + Ankle-foot taping</td>
<td>Conventional rehabilitation</td>
</tr>
<tr>
<td>Farina et al. (2007)</td>
<td>RCT (5)</td>
<td>13</td>
<td>BTx (190-320U) + Ankle-foot casting</td>
<td>BTx (190-320U)</td>
</tr>
</tbody>
</table>

- Indicates non-statistically significant differences between treatment groups
+ Indicates statistically significant differences between treatment groups

**Discussion**

The studies identified in assessing BTx evaluated a variety of interventions and outcomes, making conclusions difficult. Dosage of BTx can also be a problematic variable as Mancini et al. (2005) noted that patients receiving moderate and higher doses of BTx did not differ significantly in reducing spasticity and improving gait although both were significantly more efficacious than lower doses of BTx. Six RCTs compared the effects of BTx to a placebo. Kaji et al. (2010) initially observed a significant improvement in spasticity up to 8 weeks post-treatment but this effect diminished at weeks 10 and 12. Gait did not improve at any time with the authors suggesting that this may have been the result of failing to adapt from a spastic gait to a gait requiring normal grounding of the foot, especially as the mean time post-stroke was more than 6 years. Dunne et al. (2012) did not find a significant difference between BTx and placebo groups but a subgroup analysis of patients with severe spasticity indicated significantly greater improvement in those receiving BTx. Ward et al. (2014) found that patients treated with BTx and placebo demonstrated similar changes from baseline to 10 weeks post-treatment; however, a subgroup of patients with ankle plantar-flexor spasticity were found to improve to a significantly greater degree after BTx treatment compared to placebo. Pittock et al. (2003) reported an improvement in spasticity, but not function.

Three studies, including two RCTs, compared BTx injection to a phenol block, with mixed results in terms of measures of spasticity; function was not evaluated. In one high-quality RCT conducted by Kirazli et al. (1998), significant transient reductions in spasticity of the ankle compared to a phenol block injection were reported for up to 4 weeks post-treatment. It was also noted that 30% of patients provided with phenol injections experienced dysesthesia with walking capacity negatively affected while no adverse events were reported by patients who had received BTx.

Three studies also evaluated orthotic support and taping in comparison with BTx. Karadag-Saygi et al. (2010) compared taping using the kinesiotaping method with a sham taping protocol (taping of
ineffective muscles) with both groups receiving BTx but no between-group differences in spasticity, gait velocity or step length were found. As both groups improved significantly, it was suggested that improvements were the result of the BTx treatment. In combining BTx treatment with an ankle foot brace and conventional rehabilitation, Ding et al. (2015) reported significantly greater improvements in spasticity, balance and motor function compared to a BTx plus conventional rehabilitation group and a conventional rehabilitation only treatment group. The authors conclude that BTx is effective in reducing tone but improvements can be enhanced further with the use of orthotic treatment to prevent or correct limb deformity. Carda et al. (2011) reported significant improvements in the recovery of spasticity in patients who received BTx and a serial cast around the ankle compared to patients provided with BTx and stretching exercises. This may have been achieved through a maximal elongation of the muscle, which is maintained longer in a cast than taping or stretching (Carda et al. 2011). However, no differences were reported between BTx + casting, BTx + taping, and BTx + stretching exercises for measures of ambulation.

Bollens et al. (2013) observed significant reductions in spasticity after both BTX and tibial nerve neurotomy (TNN) but significantly greater improvements were noted for patients provided with TNN treatment compared to BTx. Gait ability such as knee and ankle kinematics and speed did not differ significantly between the two treatments. Bollens et al. (2013) propose that intensive rehabilitation in conjunction with TNN may provide a synergistic effect and allow for greater enhancements of lower limb function. In direct comparison of the two treatments, it was noted that BTx is reversible and requires regular administration whereas TNN can provide long-term relief of spasticity after one surgical procedure. Although a follow-up of 6 months was employed, the authors suggest future studies with longer follow-ups may be required in order to determine the full extent of improvement and the effectiveness of TNN.

**Conclusions Regarding Botulinum Toxin**

There is level 1a evidence that treatment with botulinum toxin compared to placebo improves lower limb spasticity, but gains for functional recovery have not been significant.

There is level 1b and limited level 2 evidence that treatment with botulinum toxin compared to phenol may improve lower limb spasticity.

There is level 1b and limited level 2 evidence that treatment with botulinum toxin combined with casting or taping may improve lower limb spasticity but not gait.

There is level 1b evidence that tibial nerve neurotomy (TNN) treatment to the soleus nerve, tibialis posterior, and the flexor hallucus longus, may be more effective for the improvement of spasticity than botulinum toxin injections in the same muscles.

**Treatment with botulinum toxin improves lower-limb spasticity, but may not improve functional outcomes.**

**9.10.3 Nerve Blocking in the Lower Extremity**

Chemical neurolysis using either alcohol or phenol can be used in the management of lower limb spasticity although alcohol is less effective. Neurolysis destroys a portion of the nerve and impairs nerve conduction and the effects of phenol may last for several months to years (Bhakta 2000).
Table 9.10.3.1 Summary RCTs Evaluating Nerve Blocking

<table>
<thead>
<tr>
<th>Author, Year PEDro Score Sample Size</th>
<th>Intervention</th>
<th>Outcomes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Beckerman et al. (1996) RCT (8) N=60</td>
<td>E1: Thermocoagulation (TH) of peripheral nerves + Ankle-foot orthosis (AFO) in five degrees of dorsiflexion E2: Placebo thermocoagulation (PTH) + AFO E3: TH + Placebo AFO (PAFO) with free range motion of dorsiflexion E4: PTH + PAFO</td>
<td>• Modified Ashworth Scale: E1 &amp; E3 vs E2 &amp; E4)(+) • Clonus score of the ankle: E1 &amp; E3 vs E2 &amp; E4 (+) • Achilles tendon reflex: E1 &amp; E3 vs E2 &amp; E4 (+) • Range of motion (-)</td>
</tr>
<tr>
<td>Kocabas et al. (2010) RCT (4) N=20</td>
<td>E1: 5% phenol 50% ethyl alcohol to motor branches of tibial nerve E2: 50% ethyl alcohol to motor branches of tibial nerve</td>
<td>• Medical Research Council (-) • Modified Ashworth Scale (-) • Passive Range of Motion (-) • Clonus of the ankle (-) • Strength of the ankle plantar flexor (-)</td>
</tr>
</tbody>
</table>

- Indicates non-statistically significant differences between treatment groups
+ Indicates statistically significant differences between treatment groups

Discussion

Only two RCTs have been identified for the investigation of chemical neurolysis of the lower extremities post stroke. Beckerman et al. (1996) reported that the use of thermocoagulation was significantly more efficacious than placebo and an ankle foot orthosis with improvements in spasticity, clonus, and tendon reflexes. However, correlation coefficients between functional outcomes (i.e. walking ability, speed, etc.) and spasticity were very weak, indicating that although spasticity improved, ambulation did not. Moreover, 24.4% of patients who received thermocoagulation did not respond to treatment, although this may reflect a need for validated measures with greater responsiveness in quantifying spasticity (Beckerman et al. 1996).

Kocabas et al. (2010) did not report any differences between groups when comparing a single injection of 5% phenol with an ethyl alcohol injection. Both groups resulted in significant improvements in spasticity, clonus and passive range of motion for up to 6 months. Despite both groups demonstrating an improvement in ambulation, the authors note however that gait was assessed by visual evaluation rather than an objective measure and so the validity of this particular finding may be compromised. In terms of adverse events, both groups were comparable in post-injection pain which was resolved within 48 hours.

There is currently a lack of literature exploring the efficacy of nerve blocking as an intervention for spasticity in the lower extremity. Further research is required to fully understand the use of this approach and to determine its effectiveness.

Conclusions Regarding Neurolysis

There is level 1b evidence that thermocoagulation treatment may improve lower limb spasticity, Achilles tendon flexion, and ankle clonus.

There is limited level 2 evidence from one low-quality RCT that treatment with a single injection of phenol or ethyl alcohol may not improve spasticity, range of motion, neurological status or strength of the ankle plantar flexors.
Neurolysis in the lower limb may reduce spasticity, ankle clonus, and improve Achilles tendon flexion. More research is needed to determine whether phenol or alcohol injections improve spasticity.

9.10.4 Antispastic Medications Post Stroke
A variety of antispastic medications have been studied. Traditional pharmacotherapies for spasticity treatment have been studied, including centrally acting depressants (baclofen, benzodiazepines, clonidine, and tizanidine) and muscle relaxants (Dantrolene). There is evidence from RCTs published in the 1960’s and 1970’s that these treatments are only partially effective in treating spasticity and have negative side effects of weakness and sedation. With the introduction of more focal spasticity treatments, the use of systemic agents has been theorized to decrease.

Table 9.10.4.1 Summary of RCTs Evaluating Antispastic Medications Post Stroke

<table>
<thead>
<tr>
<th>Author, Year</th>
<th>PEDro Score</th>
<th>Sample Size</th>
<th>Intervention</th>
<th>Outcomes</th>
</tr>
</thead>
</table>
| Stamenova et al. (2005) | RCT (8) | N=120 | E: Tolperisone  
C: Placebo | • Ashworth Scale (+)  
• Modified Barthel Index (+) |
| Katrak et al. (1992) | RCT (7) | N=31 | E1: Dantrolene  
C: Placebo | • Modified Ashworth Scale (-)  
• Barthel Index (-) |
| Medici et al. (1989) | RCT (6) | N=30 | E1: Oral Tizanidine  
E2: Baclofen | • Ashworth Scale (-)  
• Pedersen Scale (-) |
| Zhu et al. (2014) | RCT (6) | N=60 | E: Total glucosides from Shaoyao Gancao + Rehabilitation exercise therapy  
C: One-to-one exercise. | • Modified Ashworth Scale & Composite Spasticity Scale (+)  
• Fugl-Meyer Assessment: Lower Extremity (+)  
• Barthel Index: Lower Extremity (+) |
C: Placebo | • Spasticity 6-point grading scale (+)  
• Ability to perform activities of daily living (+) |

- Indicates non-statistically significant differences between treatment groups  
+ Indicates statistically significant differences between treatment groups

Discussion
A total of six studies were identified in the treatment of spasticity using antispasticity pharmacology. The sample sizes were generally small (n=14-60), with the exception of one larger study (n=120). There were two studies on Dantrolene sodium, including one study of a good quality (PEDro=7) (Katrak et al. 1992), which reported null results and was associated with significant side effects when compared to the placebo group. Katrak et al. (1992) highlight that despite adhering to the Australian maximum recommended dose, other studies had reported improvements with greater dosages and thus patients may have been prescribed insufficient doses of Dantrium. In the other study, the results indicated a positive outcome with improvements in spasticity, motor function and activities of daily living (ADL) function (Ketel & Kolb 1984), but was found to be a poor-quality study (PEDro=3) lacking in standardised and validated outcome measures. Medici et al. (1989) compared Tizanidine and Baclofen and found that both were beneficial with no significant differences between the two although there was not a placebo control group; therefore, it was difficult to know whether either drug was helpful beyond that of placebo. Stamenova et al. (2005) reported a significant reduction in spasticity and an increase in
ADL functioning associated with the drug tolperisone, a centrally acting muscle relaxant, which does not cause sedation. The authors suggested that the reduction of spasticity allowed for greater performance of ADL rather than a direct association between tolperisone and ADL functioning. Many patients (62%) were treated with a dose generally higher than recommended, with no dropouts due to adverse events. In combining shaoyao and gancao, Zhu et al. (2014) adopted a traditional Chinese herbal medicine approach alongside exercise therapy and reported significant improvements in lower extremity recovery compared to an exercise therapy only group. It is believed that shaoyao and gancao possess spasmolysis and analgesic properties and could potentially produce synergistic effects (Zhu et al. 2014). Future research investigating shaoyao and gancao may be recommended to utilise the treatment by itself without combination with another treatment as it is possible the exercise therapy provided by Zhu et al. (2014) enhanced outcomes even further.

