

Electromechanical-assisted training for walking after stroke (Review)

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ABSTRACT

Background

Electromechanical and robotic-assisted gait training devices are used in rehabilitation and might help to improve walking after stroke.

Objectives

To investigate the effect of automated electromechanical and robotic-assisted gait training devices for improving walking after stroke.

Search strategy

We searched the Cochrane Stroke Group Trials Register (last searched September 2006), the Cochrane Central Register of Controlled Trials (CENTRAL) (*The Cochrane Library*, Issue 3, 2006), MEDLINE (1966 to September 2006), EMBASE (1980 to September 2006), CINAHL (1982 to October 2006), AMED (1985 to October 2006), SPORTDiscus (1949 to August 2006), the Physiotherapy Evidence Database (PEDro, searched September 2006) and the engineering databases COMPENDEX (1972 to October 2006) and INSPEC (1969 to October 2006). We handsearched relevant conference proceedings, searched trials and research registers, checked reference lists and contacted authors in an effort to identify further published, unpublished and ongoing trials.

Selection criteria

We included studies using random assignment.

Data collection and analysis

Two review authors independently selected trials for inclusion, assessed trial quality and extracted the data. The primary outcome was the proportion of patients walking independently (without assistance or help of a person) at follow up.

Main results

Eight trials (414 participants) were included in this review. Electromechanical-assisted gait training in combination with physiotherapy increased the odds of becoming independent in walking (odds ratio (OR) 3.06, 95% confidence interval (CI) 1.85 to 5.06; $P < 0.001$), and increased walking capacity (mean difference (MD) = 34 metres walked in six minutes, 95% CI 8 to 60; $P = 0.010$), but did not increase walking velocity significantly (MD = 0.08 m/sec, 95% CI -0.01 to 0.17; $P = 0.08$). However, the results must be interpreted with caution because (1) variations between the trials were found with respect to duration and frequency of treatment and differences in ambulatory status of patients, and (2) some trials tested electromechanical devices in combination with functional electrical stimulation.

Authors' conclusions

Patients who receive electromechanical-assisted gait training in combination with physiotherapy after stroke are more likely to achieve independent walking than patients receiving gait training without these devices. However, further research should address specific questions, for example, which frequency or duration of electromechanical-assisted gait training might be most effective and at what time after stroke, and follow-up studies are needed to find out how long the benefit lasts. Future research should include estimates of the costs (or savings) due to electromechanical gait training.

PLAIN LANGUAGE SUMMARY

Electromechanical-assisted training for walking after stroke

Many patients after stroke have difficulties with walking and improving walking is one of the main goals of rehabilitation. Electromechanical-assisted gait training uses specialist machines to assist walking practice. This review of eight trials, which included 414 participants, found some evidence that electromechanical-assisted gait training combined with physiotherapy may improve recovery of independent walking and increase walking distance in patients after stroke who could not initially walk independently. However, it is still not clear if such devices should be applied in routine rehabilitation, or when and how often they should be used.

BACKGROUND

A stroke is a sudden, non-convulsive loss of neurological function due to an ischemic or hemorrhagic intracranial vascular event (WHO 2006). In general, cerebrovascular accidents are classified by anatomic location in the brain, vascular distribution, etiology, age of the affected individual, and hemorrhagic versus non-hemorrhagic nature (Adams 1993). Stroke is a leading cause of death and a leading cause of serious, long-term disability in adults. Three months after stroke, 20% of patients remain wheelchair bound, and approximately 70% walk at reduced velocity and capacity (Jorgensen 1995). Restoration of walking ability and gait rehabilitation is therefore highly relevant for patients who are unable to walk independently after stroke (Bohannon 1991), as well as for their relatives. To restore gait, modern concepts of rehabilitation favour a task-specific repetitive approach (Carr 2003). In recent years it has also been shown that higher intensities of walking practice (resulting in more repetitions trained) result in better outcomes for patients after stroke (Kwakkel 1999; Van Peppen 2004).