**Conclusions Regarding Medications for Spasticity**

*There is conflicting level 1b and level 2 evidence regarding the use of Dantrolene on lower limb spasticity.*

*There is level 1b evidence that there is no significant difference between treatment with Tizanidine or Baclofen for spasticity.*

*There is level 1b evidence that Tolperisone may improve spasticity and ADL performance outcomes post-stroke.*

*There is level 1b evidence that total glucosides from Shaoyao and Gancao offered with rehabilitation exercise therapy may improve lower limb spasticity and functional recovery.*

**Oral pharmacological agents may be effectively used in the management of spasticity, although some may be associated with side effects.**

### 9.10.5 Intrathecal Drug Therapy for Post Stroke Spasticity

Drugs can be delivered into the subarachnoid space of the CNS, through an implantable, programmable pump device. Baclofen is the most commonly administered intrathecal drug and usually reserved for patients with severe spasticity. Intrathecal administration of Baclofen has been studied more extensively in other disease states, compared to stroke, including multiple sclerosis, cerebral palsy and spinal cord injury. Intrathecal injections have the advantage that they can deliver constant doses of a drug, which results in fewer systemic side effects, although in stroke patients with unilateral spasticity, there is a danger of weakening muscles on the unaffected side.

**Table 9.10.5.1 Summary of RCTs Evaluating the Effectiveness of Intrathecal Baclofen**

<table>
<thead>
<tr>
<th>Author, Year</th>
<th>PEDro Score</th>
<th>Sample Size</th>
<th>Intervention</th>
<th>Outcomes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Meythaler et al. (2001)</td>
<td>RCT (7)</td>
<td>N=21</td>
<td>E: Intrathecal baclofen, C: Placebo</td>
<td>• Modified Ashworth Scale: Lower Extremity (+) • Penn Spasm Frequency: Lower Extremity (+) • Reflex Scale Score: Lower Extremity (+)</td>
</tr>
</tbody>
</table>

- Indicates non-statistically significant differences between treatment groups
+ Indicates statistically significant differences between treatment groups
Discussion
Only a single RCT that evaluated the effectiveness of intrathecal Baclofen (ITB) was identified. Compared to placebo, infusion of ITB was associated with significant reductions in measures of spasticity, although no assessments of functional outcome were evaluated. Meythaler et al. (2001) found that ITB was more effective than placebo. This benefit was achieved without nonselective decreases of lower muscle tone, which could have impaired walking ability. Three patients, formerly wheelchair ambulators, were able to ambulate following therapy. The results from two single intervention group studies also reported benefits associated with ITB.

Among the four non RCTs, three reported benefits associated with treatment, and one study reported clinical deterioration in walking ability associated with a weakening on their paretic side, resulting in a loss of motor control (Kofler et al. 2009). The authors suggested that patients who benefit from ITB were those who had less severe spasticity and greater control of the lower limb during the swing phase.

Conclusions Regarding Intrathecal Baclofen for the Management of Spasticity

There is level 1b evidence that ITB may improve spasticity in the chronic stages of stroke.

Further research is required to determine the efficacy of ITB for reducing post-stroke spasticity.

9.10.6 Electrical Stimulation for Post Stroke Spasticity
While electrical stimulation treatments, including transcutaneal electrical nerve stimulation (TENS) and functional electrical stimulation (FES), have been examined in previous sections, several studies were identified in which evaluation of spasticity was the primary objective of the investigation. It has been suggested that electrical stimulation may reduce muscle tonicity through an enhancement in presynaptic inhibition of the spastic plantarflexors, and partly to a possible "disinhibition" of descending voluntary commands to the paretic dorsiflexor motor neurons (Bakhtiary & Fatemy 2008). Electrical stimulation can also reduce spasticity without the adverse effect of muscle weakness and paralysis, which have been associated with other anti-spasticity treatments such as botulinum toxin.

The results from two good-quality RCTs suggest that electrical stimulation can help to reduce spasticity following stroke although the studies assessed slightly different treatments over different time periods. Bakhtiary et al. (2008) demonstrated that FES combined with therapy can reduce spasticity assessed immediately after treatment, although it remains unclear whether this treatment is also associated with improved function or if the results are durable. Levin and Hui-Chan (1992) assessed the efficacy of repetition of TENS treatment over a 3-week period, and reported a benefit for up to two weeks.

Table 9.10.6 Summary of RCTs Evaluating Electrical Stimulation for Spasticity

<table>
<thead>
<tr>
<th>Author, Year</th>
<th>PEDro Score</th>
<th>Sample Size</th>
<th>Intervention</th>
<th>Outcomes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bauer et al. (2015)</td>
<td>RCT (9)</td>
<td>N_start=37 N_end=21</td>
<td>E: Active leg cycling + FES C: Active leg cycling</td>
<td>• Modified Ashworth Scale (-)</td>
</tr>
<tr>
<td>Study</td>
<td>Treatment Groups</td>
<td>Outcome Measures</td>
<td></td>
<td></td>
</tr>
<tr>
<td>-------------------------------</td>
<td>----------------------------------------------------------------------------------</td>
<td>-----------------------------------------------</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Bakhtiary &amp; Fatemy (2008)</td>
<td>E: Electrical stimulation + Conventional therapy C: Conventional therapy</td>
<td>• Modified Ashworth Score (+)</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>RCT (8)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>N=40</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Park et al. (2014)</td>
<td>E: TENS + Therapeutic exercise C: Placebo TENS + Therapeutic exercise</td>
<td>• Modified Ashworth Scale (-)</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>RCT (7)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>N_{Start}=34</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>N_{End}=29</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>You et al. (2014)</td>
<td>E: FES C: No treatment</td>
<td>• Composite Spasticity Scale (+)</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>RCT (7)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>N_{Start}=42</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>N_{End}=37</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Levin &amp; Hui-Chan (1992)</td>
<td>E: TENS C: Sham TENS</td>
<td>• Clinical Spasticity Scale (+)</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>RCT (6)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>N=13</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ng &amp; Hui-Chan (2007)</td>
<td>E1: TENS E2: TENS + Task-related training E3: Sham TENS + Task-related training</td>
<td>• Plantarflexor Spasticity (+)</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>C: No treatment</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>RCT (6)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>N=88</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cheng et al. (2010)</td>
<td>E: FES + Conventional therapy C: Conventional therapy</td>
<td>• Spasticity Index (+)</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>RCT (6)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>N=15</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yan &amp; Hui-Chan (2009)</td>
<td>E: TENS C1: Sham TENS C2: Conventional rehabilitation</td>
<td>• Spasticity (+)</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>RCT (6)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>N=62</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hussain et al. (2013)</td>
<td>E: Bobath + TENS C: Bobath</td>
<td>• Modified Ashworth Scale (+)</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>RCT (6)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>N_{Start}=35</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>N_{End}=30</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cho et al. (2013)</td>
<td>E: TENS C: Sham TENS</td>
<td>• Modified Ashworth Scale (-)</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>RCT (5)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>N=42</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mesci et al. (2009)</td>
<td>E: FES C: Conventional therapy</td>
<td>• Modified Ashworth Scale (+)</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>RCT (5)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>N=40</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

- Indicates non-statistically significant differences between treatment groups
+ Indicates statistically significant differences between treatment groups

**Discussion**

There is evidence for the effect of FES on improving muscle spasticity following stroke. Functional electrical stimulation combined with conventional therapy has been shown to significantly decrease muscle spasticity compared to conventional therapy alone (Bakhtiary & Fatemy 2008; Cheng et al. 2010; Mesci et al. 2009). Yamaguchi et al. (2012) reported no statistical significance between electrical stimulation in combination with passive locomotion-like movement and locomotion-like movement alone. However, 66.6% of participants in the electrical stimulation combination group improved on the Modified Ashworth Scale, whereas only 22.2% of the passive movement group improved. Furthermore, active leg cycling with FES may not improve spasticity compared to active cycling alone (Bauer et al. 2015).
Much like FES, TENS has a similar effect on muscle spasticity. Transcutaneous electrical stimulation has been shown to improve muscle spasticity alone (Cho et al. 2013; Levin & Hui-Chan 1992; Yan & Hui-Chan 2009) and in combination with therapeutic exercise/physical therapy (Shamay SM Ng & Hui-Chan 2007; J. Park et al. 2014) and Bobath therapy (Hussain & Mohammad 2013). Both FES and TENS appear to have a positive effect on muscle spasticity post-stroke.

**Conclusions Regarding Electrical Stimulation for the Management of Spasticity**

*There is level 1a and limited level 2 evidence transcutaneous electrical stimulation may improve spasticity outcomes post-stroke.*

*There is level 1a and limited level 2 evidence functional electrical stimulation may improve spasticity outcomes post-stroke.*

**Transcutaneous electrical stimulation and functional electrical stimulation may improve spasticity outcomes post-stroke.**

### 9.10.7 Therapeutic Ultrasound for Post Stroke Spasticity

Therapeutic ultrasound can be used to treat a variety of conditions including pressure ulcers, scar tissue, and spasticity. In this form of treatment, sound waves pass through the skin and cause the tissues to vibrate. This vibration or cavitation can cause a deep heating locally though usually no sensation of heat will be felt by the patient. In situations where a heating effect is not desirable, such as a fresh injury with acute inflammation, the ultrasound can be pulsed rather than continuously transmitted.

Ultrasound has been shown to cause increases in tissue relaxation, local blood flow, and scar tissue breakdown. The effect of the increase in local blood flow can be used to help reduce local swelling and chronic inflammation. A single RCT has been conducted examining the effectiveness of ultrasound on plantarflexor spasticity.

Results from the single study show that treatment with ultrasound can reduce Hmax/Mmax ratio as a measure of alpha motor neuron excitability and spasticity measure of Ashworth Score in stroke patients with ankle plantarflexor spasticity.

**Table 9.10.7 Summary of RCT(s) Evaluating Therapeutic Ultrasound**

<table>
<thead>
<tr>
<th>Author, Year</th>
<th>PEDro Score</th>
<th>Sample Size</th>
<th>Methods</th>
<th>Outcomes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ansari et al. (2007) RCT (5) N=12</td>
<td></td>
<td></td>
<td>E: Continuous therapeutic ultrasound C: Sham therapeutic ultrasound</td>
<td>• Ashworth Scale (-) • Hmax/Mmax ratio (-)</td>
</tr>
</tbody>
</table>

- Indicates non-statistically significant differences between treatment groups
+ Indicates statistically significant differences between treatment groups

**Discussion**

Results from the single study show that treatment with US can reduce Hmax/Mmax ratio as a measure of alpha motor neuron excitability and spasticity measure of Ashworth Score in stroke patients with ankle plantarflexor spasticity (Ansari et al. 2007). Although there was no statistical significance between
groups, both alpha motor neuron excitability and spasticity decreased more in the US group compared to the control group.

**Conclusions Regarding Therapeutic Ultrasound for the Management of Spasticity**

*There is limited level 2 evidence that therapeutic ultrasound may reduce alpha motor neuron excitability that is associated with ankle plantar flexor spasticity.*

### 9.10.8 Physical Therapy to Reduce Spasticity

While spasticity of the calf muscles is widely believed to interfere with walking after stroke, there is evidence that increased tone may be due to other mechanisms such as intrinsic changes to muscles (Sommerfeld et al. 2004). Ada et al. (1998) suggested that it is inappropriate to attempt to reduce spasticity in an effort to improve functional performance.

Nevertheless, the reduction of spasticity remains a focus of many rehabilitation interventions. While many therapeutic approaches including Bobath and Brunnstrom methods aim to prevent the development of spasticity by normalizing tone and motor patterns, several trials have examined specific therapeutic manoeuvres to decrease spasticity in the lower extremity; these are examined below.

#### Table 9.10.8 Summary of RCTs Evaluating Physical Therapy to Reduce Spasticity

<table>
<thead>
<tr>
<th>Author, Year</th>
<th>PEDro Score</th>
<th>Sample Size</th>
<th>Intervention</th>
<th>Outcomes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bai et al. (2014)</td>
<td>RCT (7)</td>
<td>N&lt;sub&gt;start&lt;/sub&gt;=165 N&lt;sub&gt;start&lt;/sub&gt;=154</td>
<td>E: Standard rehabilitation program C: Standard medications</td>
<td>• Modified Ashworth Scale: elbows, fingers, plantar flexors at 3 months (+)</td>
</tr>
<tr>
<td>Yom et al. (2015)</td>
<td>RCT (6)</td>
<td>N&lt;sub&gt;start&lt;/sub&gt;=26 N&lt;sub&gt;end&lt;/sub&gt;=22</td>
<td>E: Virtual reality-based ankle exercise C: Video-based ankle exercise</td>
<td>• Modified Ashworth Scale (-) • Timed Up-and-Go Test (-) • Gait (-)</td>
</tr>
<tr>
<td>Kluding et al. (2008)</td>
<td>RCT (6)</td>
<td>N=16</td>
<td>E: Functional task practice + Ankle joint mobilizations C: Functional task practice</td>
<td>• Lower-extremity weight-bearing symmetry (+) • Ankle range of motion (-) • Ankle kinematics (-) • Gait (-)</td>
</tr>
<tr>
<td>Dundar et al. (2014)</td>
<td>Retrospective</td>
<td>N=107</td>
<td>E: Robotic training + Conventional physiotherapy C: Conventional physiotherapy</td>
<td>• Berg Balance Scale (-) • Modified Ashworth Scale (-) • Functional Ambulation Category (-) • Brunnstrom Recovery Scale: Lower Extremity (+)</td>
</tr>
</tbody>
</table>

- Indicates non-statistically significant differences between treatment groups
+ Indicates statistically significant differences between treatment groups

### Discussion

Physical therapy is a widely used treatment in the recovery of stroke patients and may have some benefit in the reduction of spasticity. Bai et al. (2014) determined that a standard rehabilitation program was significantly more effective in reducing spasticity in the elbows, fingers and plantar flexors then
standard medications after three months of treatment. However, various specific forms of physical therapy have not been as successful. Several specific methods, including ankle joint mobilizations (Changho et al. 2015; Kluding & Santos 2008) and robotic training (Dundar et al. 2014), were ineffective in improving spasticity or gait.

**Conclusions Regarding Physical Therapy to Reduce Spasticity**

*There is level 1b evidence that rehabilitation programs compared to standard medications may improve spasticity for the elbows, fingers and plantar flexion.*

*There is level 1a evidence that ankle exercises compared to conventional therapy may not improve gait, ankle range of motion or spasticity but may improve balance.*

*There is level 3 evidence that robotic training may not improve spasticity, gait, or spasticity.*

*There is level 1b evidence that a single session of isokinetic or isotonic muscle stretch may not improve measures of gait.*

**Evidence is inconclusive for the effect of rehabilitation programs, ankle exercises, robotic training and other physical therapies on spasticity post-stroke.**

### 9.11 Brain Stimulation

#### 9.11.1 Repetitive Transcranial Magnetic Stimulation (rTMS)

Prior to a stroke, both hemispheres remain balanced with motor cortex interactions mostly inhibited but after a stroke, the contralesional hemisphere becomes disinhibited with the ipsilesional hemisphere increasingly inhibited (Elkholy et al. 2014). Previous literature into regaining this hemispheric balance has advocated the use of applying high-frequency rTMS to the ipsilesional hemisphere in order to enhance excitability and low-frequency rTMS to the contralesional hemisphere to reduce excitability (Fregni et al. 2006). The characteristic of rTMS involves a series of non-invasive magnetic pulses that can alter neural activity, and modulate excitability of the motor cortex transiently but beyond the duration of stimulation (Cha et al. 2014). It has been suggested that use of rTMS may result in quicker recovery times due to enhanced reinnervation of paretic limbs and changes in neuroplasticity potentially affecting behaviour and motor ability (Mally & Dinya 2008). A study by Stinear and Hornby (2005) also revealed that TMS, when combined with lower limb muscular electrical stimulation, resulted in a significant increased the size of evoked responses in the tibialis anterior as well as an inhibitory effect on non-stimulated neural pathways. Wang et al. (2012) suggest that rTMS, as a method of promoting neuroplasticity, may enhance motor abilities even further when combined with intensive task-oriented training. However, despite the large volume of research into rTMS, there remains relatively few studies that have investigated the use of rTMS in providing treatment for lower extremity dysfunction. A potential reason for this may be due to the deep location of the leg motor ability in the motor cortex which may be difficult to target with rTMS (Lin et al. 2015).

**Table 9.11.1.1 Summary of RCT(s) Evaluating rTMS**

<table>
<thead>
<tr>
<th>Author, Year</th>
<th>Study Design (PEDro Score)</th>
<th>Sample Size</th>
<th>Intervention</th>
<th>Main Outcome(s) Result</th>
</tr>
</thead>
</table>

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<table>
<thead>
<tr>
<th>Study</th>
<th>Design</th>
<th>N Start</th>
<th>N End</th>
<th>Treatment 1</th>
<th>Treatment 2</th>
<th>Outcomes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chieffo et al. (2014)</td>
<td>RCT(10)</td>
<td>10</td>
<td>9</td>
<td>E: Real rTMS</td>
<td>C: Sham rTMS</td>
<td>• Fugl-Meyer Assessment (+)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>• 6-minute Walk Test (-)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>• 10-meter Walk Test (-)</td>
</tr>
<tr>
<td>Lin et al. (2015)</td>
<td>RCT(9)</td>
<td>32</td>
<td>31</td>
<td>E: Real rTMS</td>
<td>C: Sham rTMS</td>
<td>• Postural Assessment Scale for Stroke (+)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>• Performance oriented mobility assessment (+)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>• Barthel Index (+)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>• Timed Up-and-Go Test (+)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>• Fugl-Meyer Assessment (-)</td>
</tr>
<tr>
<td>Wang et al. (2012)</td>
<td>RCT(8)</td>
<td>24</td>
<td></td>
<td>E: 1 HZ rTMS</td>
<td>C: Sham rTMS</td>
<td>• Fugl-Meyer Assessment (lower extremity) (+)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>• Gait speed cm/sec (+)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>• Cadence step/min (+)</td>
</tr>
<tr>
<td>Cha et al. (2015)</td>
<td>RCT(8)</td>
<td>36</td>
<td></td>
<td>E: rTMS and Mirror Therapy</td>
<td>C: rTMS and sham Mirror Therapy</td>
<td>• Dynamic limits of stability (+)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>• Berg Balance Scale (+)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>• Timed Up-and-Go Test (+)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>• Barthel Index (+)</td>
</tr>
<tr>
<td>Cha et al. (2014)</td>
<td>RCT(7)</td>
<td>24</td>
<td></td>
<td>E: High frequency rTMS</td>
<td>C: Low frequency rTMS</td>
<td>• Balance Index (+)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>• Berg Balance Scale (+)</td>
</tr>
<tr>
<td>Kakuda et al. (2013)</td>
<td>RCT(7)</td>
<td>18</td>
<td></td>
<td>E: Real rTMS followed by Sham stimulation</td>
<td>C: Sham stimulation followed by real rTMS</td>
<td>• Walking velocity (+)</td>
</tr>
<tr>
<td>Khedr et al. (2005)</td>
<td>RCT(6)</td>
<td>52</td>
<td></td>
<td>E: Real rTMS</td>
<td>C: Sham rTMS</td>
<td>• Barthel Index (+)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>• NIH stroke scale (+)</td>
</tr>
<tr>
<td>Jayaram &amp; Stinear (2009)</td>
<td>RCT(5)</td>
<td>9</td>
<td></td>
<td>E1: rTMS</td>
<td>E2: Anodal TDCS</td>
<td>• Motor Evoked Potentials (-)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>E3: Inhibitory paired associative stimulation</td>
<td></td>
</tr>
<tr>
<td>Kakuda et al. (2013)</td>
<td>RCT(4)</td>
<td>18</td>
<td></td>
<td>E: Real rTMS followed by sham stimulation</td>
<td>C: Sham stimulation followed by real rTMS</td>
<td>• Walking Velocity (+), up to 20 min after treatment</td>
</tr>
</tbody>
</table>

- Indicates non-statistically significant differences between treatment groups
+ Indicates statistically significant differences between treatment groups

**Discussion**

The majority of the studies identified compared real rTMS with a sham rTMS protocol with largely positive results. Both Wang et al. (2012) and Chieffo et al. (2014) reported significantly greater gains on the Fugl-Meyer Assessment (FMA) at post-treatment with gains maintained at 1 month follow-up (Chieffo et al. 2014). Although Wang et al. (2012) reported significantly greater gains in gait speed, Chieffo et al. (2014) did not find any group x time interactions for performance on the 6-Minute Walk Test and the 10-Meter Walk Test. However, it was also noted that all patients were able to walk independently therefore the margin of improvement may have been smaller compared to patients with more severe deficits (Chieffo et al. 2014). Real rTMS over the unaffected primary motor cortex (M1) compared to a sham was performed by Lin et al. (2015) and Wang et al. (2012) with the rationale that reducing excitability of the unaffected M1 will restore interhemispheric balance and therefore improvements in motor ability. This was evidenced by Wang et al. (2012) in that motor evoked potentials (MEPs) in the unaffected hemisphere decreased whilst excitability in the affected hemisphere increased after rTMS. Both studies reported improvements in lower limb functioning. Further, rTMS may enhance lower limb motor excitability by reducing spatial asymmetry between hemispheres (Jayaram &...
Stinear 2009) as detailed by Wang et al. (2012) who reported significantly larger increases of MEP latency and amplitude in the affected region and decreases of MEP amplitude in the unaffected region.