In recent years treadmill training, with and without body weight support, was introduced for the rehabilitation of patients after stroke. Treadmill training with and without partial body weight support enables the repetitive practice of complex gait cycles for these patients. One disadvantage of treadmill training, however, might be the necessary effort by therapists to set the paretic limbs and to control weight shift, thereby possibly limiting the therapy intensity especially in more severely disabled patients. Automated electromechanical gait machines were developed to reduce dependence on therapists. They consist either of a robot-driven exoskeleton orthosis (Colombo 2000) or an electromechanical solution with two driven foot plates simulating the phases of gait (Hesse 1999).

One example of automated electromechanical gait rehabilitation is the 'Lokomat' (Colombo 2000). A robotic gait orthosis combined with a harness-supported body weight system is used in combination with a treadmill. However, the main difference from treadmill training is that the patient's legs are guided by the robotic device according to a pre-programmed gait pattern. A computer-controlled robotic gait orthosis guides the patient, the process of gait training is automated.

A second example is the 'Gait Trainer' which is based on a double crank and rocker gear system (Hesse 1999). In contrast to a treadmill, the electromechanical 'Gait Trainer' consists of two foot plates positioned on two bars, two rockers and two cranks, which provide the propulsion. The harness-secured patient is positioned on the foot plates, which symmetrically simulate the stance and the swing phases of walking (Hesse 1999). A servo-controlled motor guides the patient during walking exercise. Vertical and horizontal movements of the trunk are controlled in a phase-dependant manner. Again, the main difference to treadmill training is that the process of gait training is automated and supported by an electromechanical solution.

Other more recently developed similar electromechanical devices include the 'Haptic Walker' (Schmidt 2005), the 'Anklebot' (MIT 2005) and the 'LOPES' (Veneman 2005).

Electromechanical devices (such as described above) can be used to give non-ambulatory patients intensive practice (in terms of high repetitions) of complex gait cycles. The advantage of these electromechanical devices, as compared to treadmill training with partial body weight support, may be the reduced effort for therapists, as they no longer need to set the paretic limbs or assist trunk movements (Hesse 2003).

However, until now scientific evidence for the benefits of these technologies, which could justify their relatively high cost, is lacking. Additionally, until now there has been no systematic evaluation concerning the effectiveness and acceptability of these electromechanical devices in patients after stroke. Therefore, the aim of this systematic review was to provide the best available evidence about the above-mentioned approach based on a protocol which was published in *The Cochrane Library*, Issue 4, 2006 (Mehrholtz 2006).

OBJECTIVES

The main objective of this systematic review was to investigate the effect of automated electromechanical and robotic-assisted gait training devices for improving walking after stroke.

CRITERIA FOR CONSIDERING STUDIES FOR THIS REVIEW

Types of studies

We searched for all randomised controlled trials and randomised controlled cross-over trials for inclusion in this review. If randomised controlled cross-over trials were included, we analysed only the first period as a parallel group trial in this review.

Types of participants

We included studies with participants of any gender over 18 years of age after stroke (using the World Health Organization (WHO 2006) definition of stroke, or a clinical definition of stroke if the WHO definition was not specifically stated).

Types of intervention

We included all trials that evaluated electromechanical and robotic-assisted gait training plus physiotherapy versus physiotherapy (or usual care) for regaining and improving walking after stroke. Automated electromechanical devices which were used in combination with functional electrical stimulation applied to the legs during gait training were also included. Automated electromechanical devices were defined as any device with an electromechanical solution designed to assist (by supporting body weight and automating the walking therapy process) stepping cycles in patients after stroke. This category included any mechanical or computerised device designed to improve walking function. We also searched for electromechanical devices such as robots for gait training after stroke (MIT 2005; Schmidt 2005; Veneman 2005). We did not include non-weight-bearing interventions such as non-interactive devices that delivered continuous passive motion only (Nuyens 2002). Trials testing the effectiveness of treadmill training or other approaches such as repetitive task training in physiotherapy or electrical stimulation alone were not included (to prevent duplication with other Cochrane reviews and protocols (for example, Moseley 2005).