Cha et al. (2015) reported a significant improvement in balance after combining rTMS with mirror therapy compared to rTMS with a sham mirror therapy. These findings suggest that visual feedback in addition to rTMS demonstrates promising enhancement of balance functioning. However, caution is required when generalising these results as all patients recruited into the study were able to walk independently and so patients with gait deficits or lower-limb disabilities may not necessarily experience the same outcomes.

In comparing high and low rTMS frequencies performed over the ipsilesional hemisphere, Cha et al. (2014) revealed significant differences between the two types of intensities. The findings suggest that patients receiving high-frequency rTMS demonstrated a decrease in latency and an increase in amplitude of MEPs compared to low-frequency rTMS. The authors also suggest that high-frequency rTMS activated the M1 and performance of the cerebrum and cerebellum, both responsible for activation of balance, visual, vestibular, and proprioceptive sensory abilities were improved therefore demonstrating an increase in neuroplasticity (Cha et al. 2014).

**Conclusions Regarding Repetitive Transcranial Magnetic Stimulation**

*There is level 1a and limited level 2 evidence that repetitive transcranial magnetic stimulation may improve ADL performance, gait and balance.*

Repetitive transcranial magnetic stimulation at high and low frequencies may be effective in improving balance, gait, and ADL performance.

### 9.11.2 Transcranial Direct Current Stimulation (tDCS)

Similar to rTMS, tDCS is a form of non-invasive electrical stimulation that involves the application of mild electrical currents conducted through two saline soaked, surface electrodes applied to the scalp, over the area of interest. There are two forms of stimulation; anodal which increases cortical excitability, and cathodal which decreases excitability (Alonso et al. 2007). However, in contrast to TMS, tDCS does not induce action potentials but instead manipulates the ion balance inside and outside the resting neural membrane through polarising and depolarising the brain tissue (lonso et al. 2007; Schlaug et al. 2008). Furthermore, tDCS is a good candidate for a study since, unlike TMS, it does not elicit somatosensory changes that would allow a subject to determine that a real or sham treatment was being applied due to the low intensity of tDCS and no difference in “clicking” sounds between sham and real tDCS (Priori et al. 2006). Anodal tDCS over the sensorimotor cortex has been found to increase the size evoked potentials of ipsilateral cortical components and enhances synaptic strength while anodal tDCS of the primary motor cortex increase spinal network excitability (Dutta et al. 2014). However, literature regarding lower extremity recovery and tDCS is currently lacking and knowledge regarding the mechanisms of motor recovery is limited.

Studies evaluating tDCS for motor rehabilitation are detailed in Table 9.11.2.1. tDCS is also growing in popularity as a treatment for other post-stroke deficits (e.g. aphasia [see Chapter 14], and perceptual disorders [see Chapter 13]).

**Table 9.11.2.1 Summary of RCTs Evaluating tDCS**
<table>
<thead>
<tr>
<th>Author, Year</th>
<th>Study Design (PEDro Score)</th>
<th>Intervention</th>
<th>Main Outcome(s)</th>
</tr>
</thead>
</table>
| Chang et al. (2015) | RCT (8) N_{Start}=24 N_{End}=24 | E: tDCS + Physiotherapy C: Sham tDCS + Physiotherapy                         | • Motricity Index (lower extremity) (+)  
• Fugl-Meyer Assessment (+)  
• Cadence (-)  
• Speed (-)  
• Stride length (-)  
• Step time (-)  
• Step length (-)  
• Functional Ambulation Category (-)  
• Balance Berg Scale (-) |
| Geroin et al. (2011) | RCT (6) N=30 | E1: tDCS + Robot-assisted gait training E2: Sham tDCS + Robot-assisted gait training C: Overground walking exercises using the Bobath approach | • 6-Minute Walk Test (-)  
• 10-Meter Timed Walk (-) |
| Tanaka et al. (2011) | RCT (6) N=8 | E: Real (anodal) tDCS C: Sham tDCS                                           | • Knee extension maximum force (+)  
• Visual Analogue Scale (-) |
| Danzl et al. (2013) | RCT (6) N_{Start}=10 N_{End}=8 | E: Real tDCS + Robot-assisted gait training C: Sham tDCS + Robot-assisted gait training | • Functional Ambulation Category (+)  
• Berg Balance Scale (-)  
• Stroke Impact Scale (-)  
• Timed Up-and-Go Test (-)  
• 10-meter Walk Test (-) |

- Indicates non-statistically significant differences between treatment groups  
+ Indicates statistically significant differences between treatment groups

**Discussion**

Of the five RCTs identified, four compared active tDCS with a sham condition. Chang et al. (2015), Danzl et al. (2013) and Geroin et al. (2011) all were unable to find improvements in gait or balance ability. It has been suggested that walking mechanisms are determined at the spinal level through activity of the central pattern generators as well as the primary motor cortex (M1), therefore cortical influence from tDCS may have been limited (Geroin et al. 2011). However, motor evoked potentials of the corticospinal tract from the affected tibialis anterior muscle were found to increase in activation after tDCS (Chang et al. 2015) which may somewhat contradict Geroin et al.’s (2011) theory. Chang et al. (2015) note that caution should be taken when interpreting the results of the Fugl-Meyer Assessment (FMA) as the difference in change from baseline to post-treatment was only 0.1 (in favour of sham tDCS) despite the significant difference in score at treatment end favouring the tDCS group. Use of the Berg Balance Scale failed to yield any significant differences between groups in two RCTs, indicating that balance was not influenced by tDCS, however, other methods of measuring balance such as the Postural Assessment Scale for Stroke Patients or the Activities-Specific Balance Confidence Scale may provide different findings (Danzl et al. 2013).

Although function may not have improved significantly, Chang et al. (2015) note that significantly greater gains on the Motricity Index in their study reflected improvements in strength. Tanaka et al. (2011) reported a significantly greater gain in knee extension maximum force in favour of tDCS.
compared to a sham condition. Moreover, these gains were not dependant on differences in fatigue, pain, discomfort or attention as both groups did not differ significantly on any of these measures on the Visual Analogue Scale, suggesting that gains were the result of an increase in excitability in the ipsilesional M1. The authors propose that tDCS can enhance multiple muscle groups in the lower extremities (hamstrings, ankles, tibialis anterior, etc.) although future research is required to examine strength facilitation in these muscles (Tanaka et al. 2011).

Conclusions Regarding Transcranial Direct Current Stimulation

There is level 1a evidence that transcranial direct current stimulation may not improve gait or balance outcomes, but may improve functional recovery and knee extension force.

Transcranial direct current stimulation treatment may not improve gait or balance outcomes.

9.11.3 Galvanic Vestibular Stimulation (GVS)

GVS has been utilised to treat “pusher behaviour”, a phenomenon during which patients push with their non-affected limbs towards their paretic side, even to the point of resisting physical corrections, causing a shift in the centre of gravity and thereby impairing postural balance (Krewer et al. 2013). The concept behind GVS is to provide an anodal and cathodal currents behind each ear between the mastoid processes causing patients to sway towards the anodal side (Fitzpatrick et al. 1999). A case series consisting of two patients reported greater improvements in reducing pusher behaviour after receiving GVS prior to physical therapy compared to physical therapy alone (Nakamura et al. 2014). Only one RCT investigated the use of GVS in lower-extremity functioning, as detailed in Table 9.11.3.1.

Table 9.11.3.1 Summary of RCT(s) Evaluating Galvanic Vestibular Stimulation

<table>
<thead>
<tr>
<th>Author, Year</th>
<th>Study Design (PEDro Score)</th>
<th>Sample Size</th>
<th>Intervention</th>
<th>Main Outcome(s): Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Krewer et al. (2013)</td>
<td>RCT (8)</td>
<td></td>
<td>E1: Galvanic vestibular stimulation</td>
<td>Scale for Contraversive Pushing (PB patients only) (-)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>N&lt;sub&gt;Start&lt;/sub&gt;=25</td>
<td>E2: Driven-gait Orthosis Lokomat</td>
<td>Burke Lateropulsion Scale: E1 vs E3 (-); E1 vs E2 (-); E2 vs E3 (+)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>N&lt;sub&gt;End&lt;/sub&gt;=24</td>
<td>E3: Physiotherapy with visual feedback components (PT-vf)</td>
<td></td>
</tr>
</tbody>
</table>

- Indicates non-statistically significant differences between treatment groups
+ Indicates statistically significant differences between treatment groups

Discussion

Krewer et al. (2013) did not report significant differences in improvement among patients who exhibited pusher behaviour between GVS, Driven-gait Orthosis Lokomat (DGO) and Physiotherapy with visual feedback components (PT-vf). Furthermore, no significant improvements from baseline to post-treatment were observed in the GVS condition although there was a trend towards improvement. A possible explanation could be that pusher behaviour and lateropulsion are not primarily due to vestibular graviception, but also somaesthetic graviception (Krewer et al. 2013). It is also worth noting that there was no placebo group and so potential improvements compared to a sham or no treatment group may provide a greater insight into the effectiveness of GVS. Further studies are required to fully evaluate the efficacy of GVS.

Conclusion Regarding Galvanic Vestibular Stimulation
There is level 1b evidence that galvanic vestibular stimulation may not improve pusher behaviour or lateropulsion.

Galvanic vestibular stimulation may not improve pusher behavior or lateropulsion; however, further research is necessary.

9.12 Acupuncture Treatments

Rabinstein and Shulman (2003) state that, “Acupuncture is a therapy that involves stimulation of defined anatomic locations on the skin by a variety of techniques, the most common being stimulation with metallic needles that are manipulated either manually or that serve as electrodes conducting electrical currents.”. The traditional concept is that life energy flows through channels that connect all organs to each other. Disease is explained as an imbalance in the energy flow, and acupuncture treatment is believed to restore the healthy energy by stimulating specific points along the channels (Rabinstein & Shulman 2003). Acupuncture may stimulate the release of neurotransmitters (Han & Terenius 1982) and have an effect on the deep structure of the brain (Wu et al. 2002). Lo et al. (2005) also established that acupuncture, when applied for at least a 10-min duration, led to long-lasting changes in cortical excitability and plasticity even after the needle stimulus was removed.