Types of outcome measures

Regaining walking is a very important goal for patients after stroke (Bohannon 1988). We, therefore, defined the primary outcome as the ability to walk independently. We measured the ability to walk with the Functional Ambulation Category (FAC) (Holden 1984). A FAC score of four or five indicated independent walking over a 15 metre surface irrespective of aids used, such as a cane. A FAC score of less than four indicates dependency in walking (supervision or assistance, or both, must be given in performing walking).

If FAC scores were not reported in the included studies we used alternative indicators of independent walking such as:

- a score of three on the ambulation item of the Barthel Index (BI) (Wade 1988); or

- a score of six or seven for the walking item of the Functional Independence Measure (FIM) (Hamilton 1994); or
- a 'yes' response to the item 'walking inside, with an aid if necessary (but with no standby help)' or 'yes' to 'walking on uneven ground' in the Rivermead Mobility Index (RMI) (Collen 1991).

Secondary outcomes were defined as measures of impairments in body structures. As relevant measures of impairments we used walking speed (in metres per second), walking capacity (metres walked in six minutes) and the RMI score if stated by the trialists. Additionally, as a secondary outcome, we used death from all causes.

We investigated the safety of electromechanical-assisted gait training devices with the incidence of adverse outcomes such as thrombosis, major cardiovascular events, injuries and pain and any other reported adverse events. To measure the acceptance of electromechanical-assisted gait training devices in walking therapies we used, depending on data provided by the study authors, visual analog scales or withdrawal from study for all reasons (drop out rates), or both, during the study period.

Depending on the above-stated categories and the availability of variables used in the included trials, all review authors discussed and reach consensus on which outcome measures should be included in the analysis.

SEARCH METHODS FOR IDENTIFICATION OF STUDIES

See: methods used in reviews.

We searched the Cochrane Stroke Group Trials Register, which was last searched by the Review Group Co-ordinator in September 2006. We also searched the Cochrane Central Register of Controlled Trials (CENTRAL) (*The Cochrane Library*, Issue 3, 2006), MEDLINE (1966 to September 2006), EMBASE (1980 to September 2006), CINAHL (1982 to October 2006), AMED (Allied and Complementary Medicine Database) (1985 to October 2006), SPORTDiscus (1949 to August 2006), the Physiotherapy Evidence Database (PEDro, searched September 2006) and the engineering databases COMPENDEX (1972 to October 2006) and INSPEC (1969 to October 2006).

The following search strategy was used for MEDLINE and was modified for the other databases.

1. exp cerebrovascular disorders/ or brain injuries/ or brain injury, chronic/
2. (stroke\$ or cva or poststroke or post-stroke).tw.
3. (cerebrovasc\$ or cerebral vascular).tw.
4. (cerebral or cerebellar or brain\$ or vertebrobasilar).tw.
5. (infarct\$ or isch?emi\$ or thrombo\$ or emboli\$ or apoplexy).tw.

6. 4 and 5
7. (cerebral or brain or subarachnoid).tw.
8. (haemorrhage or hemorrhage or haematoma or hematoma or bleed\$).tw.
9. 7 and 8
10. exp hemiplegia/ or exp paresis/
11. (hempar\$ or hemipleg\$ or brain injur\$).tw.
12. Gait Disorders, Neurologic/
13. 1 or 2 or 3 or 6 or 9 or 10 or 11 or 12
14. physical therapy modalities/ or exercise therapy/ or motion therapy, continuous passive/
15. *exercise/ or *exercise test/
16. robotics/ or automation/ or orthotic devices/
17. body weight/ or weight-bearing/
18. ((gait or locomot\$) adj5 (train\$ or therapy or rehabilitat\$ or re-educat\$)).tw.
19. (electromechanical or electro-mechanical or mechanical or mechanised or mechanized or driven).tw.
20. ((body-weight or body weight) adj3 (support\$ or relief)).tw.
21. (robot\$ or orthos\$ or orthotic or automat\$ or computer aided or computer assisted).tw.
22. (bws or harness or treadmill or exercise\$ or fitness train\$ or Lokomat or Locomat or GaiTrainer or Kinetron).tw.
23. ((continuous passive or cpm) adj3 therap\$).tw.
24. or/14-23
25. gait/ or exp walking/ or locomotion/
26. "Range of Motion, Articular"/
27. recovery of function/
28. (walk\$ or gait\$ or ambulat\$ or mobil\$ or locomot\$ or balanc\$ or stride).tw.
29. 25 or 26 or 27 or 28
30. 13 and 24 and 29
31. limit 30 to humans