A number of reviews and meta-analyses have been conducted to evaluate the use of acupuncture as a treatment method. Kim et al. (2010) conducted a systematic review to determine whether contralateral acupuncture (CAP) is superior to ipsilateral acupuncture (IAP). The review included the results from 8 RCTs all originating from China and Korea. The conventional wisdom is that CAP is better, although the causal mechanism has not been established. In pooled analyses, CAP was associated with a higher response rate (risk ratio: 1.12 95% CI 1.04 to 1.22, p=0.005), but there was no advantage with respect to the outcomes of ADL, motor function or neurological deficit. A review by Kong et al. (2010) was restricted to RCTs that included a sham condition and reported the results from only 10 RCTs evaluating traditional acupuncture or electroacupuncture. Pooled analyses were conducted for the outcomes of ADL (Barthel Index) and global neurological deficit (NIHSS and Scandinavian Stroke Scale). The authors found no evidence of benefit of acupuncture as a treatment for functional recovery. Sze et al. (2002) reported in their meta-analysis that acupuncture had no additional effect on motor recovery but did have a small positive effect on disability. However, it was noted that the benefits reported could be explained by a placebo effect, or poor study quality. Similar to the previous reviews, the authors concluded that the efficacy of acupuncture without stroke rehabilitation remained uncertain, mainly because of the poor quality of available studies.

While the exact mechanisms are not all well-defined, there are biological responses that occur both at local areas that are being stimulated and at remote areas of the body. With respect to stroke rehabilitation, the benefit of acupuncture has been evaluated most frequently for pain relief and recovery from hemiplegia. Despite evidence from several RCTs and meta-analyses, the effectiveness of acupuncture remains unclear. The present evidence-based review of acupuncture treatment for stroke identified a large number of studies. A number of RCTs not included in this review were published in non-English languages, Chinese, most frequently. The methodological quality of RCTs evaluating efficacy of acupuncture are generally poor (Zhao et al. 2012), leading to inconclusive evidence.

Table 9.12.1 Summary of RCTs Evaluating Acupuncture Therapy

<table>
<thead>
<tr>
<th>Author, Year</th>
<th>Stud Design (PEDro Score)</th>
<th>Intervention</th>
<th>Main Outcome(s) Result</th>
</tr>
</thead>
</table>

9. Mobility and the Lower Extremity

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<table>
<thead>
<tr>
<th>Sample Size</th>
<th>Study Details</th>
<th>Interventions</th>
<th>Outcomes</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Bai et al. (2013)</strong>&lt;br&gt;RCT (10)&lt;br&gt;N&lt;sub&gt;Start&lt;/sub&gt;=120&lt;br&gt;N&lt;sub&gt;End&lt;/sub&gt;=120</td>
<td>E1: Physiotherapy&lt;br&gt;E2: Acupuncture&lt;br&gt;E3: Physiotherapy and Acupuncture</td>
<td>• Fugl-Meyer Assessment: Lower Limb (28d) (-)&lt;br&gt;• Fugl-Meyer Assessment: Lower Limb (56d) (+)&lt;br&gt;• Modified Barthel Index (-)</td>
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<tr>
<td><strong>Zhao et al. (2015)</strong>&lt;br&gt;RCT (9)&lt;br&gt;N&lt;sub&gt;Start&lt;/sub&gt;=60&lt;br&gt;N&lt;sub&gt;End&lt;/sub&gt;=51</td>
<td>E1: 100Hz of Transcutaneous Electrical Acupoint Stimulation (TEAS)&lt;br&gt;E2: 2Hz TEAS&lt;br&gt;C: Sham TEAS</td>
<td>• Modified Ashworth Scale (-)&lt;br&gt;• Disability assessment scale (-)&lt;br&gt;• Holden functional ambulation (-)&lt;br&gt;• Global assessment scale (-)&lt;br&gt;• Barthel Index (-)</td>
<td></td>
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<tr>
<td><strong>Park et al. (2005)</strong>&lt;br&gt;RCT (9)&lt;br&gt;N=116</td>
<td>E1: 100Hz of Transcutaneous Electrical Acupoint Stimulation (TEAS)&lt;br&gt;E2: 2Hz TEAS&lt;br&gt;C: Sham TEAS</td>
<td>• Modified Ashworth Scale (-)&lt;br&gt;• Disability assessment scale (-)&lt;br&gt;• Holden functional ambulation (-)&lt;br&gt;• Global assessment scale (-)&lt;br&gt;• Barthel Index (-)</td>
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<tr>
<td><strong>Salom-Moreno et al. (2014)</strong>&lt;br&gt;RCT (8)&lt;br&gt;N&lt;sub&gt;Start&lt;/sub&gt;=34&lt;br&gt;N&lt;sub&gt;End&lt;/sub&gt;=34</td>
<td>E: Deep dry needling&lt;br&gt;C: No intervention</td>
<td>• Pain pressure thresholds bilaterally (+)&lt;br&gt;• affected side deltoid,&lt;br&gt;• affected side metacarpal&lt;br&gt;• affected side tiabialis anterior.&lt;br&gt;• % of load in the forefoot (+)&lt;br&gt;• support surface in the rear foot (+)&lt;br&gt;• maximum pressure (+)&lt;br&gt;• Modified modified Ashworth Scale (-)</td>
<td></td>
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<tr>
<td><strong>Johannsson et al. (2001)</strong>&lt;br&gt;RCT (8)&lt;br&gt;N=150</td>
<td>E1: Acupuncture + Electroacupuncture&lt;br&gt;E2: High-intensity, low frequency TENS&lt;br&gt;E3: Low-intensity, high-frequency TENS</td>
<td>At 3 and 12 month follow-up:&lt;br&gt;• Rivermead Mobility Index (-)&lt;br&gt;• Ability to walk 10 metres (-)&lt;br&gt;• Barthel Index (-)</td>
<td></td>
</tr>
<tr>
<td><strong>Hsieh et al. (2007)</strong>&lt;br&gt;RCT (8)&lt;br&gt;N=62</td>
<td>E: Electroacupuncture&lt;br&gt;C: No acupuncture</td>
<td>• Fugl-Meyer Assessment (-)&lt;br&gt;• Barthel Index (-)</td>
<td></td>
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<tr>
<td><strong>Zhuang et al. (2012)</strong>&lt;br&gt;RCT (7)&lt;br&gt;N=295</td>
<td>E1: Acupuncture&lt;br&gt;E2: Physiotherapy&lt;br&gt;E3: Acupuncture + Physiotherapy</td>
<td>• Fugl-Meyer Assessment (-)&lt;br&gt;• Barthel Index (-)</td>
<td></td>
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<tr>
<td><strong>Gosman-Hedstom et al. (1998)</strong>&lt;br&gt;RCT (7)&lt;br&gt;N=104</td>
<td>E1: Superficial&lt;br&gt;E2: Deep Acupuncture&lt;br&gt;C: No acupuncture</td>
<td>At 3 and 12 month follow-up:&lt;br&gt;• Neurological Score (-)&lt;br&gt;• Barthel Index (-)&lt;br&gt;• Sunnaas Index (-)&lt;br&gt;• Nottingham Health Profile (-)</td>
<td></td>
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<tr>
<td><strong>Sze et al. (2002)</strong>&lt;br&gt;China&lt;br&gt;RCT (7)&lt;br&gt;N=106</td>
<td>E: Acupuncture + Standard Therapy&lt;br&gt;C: Standard Therapy</td>
<td>At 0, 5 and 10 weeks:&lt;br&gt;• Fugl-Meyer (-)&lt;br&gt;• Barthel Index (-)&lt;br&gt;• FIM(-)&lt;br&gt;• Abbreviated Mental Test (-)&lt;br&gt;• NIH stroke scale(-)</td>
<td></td>
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<tr>
<td><strong>Hopwood et al. (2008)</strong>&lt;br&gt;RCT (7)&lt;br&gt;N=105</td>
<td>E: Electroacupuncture + usual care&lt;br&gt;C: Mock TENS + usual care</td>
<td>• Barthel Index (-)&lt;br&gt;• Motricity Index (-)&lt;br&gt;• Nottingham Health Profile (-)</td>
<td></td>
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<tr>
<td><strong>Liu et al. (2009)</strong>&lt;br&gt;RCT (7)&lt;br&gt;N=30</td>
<td>E: Acupuncture + manual twisting&lt;br&gt;C: No twisting</td>
<td>• Measures of balance (-/+)&lt;br&gt;• Muscle strength (+)&lt;br&gt;• 6 meter walk test (-)&lt;br&gt;• Displacement of centre of gravity (+)</td>
<td></td>
</tr>
<tr>
<td><strong>Alexander et al. (2004)</strong>&lt;br&gt;RCT (6)</td>
<td>E: Acupuncture + Standard Rehabilitation&lt;br&gt;C: Standard Rehabilitation</td>
<td>• Fugl-Meyer Assessment (-)&lt;br&gt;• Functional Independence Measure (-)</td>
<td></td>
</tr>
<tr>
<td>Study</td>
<td>Year</td>
<td>RCT</td>
<td>N</td>
</tr>
<tr>
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<tr>
<td>Fink et al. (2004)</td>
<td></td>
<td>RCT</td>
<td>6</td>
</tr>
<tr>
<td>Naeser et al. (1994)</td>
<td></td>
<td>RCT</td>
<td>6</td>
</tr>
<tr>
<td>Huang et al. (2014)</td>
<td></td>
<td>RCT</td>
<td>6</td>
</tr>
<tr>
<td>Zhao et al. (2009)</td>
<td></td>
<td>RCT</td>
<td>5</td>
</tr>
<tr>
<td>Wong et al. (1999)</td>
<td></td>
<td>RCT</td>
<td>5</td>
</tr>
<tr>
<td>Johansson et al. (1993)</td>
<td></td>
<td>RCT</td>
<td>5</td>
</tr>
<tr>
<td>Hegyi et al. (2012)</td>
<td></td>
<td>RCT</td>
<td>5</td>
</tr>
<tr>
<td>Si et al. (1998)</td>
<td></td>
<td>RCT</td>
<td>5</td>
</tr>
</tbody>
</table>

- Indicates non-statistically significant differences between treatment groups
+ Indicates statistically significant differences between treatment groups

**Discussion**

A large number of RCTs have been conducted investigating the efficacy of acupuncture with the majority of which unable to demonstrate clear benefits. In comparison to a sham acupuncture condition, in which patients received acupuncture that did not penetrate the skin, Park et al. (2005) did not report any significant between-group differences. A significant difference was reported by Naeser et al. (Naeser et al. 1994) but only within patients with lesions in less than half of the motor pathways and there was no stratification of upper and lower motor ability, as measured by the Boston Motor Inventory, therefore lacking clarity regarding lower limb recovery.