In an effort to identify published, unpublished and ongoing trials not available in the major databases we:

(1) handsearched the following relevant conference proceedings:

- 3rd and 4th World Congress of NeuroRehabilitation (2002 and 2006);
- 1st , 2nd and 3rd World Congress of Physical Medicine and Rehabilitation (2001, 2003, 2005);
- World Congress of Physical Therapy (2003);
- Deutsche Gesellschaft für Neurotraumatologie und Klinische Neurorehabilitation (2001 to 2005);
- Deutsche Gesellschaft für Neurologie (2000 to 2006);
- Deutsche Gesellschaft für Neurorehabilitation (1999 to 2005);

(2) screened reference lists of all relevant articles;

(3) identified and searched the following ongoing trials and research registers:

- International Standard Randomised Controlled Trial Number Register, <http://www.controlled-trials.com/isrctn/>, (searched October 2006);
 - Clinical trials.gov , www.clinicaltrials.gov, (searched October 2006);
 - Stroke Trials Register, www.strokecenter.org (searched October 2006);
- (4) contacted trialists, experts and researchers in our field of study.

METHODS OF THE REVIEW

Selection and identification of relevant trials

Two authors (JM and MP) independently read the titles and abstracts of the identified references and eliminated obviously irrelevant studies. The full text for the remaining studies was obtained. Based on our inclusion criteria (types of studies, participants, aims of interventions, outcome measures) two review authors (JM and MP) independently ranked these studies as relevant, irrelevant or possibly relevant. We excluded all trials ranked initially as irrelevant, but included all other trials at this stage. We excluded all trials of specific treatment components such as electrical stimulation as stand-alone treatment, treadmill training and continuous passive motion treatment, because these have been the subject of other Cochrane reviews (for example, Moseley 2005). Any disagreements were resolved through discussion between all four review authors. If further information was necessary to reach consensus we contacted trialists in an effort to obtain the missing information.

Methodological quality assessment

Two review authors independently evaluated the methodological quality of the included trials using the 11-item PEDro scale (Maher 2003; PEDro 2006). If a review author was involved in any of the selected studies, another member of our author group not involved in the study was requested to evaluate the methodological quality of the trial. The results of quality ratings are shown in the additional table 'PEDro scores' (Table 02). The items of the PEDro scale are: specification of eligibility criteria; random allocation to groups; concealed allocation; groups similar at baseline; blinding of participants, therapists and assessors; outcome measurements obtained from more than 85% of participants; presence of an intention to treat analysis; reporting of results of between-group statistical comparisons; reporting of point measures and measures of variability (Herbert 1998). The maximum achievable PEDro sum score is 10 points (PEDro 2006). All methodological quality assessments were checked for agreement between the two review authors (JM and MP), with a third review author (JC) arbitrating any items where consensus could not be reached. We contacted study authors for clarification and to request missing information.

Data extraction

Two review authors (JM and MP) independently extracted trial and outcome data from the selected trials. We established the characteristics of unpublished trials through correspondence with the trial co-ordinator or principal investigator. We used checklists to independently record the following details:

- the methods of generating the randomisation schedule;
- the method of concealment of allocation;
- blinding of assessors;
- use of an intention-to-treat analysis (all patients initially randomised were included in the analyses as allocated to groups);
- adverse events and drop outs for all reasons;
- important imbalance in prognostic factors;
- participants (country, number of participants, age, gender, type of stroke, time from stroke onset to entry to the study, inclusion and exclusion criteria);
- comparison (details of the intervention in the treatment and control groups, details of co-intervention(s) in both groups, duration of treatment);
- outcomes and time points of measures (number of participants in each group and outcome, regardless of compliance).