The use of electroacupuncture has also been investigated. Johansson et al. (2001) compared an acupuncture and electroacupuncture protocol with high-intensity and low-intensity transcutaneous electrical nerve stimulation (TENS) but revealed no significant differences between all three groups at 12-month follow-up in walking ability, mobility, and activities of daily living, although all three groups demonstrated marked improvements. It is possible that despite the low-intensity of TENS in the control group, the patients may still have experienced stimulation and therefore brain activation (Barbro B. Johansson et al. 2001). Furthermore, electroacupuncture was not found to be any more efficacious than a sham TENS condition as evidenced by Hopwood et al. (2008). Although the groups were significantly different at baseline on the Motricity Index and subsequently non-significantly different at post-treatment, suggesting a notable gain for the acupuncture group, no significant Group x Time interaction
was reported. In comparing electroacupuncture with a no acupuncture control condition, Hsieh et al. (2007) did not find any significant differences in Fugl-Meyer Assessment (FMA) lower extremity and FIM scores. The authors suggest that the FMA may be more sensitive to changes in the upper limb compared to lower limb recovery. Zhao et al. (2015) adopted an alternative approach of electrical stimulation on acupuncture sites but with limited success. Upper limb spasticity improved significantly but there was no change in lower limb spasticity or ambulation. However, it should be noted that the acupoints selected by Zhao et al. (2015) were based on previous data of patients with spinal cord injury and so different or additional acupoints should be considered by future research.

Acupuncture was also compared to physiotherapy with largely insignificant results. A high-quality RCT conducted by Bai et al. (2013) revealed no significant differences between acupuncture, physiotherapy, and a combination of both after 28 days of therapy. At 56 days of therapy, FMA lower extremity scores were significantly higher in the physiotherapy group compared to the acupuncture group. Although Bai et al. (2013) highlight that all three groups improved over time, acupuncture may not be as efficacious as physiotherapy. A larger but similar study conducted by Zhuang et al. (2012) did not find any significant differences in FMA and Modified Barthel Index scores between all three groups after 14 and 28 days of therapy. A combination of the two therapies resulted in a favourable trend but this did not reach statistical significance. However, there was no stratification between upper and lower scores on the FMA. The authors suggest that as physiotherapy did not result in significantly greater gains or improvements, acupuncture may be an equivalent alternative and could be a useful option for individuals who do not have access to a physiotherapist or the equipment required for physiotherapy. Huang et al. (2014) found no changes in posture and balance when comparing acupuncture and physiotherapy with physiotherapy alone. However, patients in the combined condition with low Brunnstrom Recovery Stage score demonstrated significantly greater improvement on the maintenance of posture subscale.

Conclusions Regarding Acupuncture Treatments

There is level 1a evidence from high-quality, high-powered studies that acupuncture may not improve balance, gait, motricity, spasticity or independent functioning. However, there is limited level 2 evidence from low-quality studies that balance, motor function and performance of activities of daily living may be improved following acupuncture.

There is level 1a evidence that electroacupuncture may not improve motor function or ADL.

Acupuncture may not improve lower extremity motor function or ADLs.

9.13 Meridian Acupressure

Meridian acupressure is a form of treatment whereby finger pressure is applied to meridian points on the body. Meridians are either yin or yang, depending on the direction they flow on the body's surface and can theoretically increase blood flow (qi) thus improving function (H. S. Kang et al. 2009). Yang meridians of the foot flow from the head to the lower limbs whereas yin meridians of the foot flow from the lower limbs to the chest (de Morant & Zmiewski 1994). Not only is acupressure painless and inexpensive, it has been found to be effective in increasing function and activities of daily living (ADLs) (Yue et al. 2013). Although used in clinical practice in eastern parts of the world, only a single study has examined its use on lower extremity recovery following stroke.
Table 9.13.1 Summary RCT(s) Evaluating Meridian Acupressure

<table>
<thead>
<tr>
<th>Author, Year</th>
<th>Study Design (PEDro)</th>
<th>Sample Size</th>
<th>Intervention</th>
<th>Main Outcome(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yue et al. (2013)</td>
<td>RCT (6)</td>
<td>N=78</td>
<td>E: Acupressure + routine care C: Routine Care</td>
<td>• Barthel Index (+) &lt;br&gt; • Fugl-Meyer motor scores (+)</td>
</tr>
</tbody>
</table>

- Indicates non-statistically significant differences between treatment groups<br>+ Indicates statistically significant differences between treatment groups

**Discussion**

Yue et al. (2013) reported significantly greater improvements in Barthel Index and Fugl-Meyer Assessment scores in the intervention group compared to a control group who only received standard care. Although these findings cannot be generalised to lower limb extremity specifically, the study revealed that patients were able to demonstrate greater proficiency in ADLs and motor skills of both upper and lower limb activity. No between-group differences were noted after 1 month of treatment with significant improvements not observed until after 3 months, indicating that acupressure requires greater time to demonstrate treatment efficacy (Yue et al. 2013).

**Conclusion Regarding Meridian Acupressure**

*There is level 1b evidence that acupressure led by nurses may improve lower limb motor function.*

**Acupressure may improve functional recovery.**

**9.14 Chinese Herbal Medicine**

Traditional Chinese Herbal Medicine has been used routinely in China for the treatment of ischemic stroke, despite a dearth of empirical evidence of its safety and effectiveness. Traditional Chinese herbal medicines may assist in the promotion of stroke recovery by enhancing ischemic reperfusion injury, inhibiting the aggregation of platelets, reducing cerebral edema, dilating cerebral vessels, and improving circulation (Sze et al. 2005; Wu et al. 2002).

Pooled analysis of modified Edinburgh-Scandinavian Stroke Scale (MESSS) scores and TNA-α levels in a systematic review on *Qingkailing*, an acclaimed Chinese herbal medicine to treat cerebrovascular conditions, suggested that *Qingkailing* to be beneficial to patients with ischemic stroke when combined with conventional treatment (F. Cheng et al. 2012). Previous research into *Tokishakuyakusan* (TS) has also revealed significant decreases in blood viscosity and an improvement in microcirculation among patients with asymptomatic cerebral infarction (Yang et al. 2004). NeuroAid, a traditional Chinese herbal medicine comprised of nine herbal and five animal components, has been found to be efficacious in improving activities of daily living function according to the Modified Rankin Scale (mRS) and Barthel Index for up to 18 months when compared to a placebo condition (Venketasubramanian et al. 2015). However, Chen et al. (2013) did not find any between-group differences on the mRS when comparing NeuroAid to a placebo.

A Cochrane review identified six RCTs that compared Dan Shen, a Chinese herbal medicine from the plant *Salvia militorrhiza*, to a placebo or open placebo control following ischemic stroke (B. Wu et al. 2007). Dan Shen compounds were associated with significant neurological improvements, however, the
overall quality of the trials were poor and too few patients were included to provide reliable conclusions as to the treatment effect. Wu et al. (2007) recommended that further high-quality RCTs need to be performed.

### 9.14.1 Summary of Chinese Herbal Medicine

<table>
<thead>
<tr>
<th>Author, Year</th>
<th>Study Design (PEDro Score)</th>
<th>Sample Size (N)</th>
<th>Intervention</th>
<th>Main Outcome(s)</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Chen et al. (2012)</strong></td>
<td>RCT (9)</td>
<td>N=68</td>
<td>E: Astragalus membranaceus C: Placebo herb</td>
<td>Functional Independence Measure (week 4 &amp; 12 (+)</td>
<td>Glasgow Outcome Scale (week 12) (+)</td>
</tr>
<tr>
<td>Kong et al. (2009)</td>
<td>RCT (8)</td>
<td>N=40</td>
<td>E: Neuroaid C: Placebo</td>
<td>At baseline, week 4 and week 8</td>
<td>Fugl-Meyer Assessment (-)</td>
</tr>
<tr>
<td>Goto et al. (2009)</td>
<td>RCT (6)</td>
<td>N=31</td>
<td>E: Tokishakuyakusan C: No treatment</td>
<td>Stroke Impairment Assessment Scale: Knee extension and Foot-pat items (+)</td>
<td>Stroke Impairment Assessment Scale (-)</td>
</tr>
</tbody>
</table>

- Indicates non-statistically significant differences between treatment groups
+ Indicates statistically significant differences between treatment groups

### Discussion

Chen et al. (2012) reported significantly higher FIM gains among those taking AM when compared with a placebo group. The authors propose that this may have been the result of the anti-inflammatory and antioxidant properties of AM allowing for greater recovery through reducing brain edema. No differences in Barthel Index or Modified Rankin Scale were observed therefore suggesting that functioning specific to activities of daily living did not improve. However, there were no outcomes measures used that specifically focused on upper extremity recovery thus making it unclear as to whether AM is effective in the restoration of lower limb function.

Although there were no statistically significant improvements associated with treatment for 1 month, there was a trend towards benefit among patients with more severe stroke and those with posterior circulation infarcts (Kong et al. 2009). Further, the five patients with the best recovery in the NeuroAid® group had improved more than the five best-recovered patients in the placebo group and whilst this still did not reach statistical significance, Kong et al. (2009) suggest a trend towards greater neuroplasticity may have been present and that a longer follow-up time may have been more appropriate. A systematic review of 6 studies on the efficacy of NeuroAid® in post-stroke recovery reported that the drug increased changes of achieving functional independence when compared to control treatments (Siddiqui et al. 2013). The MLC601 as an add-on to standard treatment may be beneficial to patients with non-acute stroke. Currently, there are studies focused on examining the cognitive effects of NeuroAid® II (MLC901) (Chen et al. 2013), and an extension of the CHIMES study that investigates long-term efficacy of NeuroAid® in stroke recovery (Venketasubramanian et al., 2013).

Tokishakuyakusan (TS) was associated with prevention of the worsening of impairment and disability in the chronic phase of stroke among a small sample of elderly (>80 years) stroke patients living in an
institution (Goto et al. 2009). Although the Stroke Impairment Assessment Scale (SIAS) did not show significant improvement, observation of the individual items on the SIAS reveal that knee extension and foot-pat had significantly improved more in the experimental group compared to the placebo group. The mechanism through which benefit is conferred is not well-understood. Based on previous studies, Goto et al. (2009) suggest that the anti-oxidant, antiplatelet and muscle weakness amelioration properties of TS may have contributed towards potential positive outcomes. It is also believed to be neuroprotective and may enhance the synthesis and release of neurotransmitters including acetylcholine, dopamine and norepinephrine.

Further research into traditional Chinese herbal medicine is required, not only to expand on the already small literature, but with studies that use outcome measures specific to lower extremity functioning rather than general functioning or ADLs.

**Conclusions Regarding Chinese Herbal Medicine**

*There is level 1a evidence that various Chinese Medicine therapies may not improve lower limb function compared to placebo.*

*Traditional Chinese medicine may not improve lower limb function compared to placebo.*
Summary

1. There is level 1a evidence that Motor Learning and Bobath may improve motor recovery but they are not superior to one another.

2. There is level 1a evidence that the Bobath approach may not improve balance, gait, or reduce hospital length of stay.

3. There is level 1a and limited level 2 evidence that early intensive therapy may improve gait and general motor function.

4. There is conflicting level 1a evidence regarding the effect of augmented physical therapy on gait at follow-up.

5. There is level 1a evidence that whole body and local vibration training programs may not improve balance or gait.

6. There is level 1a evidence that trunk-specific training may improve balance outcomes.

7. There is conflicting level 2 evidence regarding the effect of virtual reality balance training on gait and balance outcomes.