All of the extracted data were checked for agreement between review authors, with a third review author (JK) arbitrating any items where consensus could not be reached. If necessary, we contacted trialists to request more information, clarification and missing data.

Data analysis

We planned to compare electromechanical and robotic-assisted gait training plus physiotherapy versus physiotherapy (or usual care) for primary and secondary outcome parameters. We analysed binary (dichotomous) outcomes with odds ratio (OR) fixed-effect model with 95% confidence intervals (CI). We analysed continuous outcomes with mean differences (MD). We quantified inconsistency across studies by using the I-squared (I^2) statistic. A value greater than 50% was considered substantial heterogeneity. In the presence of heterogeneity we used a random-effects model instead a fixed-effect model approach. For all statistical comparisons we used the current version of the Cochrane Review Manager software, RevMan 4.2 (RevMan 2003).

Post hoc sensitivity analysis

A sensitivity analysis was based on the trial methodology and carried out as follows:

- including only studies with adequate concealed allocation;
- including only studies with blinded assessors for the primary outcome;
- including only studies with intention-to-treat analysis;

- including only studies with a PEDro Score of 7 points or above;
- including all studies without the largest study (Pohl 2007).

Although planned in our protocol (Mehrholtz 2006), there were insufficient data to carry out a subgroup analysis comparing patients treated in the acute and subacute phase of their stroke (within three month) with patients treated in the chronic phase (more than three months). The lack of data (insufficient number of studies) also prevented subgroup analyses being carried out to compare possible effects of different devices or types of electromechanical-assisted therapies.

DESCRIPTION OF STUDIES

Two review authors (JM and MP) independently extracted trial and outcome data from the selected trials. We used checklists to independently record details of the studies. If any review author was involved in any of the selected studies another member of our author group not involved in the study was requested to handle the study information. Twenty-two potentially eligible trials were identified by October 2006, of which seven trials were excluded (Caldwell 2000; David 2006; Gong 2003; Hesse 2001; Pitkanen 2002; Richards 1993; Richards 2004). These trials were excluded for various reasons; the details are described in the 'Characteristics of excluded studies' table. If there was any doubt whether the study should be excluded or not, the full text of the article was retrieved. In cases of disagreement between the two review authors, a third member of the author group (JK) reviewed the information to decide on inclusion or exclusion of a study.

Eight trials including a total of 414 patients met our inclusion criteria and were included in the analysis (Dias 2006; Husemann 2007; Peurala 2005; Pohl 2007; Saltuari 2004; Schwartz 2006; Tong 2006; Werner 2002) (*see* additional table 'Demographics of studies' (Table 03)). One of the included studies is still ongoing (Schwartz 2006), however we used preliminary results provided by the study authors for the analysis. Three ongoing studies were identified (Brissot 2006; MARS 2006; Sivenius 2006). Three of the included studies are not published yet (Dias 2006; Saltuari 2004; Schwartz 2006), but we obtained data for these unpublished trials through correspondence with the trial co-ordinator or principal investigator. Four studies are still awaiting assessment (Globokar 2005; Jang 2005; Kim 2001; Shirakawa 2001).

Patient characteristics in studies

The mean age in the included studies ranged from 52 years (Peurala 2005) to 68 years (Tong 2006). A detailed description of patient characteristics can be found in the additional table 'Patient characteristics in studies' (Table 01). There were more males than females (65% males with 95% CI 60 to 71), more patients with ischemic stroke than hemorrhagic stroke lesions (72% ischemic stroke with 95% CI 67 to 78) and more patients with left-sided

hemiparesis (55% left sided with 95% CI 49 to 61) included in the studies.