8. There is level 1a and level 2 evidence that feedback training may not improve balance or motor function of the lower limb.

9. There is level 1a evidence that exercise-based falls prevention programs may not reduce the rate of falls following stroke.

10. There is level 1b and limited level 2 evidence that sit-to-stand training may not improve balance or strength of the impaired lower limb when compared to conventional therapy.

11. There is level 1a and limited level 2 evidence that resistive/strength task-oriented training may improve gait, cadence and lower limb mobility; however, it may not be beneficial for improving balance.

12. There is level 1a and level 2 evidence that treadmill training either in combination with conventional therapy or delivered alone, may improve gait velocity, stride length and lower limb functional mobility; however, it may not improve balance.

13. There is level 1a and level 2 evidence that partial body weight support treadmill training may not improve gait or balance outcomes compared to conventional or other gait training interventions.

14. There is level 1a and limited level 2 evidence that virtual reality combined with treadmill training may improve gait and balance post stroke.

15. There is level 1a and level 2 evidence that virtual reality-based interventions compared to conventional therapy may improve balance; however evidence is conflicting for gait outcomes.
16. **There is level 1a and level 2 that auditory feedback may improve gait and muscle activity.**

17. **There is limited and conflicting level 1a and level 2 evidence regarding the effect of visual feedback on balance and gait.**

18. **There is conflicting level 1a and level 2 evidence regarding the effect of EMG/Biofeedback on lower limb function following stroke.**

19. **There is level 1b evidence that that bilateral leg training with a custom-made device may not improve lower limb motor function.**

20. **There is level 1a and limited level 2 evidence that mental practice/motor imagery may improve gait and balance outcomes.**

21. **There is level 1a and level 2 evidence that hippotherapy may not improve gait outcomes; however there may be an improvement on foot pressure. The evidence for balance is conflicting.**

22. **There is level 1a and level 2 evidence that rhythmic auditory stimulation training may improve gait and balance outcomes; however there is limited evidence for its effect on ankle range of motion.**

23. **There is level 1b evidence that mirror therapy combined with repetitive transcranial magnetic stimulation may improve balance; however, when provided alone, level 1b evidence indicates no additional benefit for lower limb function compared to conventional therapy.**

24. **There is level 1a evidence that self-management programs may not improve gait and balance.**

25. **There is level 1b evidence that caregiver mediated programs may improve gait and balance outcomes.**

26. **There is Level 1a evidence that functional strength training may improve gait speed but may not knee extension and flexion strength.**

27. **There is Level 1a evidence that progressive resistance training may improve strength and knee extension but may not gait.**

28. **There is level 1b evidence that eccentric resistance training may result in greater muscle activation compared to concentric resistance training but may not improve gait speed.**

29. **There is level 1a evidence that cardiovascular fitness, aquatic therapy, and mobility training programs may improve gait. There is level 1b evidence that home-based cardiovascular exercise programs may also improve gait outcomes.**

30. **There is level 1b and level 2 evidence that cycling training interventions may not improve gait.**

31. **There is conflicting level 1a evidence regarding supervised exercise training programs compared to unsupervised programs on gait.**
32. There is level 1b and limited level 2 evidence that community or outpatient exercise programs may improve mobility, lower limb strength and flexibility.

33. There is level 1b evidence that high-intensity circuit training may not improve balance when compared to low-intensity circuit training.

34. There is limited level 2 evidence that walking exercises on stairs compared to flat surfaces may improve balance post-stroke.

35. There is level 1b evidence that encouraging hemiplegic individuals to propel their own wheelchair may not improve ADLs.

36. There is level 1b and level 2 evidence that quad canes or walkers are significantly better than a one-point cane or no cane for improving gait and balance.

37. There is level 1a and level 2 evidence that wearing an AFO may improve gait and range of motion; however, there is limited evidence for its effectiveness on balance.

38. There is limited level 2 evidence showing no significant difference between brace-assisted walking and partial body weight-supported treadmill training for the improvement of gait outcomes.

39. There is level 1a evidence that an AFO when combined with posterior tibial nerve denervation, may not improve gait but may improve foot reflexes post-stroke.

40. There is level 1a and level 2 evidence that the Gait Trainer device may improve gait in the acute phase but not in the subacute or chronic phase of stroke recovery.

41. There is level 1a and level 2 evidence that the Lokomat may not improve gait and balance in the acute phase of stroke recovery. The evidence is unclear and limited regarding the use of this device in the chronic and subacute stroke phases.

42. There is level 1a and limited level 2 evidence that transcutaneous electrical nerve stimulation may improve gait, spasticity, balance, and ankle joint dorsiflexion range of motion and muscle strength.

43. There is level 1a and level 2 evidence that FES may improve gait, balance, and range of motion.

44. There is level 1b evidence that interferential current therapy may improve balance.

45. There is level 1b and limited level 2 evidence that peroneal nerve stimulation may improve gait and quality of life post-stroke.

46. There is level 1a evidence that neuromuscular electrical stimulation may not improve gait.

47. There is level 1b evidence that rPMS may improve foot muscle strength and ankle range of motion.
48. There is level 1a evidence that amphetamines may not improve lower limb function.

49. There is level 1a evidence that methylphenidate not improve motor function following stroke.

50. There is limited level 2 evidence that L-DOPS may improve functional outcomes post-stroke.

51. There is level 1b evidence that Levodopa may improve motor recovery.

52. There is level 1b evidence that ropinirole may not be superior to placebo at increasing gait, functional recovery and activities of daily living post-stroke.

53. There is level 1b evidence that citalopram may improve neurological function but not functional recovery following stroke.

54. There is level 1a evidence from high-quality, high-powered studies that fluoxetine may improve motor recovery, ADL functioning may not be enhanced.

55. There is level 1b evidence that Almitrine in combination with Raubasine may improve functional outcomes post stroke.

56. There is level 1a evidence that Piracetam may improve lower extremity motor function but not neurological status or ADL performance following stroke.

57. There is level 1b evidence that both a tilt table and night splint may prevent ankle contracture in the early period following stroke.

58. There is level 1a evidence that treatment with botulinum toxin compared to placebo improves lower limb spasticity, but gains for functional recovery have not been significant.

59. There is level 1b and limited level 2 evidence that treatment with botulinum toxin compared to phenol may improve lower limb spasticity.

60. There is level 1b and limited level 2 evidence that treatment with botulinum toxin combined with casting or taping may improve lower limb spasticity but not gait.

61. There is level 1b evidence that tibial nerve neurotomy (TNN) treatment to the soleus nerve, tibialis posterior, and the flexor hallucis longus, may be more effective for the improvement of spasticity than botulinum toxin injections in the same muscles.

62. There is level 1b evidence that thermocoagulation treatment may improve lower limb spasticity, Achilles tendon flexion, and ankle clonus.

63. There is limited level 2 evidence from one low-quality RCT that treatment with a single injection of phenol or ethyl alcohol may not improve spasticity, range of motion, neurological status or strength of the ankle plantar flexors.

64. There is conflicting level 1b and level 2 evidence regarding the use of Dantrolene on lower limb spasticity.
65. There is level 1b evidence that there is no significant difference between treatment with Tizanidine or Baclofen for spasticity.

66. There is level 1b evidence that Tolperisone may improve spasticity and ADL performance outcomes post-stroke.

67. There is level 1b evidence that total glucosides from Shaoyao and Gancao offered with rehabilitation exercise therapy may improve lower limb spasticity and functional recovery.

68. There is level 1b evidence that ITB may improve spasticity in the chronic stages of stroke.

69. There is level 1a and limited level 2 evidence transcutaneous electrical stimulation may improve spasticity outcomes post-stroke.

70. There is level 1a and limited level 2 evidence functional electrical stimulation may improve spasticity outcomes post-stroke.

71. There is limited level 2 evidence that therapeutic ultrasound may reduce alpha motor neuron excitability that is associated with ankle plantar flexor spasticity.

72. There is level 1b evidence that rehabilitation programs compared to standard medications may improve spasticity for the elbows, fingers and plantar flexion.

73. There is level 1a evidence that ankle exercises compared to conventional therapy may not improve gait, ankle range of motion or spasticity but may improve balance.

74. There is level 3 evidence that robotic training may not improve spasticity, gait, or spasticity.

75. There is level 1b evidence that a single session of isokinetic or isotonic muscle stretch may not improve measures of gait.

76. There is level 1a and limited level 2 evidence that repetitive transcranial magnetic stimulation may improve ADL performance, gait and balance.

77. There is level 1a evidence that transcranial direct current stimulation may not improve gait or balance outcomes, but may improve functional recovery and knee extension force.

78. There is level 1b evidence that galvanic vestibular stimulation may not improve pusher behaviour or lateropulsion.

79. There is level 1a evidence from high-quality, high-powered studies that acupuncture may not improve balance, gait, motricity, spasticity or independent functioning. However, there is limited level 2 evidence from low-quality studies that balance, motor function and performance of activities of daily living may be improved following acupuncture.

80. There is level 1a evidence that electroacupuncture may not improve motor function or ADL.

81. There is level 1b evidence that acupressure led by nurses may improve lower limb motor function.
82. There is level 1a evidence that various Chinese Medicine therapies may not improve lower limb function compared to placebo.
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Appendix

Acute Stroke

1. There is level 1a and level 1b evidence that Bobath does not improve balance or gait velocity; however, evidence for motor functioning and activities of daily living is conflicting.

2. There is conflicting level 1a evidence regarding the effectiveness of Bobath versus Motor Relearning at improving motor function.

3. There is conflicting level 1a and level 2 evidence regarding the effectiveness of intensive physical therapy on gait and activities of daily living at 3 and 6 months.

4. There is level 1a and level 2 evidence that task specific training improves balance and gait.

5. There is level 1b and level 2 evidence that feedback training improves gait but not balance.

6. There is level 1a evidence that thermal stimulation does not improve balance.

7. There is level 1a evidence that treadmill training in addition to conventional therapy improves gait; however, the evidence regarding its effect on balance is conflicting.

8. There is conflicting level 1a evidence regarding the effectiveness of body weight supported treadmill training for gait.

9. There is level 2 evidence that virtual reality does not improve gait or balance compared to conventional therapy.

10. There is level 1b and level 2 evidence that rhythmic auditory stimulus in combination with gait training improves gait.

11. There is level 1b evidence that mirror therapy does not improve gait or balance.

12. There is level 1b evidence that self-regulation therapy may not improve gait and balance.

13. There is conflicting level 1b and level 2 evidence regarding the effectiveness of aerobic training for gait.

14. There is level 1b evidence that high intensity circuit based training and aerobic training improve balance and are no better than one another. Level 2 evidence indicates that aerobic cycling does not improve activities of daily living.

15. There is level 1b evidence that encouraging hemiplegic individuals to propel their own wheelchair may not improve activities of daily living.

16. There is 1a evidence that robotic ankle training does not improve gait velocity but it may improve lower limb dynamic symmetry.