Six studies provided information about baseline stroke severity; four of them used the Barthel Index score which ranged from 34 Barthel Index points (Dias 2006) to 51 of 100 Barthel Index points (Tong 2006).

The following exclusion criteria were used:

- recurrent stroke (Peurala 2005; Pohl 2007; Tong 2006; Werner 2002);
- duration of illness less than six months (Peurala 2005); between 30 days and 60 days (Pohl 2007); longer than six weeks after stroke (Tong 2006);
- patients aged over 80 years (Pohl 2007); patients aged over 65 years (Peurala 2005);
- patients with an unstable cardiovascular condition (Peurala 2005; Pohl 2007; Werner 2002);
- patients with cognitive and communication deficits which do not allow comprehension of the study (Peurala 2005; Pohl 2007; Tong 2006; Werner 2002);
- patients with limited range of motion in the lower limb joints (Peurala 2005; Pohl 2007; Tong 2006; Werner 2002).

The duration of study (time frame where experimental interventions were applied) was heterogeneous, ranging from two weeks (Werner 2002) and three weeks (Saltuari 2004) to nine weeks (Schwartz 2006). Most studies (four) used a four-week study period (Dias 2006; Husemann 2007; Pohl 2007; Tong 2006). Two studies included patients that could walk independently at study onset (Dias 2006; Peurala 2005). Three studies investigated, as the experimental intervention, the robotic-assisted device 'Lokomat' (Husemann 2007; Saltuari 2004; Schwartz 2006) and five studies investigated the electromechanical device 'Gait Trainer' (Dias 2006; Peurala 2005; Pohl 2007; Tong 2006; Werner 2002).

The frequency of treatment ranged from three times a week (Schwartz 2006) to five times a week (Dias 2006; Husemann 2007; Peurala 2005; Pohl 2007; Saltuari 2004; Tong 2006; Werner 2002). The intensity (in terms of duration of experimental therapy provided) of treatment ranged from 20 minutes (Peurala 2005; Pohl 2007; Tong 2006) to 30 minutes (Husemann 2007; Werner 2002) to 45 minutes (Schwartz 2006). For some studies the intensity of the experimental treatment is still unclear (Dias 2006; Saltuari 2004). In none of the included studies did the gait training time differ between control and experimental group. Four of the eight included studies used a follow-up assessment after study end (Dias 2006; Peurala 2005; Pohl 2007; Schwartz 2006). Most studies investigated improvement in walking function as primary outcomes for analysis and used the FAC or comparable scales to assess independent walking (Peurala 2005; Pohl 2007; Saltuari 2004; Schwartz 2006; Tong 2006; Werner 2002). Furthermore,

frequently investigated outcomes were assessment of walking function using gait velocity in metres per second (Dias 2006; Peurala 2005; Pohl 2007; Saltuari 2004; Tong 2006; Werner 2002) or gait capacity in metres walked in six minutes (Peurala 2005; Pohl 2007; Saltuari 2004). Assessments of ability to perform activities of daily living were investigated with the Barthel Index (Pohl 2007; Tong 2006; Werner 2002), RMI (Pohl 2007; Saltuari 2004) or FIM (Peurala 2005; Tong 2006). A detailed description of the primary outcomes for each trial can be found in the 'Characteristics of included studies' table.

METHODOLOGICAL QUALITY

All details about the methodological quality for each included study are provided in the table of 'Characteristics of included studies' and in the additional Table 02 'PEDro scores'.

We wrote to the trialists of all the included studies (Dias 2006; Globokar 2005; Jang 2005; Kim 2001; Shirakawa 2001; Husemann 2007; Peurala 2005; Pohl 2007; Saltuari 2004; Schwartz 2006; Tong 2006; Werner 2002) requesting clarification of some design features or missing information in order to complete the quality ratings. The correspondence was via email or letter, and we wrote reminders every month if no answer was received. Most trialists provided at least some of the requested data (Dias 2006; Husemann 2007; Peurala 2005; Pohl 2007; Saltuari 2004; Schwartz 2006; Tong 2006; Werner 2002). Three trialists provided all requested and required data material (Pohl 2007; Tong 2006; Werner 2002). We did not receive data for four trials (Globokar 2005; Jang 2005; Kim 2001; Shirakawa 2001).