17. There is level 1a evidence that gait trainers improve gait; however, they are not as efficacious at improving balance.

18. There is conflicting level 1a evidence regarding the effectiveness of Lokomat on gait.

19. There is level 1b evidence that the Regent Suit improves gait, balance and activities of daily living.

20. There is level 1b evidence that transcutaneous electrical nerve stimulation reduces spasticity and improves strength, but not gait and activities of daily living.

21. There is level 1a and level 2 evidence that functional electrical stimulation in combination with traditional therapy improves gait and but not activities of daily living.

22. There is level 1a evidence that amphetamines do not improve lower limb function.
23. There is level 1b evidence that methylphenidate does not improve lower limb motor function following stroke.

24. There is level 1b evidence that citalopram improves neurological function but not functional recovery post stroke.

25. There is conflicting level 1a evidence regarding the effectiveness of fluoxetine on lower limb motor recovery.

26. There is level 1b evidence that Piracetam improves lower limb motor function but not activities of daily living.

27. There is level 1b evidence that botulinum toxin improves spasticity, gait and activities of daily living.

28. There is level 1b evidence that both FES and TENS improve spasticity.

29. There is level 1b evidence that rehabilitation programs compared to standard medications improve spasticity for the elbows, fingers and plantar flexion.

30. There is level 1b evidence that repetitive transcranial magnetic stimulation improves activities of daily living.

31. There is level 1b evidence that transcranial direct current stimulation improves activities of daily living, but not gait or balance.

32. There is level 1a evidence that acupuncture does not improve balance, gait, motricity, spasticity or independent functioning; however, there is conflicting level 2 evidence that balance, motor function and performance of activities of daily living improves following acupuncture.

33. There is level 1a evidence that electroacupuncture does not improve motor function or activities of daily living.

34. There is level 1b evidence that acupressure led by nurses improves lower limb motor function and activities of daily living.

35. There is level 1b evidence that astragalus membranaceus and neuroaid do not improve lower limb function or activities of daily living compared to placebo.

**Subacute Stroke**

1. There is level 1b evidence that Motor Relearning improves motor recovery and activities of daily living; however, the evidence for balance is conflicting.

2. There is level 1b evidence that Bobath does not improve balance; however, the evidence for gait is conflicting.

3. There is level 1a evidence that intensive physical therapy does not improve gait, balance, activities of daily living or spasticity at 3, 6, and 12 months.

4. There is conflicting level 1b and level 2 evidence regarding feedback training effectiveness on balance.

5. There is level 1b evidence that whole body vibration does not improve balance.

6. There is level 1b evidence that postural support improves balance and gait.

7. There is level 1b evidence that sit-to-stand and falls prevention training does not reduce the incidence of falls.

8. There is level 1a evidence that task-specific training improves gait and balance.
9. There is level 1a evidence that treadmill training does not improve gait.

10. There is level 1a and level 2 evidence that body weight supported treadmill training does not improve gait.

11. There is level 1b evidence that a weight bearing treadmill exercise program does not improve balance or gait.

12. There is level 1a evidence that virtual reality-based interventions in combination with conventional therapy improves gait and balance.

13. There is conflicting level 1a evidence regarding the effect of biofeedback training on lower limb function.

14. There is level 1b evidence that mental practice does not improve gait or balance.

15. There is level 1b evidence that hippotherapy improves balance and depression.

16. There is level 1b evidence that self-management programs does not improve gait and balance.

17. There is level 1a evidence that functional strength training does not improve gait or balance.

18. There is level 1a evidence that a progressive aerobic exercise program improves balance, gait, endurance and strength.

19. There is level 1b evidence that a cycle exercise program does not improve balance, gait or activities of daily living.

20. There is level 2 evidence that quad canes or walkers are significantly better than a one-point cane or no cane for improving gait and balance.

21. There is level 1b and level 2 evidence that AFOs improve gait and balance.

22. There is level 1a evidence that gait trainers improve gait and activities of daily living.

23. There is level 1a evidence that Lokomat does not improve gait.

24. There is level 1a evidence that FES does not improve gait or spasticity.

25. There is level 1b evidence that methylphenidate does not improve lower limb motor function following stroke.

26. There is level 1b evidence that Levodopa improves motor recovery of the lower extremity post stroke.

27. There is level 1b evidence that fluoxetine improves lower limb motor function.

28. There is level 2 evidence that fluoxetine does not improve gait.

29. There is level 1b evidence that Almitrine in combination with Raubasine improves functional outcomes.

30. There is level 1b evidence that both a tilt table and night splint prevents ankle contracture.

31. There is level 1b evidence that botulinum toxin is superior to phenol and placebo in reducing spasticity.

32. There is level 1b evidence that TENS in combination with Bobath improves spasticity.

33. There is level 1a evidence that repetitive transcranial magnetic stimulation improves activities of daily living, gait and balance.
34. There is level 1a evidence that acupuncture does not improve activities of daily living or gait, but it improves balance.

Chronic Stroke
1. There is level 1b and level 2 evidence that Motor Relearning does not improve gait.
2. There is level 1a evidence that intensive physical therapy improves gait at 3 months but not at 9 months. The evidence at 6 months is conflicting.
3. There is level 1a evidence that intense balance training improves balance.
4. There is level 1a evidence that whole-body vibration does not improve balance.
5. There is level 1b and level 2 evidence that virtual reality improves balance.
6. There is level 1b evidence that feedback training improves balance; however, level 2 evidence is conflicting.
7. There is level 1a evidence that yoga does not improve balance.
8. There is level 1b and level 2 evidence that dual-task training improves balance.
9. There is level 1b evidence that agility and fall prevention-based training does not reduce the incidence of falls.
10. There is level 1a and level 2 evidence that task-specific training improves gait; however, the effect on balance is conflicting.
11. There is level 1a evidence that treadmill training improves gait; however, the evidence regarding balance is conflicting.
12. There is conflicting level 1a and level 2 evidence regarding the effectiveness of body weight supported treadmill training on gait.
13. There is level 1a and level 2 evidence that virtual reality-based interventions in combination with treadmill and conventional therapy improves gait and balance.
14. There is conflicting level 1a and level 2 evidence regarding the effectiveness of visual feedback training on gait.
15. There is conflicting level 1a and level 2 evidence regarding the effect of biofeedback training on lower limb function.
16. There is level 1b evidence that bilateral leg training with a custom-made device may not improve lower limb motor function.
17. There is level 1a evidence that mental practice/motor imagery improves gait and balance.
18. There is level 1b evidence that hippotherapy does not improve balance or gait.
19. There is level 1a evidence that rhythmic auditory stimulation in combination with gait training improves gait.
20. There is level 1b evidence that mirror therapy in combination with rTMS improves balance.
21. There is level 1b evidence that caregiver mediated programs may improve gait and balance outcomes.
22. There is level 1a evidence that functional and progressive strength training improves lower limb strength; however, it does not improve gait or balance.
23. There is level 1a evidence that aerobic walking exercise and aquatic therapy improve gait, balance and strength.

24. There is level 1b evidence that unsupervised exercise programs are as effective as supervised programs at improving gait, balance and activities of daily living.

25. There is level 1b and level 2 evidence that walking exercises on stairs compared to flat surfaces may improve balance.

26. There is level 1b evidence that quad canes or walkers are significantly better than a one-point cane or no cane for improving gait and balance.

27. There is level 1b and level 2 evidence AFOs improve gait and balance.

28. There is level 1a evidence that AFOs when combined with posterior tibial nerve denervation do not improve gait but may improve foot reflexes post-stroke.

29. There is level 1a evidence that gait trainers does not improve gait, balance, activities of daily living, or spasticity.

30. There is level 1b evidence that Lokomat does not improve gait.

31. There is level 1b evidence that robotic orthosis and sideways treadmill training without vision improves gait.

32. There is level 1b evidence that LokoHelp does not improve gait.

33. There is level 1a evidence that transcutaneous electrical nerve stimulation in combination with traditional therapies improves gait, balance and spasticity. When delivered alone, level 1b and level 2 evidence suggests that it improves spasticity but not gait and strength.

34. There is conflicting level 1a evidence regarding the effectiveness of FES on gait; however, there is level 1b evidence that FES improves range of motion.

35. There is level 1b evidence that interferential current therapy improves balance.

36. There is level 1b and limited level 2 evidence that peroneal nerve stimulation may improve gait and quality of life.

37. There is level 1b and level 2 evidence that neuromuscular electrical stimulation may not improve gait.

38. There is level 1b evidence that repetitive peripheral magnetic stimulation improves foot muscle strength and ankle range of motion.

39. There is level 1b evidence that ropinirole does not improve gait, functional recovery or activities of daily living.

40. There is level 1a evidence that treatment with botulinum toxin compared to placebo improves lower limb spasticity; however, improvements in functional recovery are conflicting.

41. There is level 1b and limited level 2 evidence that treatment with botulinum toxin compared to phenol improves lower limb spasticity.

42. There is level 1b and limited level 2 evidence that treatment with botulinum toxin combined with casting or taping improves lower limb spasticity but not gait.

43. There is level 1b evidence that tibial nerve neurotomy (TNN) of the soleus nerve, tibialis posterior, and the flexor hallucis longus is more effective for the improvement of spasticity than botulinum toxin.
44. There is level 1b evidence that thermocoagulation treatment improves lower limb spasticity, Achilles tendon flexion, and ankle clonus.

45. There is limited level 2 evidence that treatment with a single injection of phenol or ethyl alcohol does not improve spasticity, range of motion, neurological status or strength of the ankle plantar flexors.

46. There is level 1b evidence that there is no significant difference between treatment with Tizanidine or Baclofen for spasticity.

47. There is level 1b evidence that Tolperisone improves spasticity and activities of daily living.

48. There is level 2 evidence that Dantrolene improves spasticity and activities of daily living.

49. There is level 1b evidence that intrathecal Baclofen improves spasticity.

50. There is level 1b and level 2 evidence that FES in combination with conventional therapy improves spasticity.

51. There is conflicting level 1a and level 2 evidence regarding the effectiveness of TENS on spasticity.

52. There is limited level 2 evidence that therapeutic ultrasound reduces alpha motor neuron excitability that is associated with ankle plantar flexor spasticity.

53. There is level 1a evidence that ankle exercises compared to conventional therapy does not improve gait, ankle range of motion or spasticity but may improve balance.

54. There is level 1b evidence that a single session of isokinetic or isotonic muscle stretch does not improve measures of gait.

55. There is level 1a and limited level 2 evidence that repetitive transcranial magnetic stimulation improves activities of daily living and balance; however, the evidence regarding gait is conflicting.

56. There is level 1a evidence that transcranial direct current stimulation improves functional recovery and strength, but does not improve gait or balance.

57. There is level 1b evidence that galvanic vestibular stimulation does not improve pusher behaviour or lateropulsion.

58. There is level 1a evidence that acupuncture does not improve activities of daily living, spasticity, pain or gait.

59. There is level 1b evidence that tokishakuyakusan does not improve lower limb function compared to placebo.