Using the PEDro scale, two authors (JM and MP) independently assessed the methodological quality of all the included trials except two (Pohl 2007; Werner 2002), which were rated by one author (JK) in an interview with the trialists. The assessors disagreed on only two out of a total of 10 PEDro test items. The items where disagreement occurred were the use of an intention-to-treat analysis (Peurala 2005; Schwartz 2006; Tong 2006; Werner 2002) and the concealment process for allocation (Saltuari 2004; Schwartz 2006). However, all disagreements were discussed and finally arbitrated by another author (JC).

The ratings for each of the PEDro items and the total PEDro score (that is, the score derived from adding all PEDro scale items) are listed in the additional table 'PEDro scores' (Table 02). For the studies included in this review, the maximum total PEDro score possible is eight (out of 10), as it is not possible to blind the participants or the physiotherapists to the intervention. Only two of the included studies achieved the highest possible score of eight points (Pohl 2007; Werner 2002). The lowest total PEDro score we found was six (Husemann 2007; Peurala 2005; Schwartz 2006), the median total PEDro score was seven points. Two trials (Saltuari 2004; Werner 2002) used a cross-over design with random allocation to the order of treatment sequences. Only the

first period was analysed as a parallel group trial in this review. All other studies used a parallel group design with true randomisation to group allocation (Dias 2006; Husemann 2007; Peurala 2005; Pohl 2007; Schwartz 2006; Tong 2006). Six included studies used concealed allocation of participants to groups (Husemann 2007; Peurala 2005; Pohl 2007; Schwartz 2006; Tong 2006; Werner 2002). The allocation concealment classification is more detailed in the 'Characteristics of included studies' table. Three included studies described outcome assessors who were blinded to group allocation (Dias 2006; Pohl 2007; Werner 2002). The drop-out rate for all reasons at the end of the treatment phase was relatively low, all included studies achieving a drop-out rate of less than 15%. The highest drop-out rate was found for the study with the longest intervention phase (nine weeks; Schwartz 2006) with 13% (four drop outs out of 46 included patients). Five trialists reported no drop outs at scheduled follow up (Dias 2006; Peurala 2005; Saltuari 2004; Werner 2002). Follow-up assessments after study end were reported for three studies (Dias 2006; Peurala 2005; Pohl 2007) and follow-up investigations are still underway for two trials (Schwartz 2006; Tong 2006). Two studies (Peurala 2005; Tong 2006) used two experimental groups and one control group. In both studies additional functional electrical stimulation of leg muscles during gait training was applied in one of the treatment groups. Since functional electrical stimulation was done as an adjunct during electromechanical-assisted gait training and the results of these experimental groups did not differ significantly, we combined the results of both experimental groups in one (collapsed) group and compared this with the results of the control group.

RESULTS

Comparison 01.01: Independent walking at the end of intervention phase, all electromechanical devices used

Eight trials with a total of 414 patients (Dias 2006; Husemann 2007; Peurala 2005; Pohl 2007; Saltuari 2004; Schwartz 2006; Tong 2006; Werner 2002) measured recovery of independent walking. The use of electromechanical-devices in gait rehabilitation of patients after stroke increased the chance to walk independently (OR 3.06 95% CI 1.85 to 5.06, $P < 0.001$; level of heterogeneity $I^2 = 48.2\%$). However, two of the eight included trials (Dias 2006; Peurala 2005) investigated mainly patients who were already independent in walking at study onset. No definitive conclusion can be drawn for a longer lasting effect of the use of electromechanical devices.

Comparison 01.02: Recovery of independent walking at follow up after study end

Data from only one study, which used a follow up after the study end, were available (Pohl 2007).

Comparison 01.03: Walking velocity (m/s) at the end of intervention phase

Six trials with a total of 328 patients (Husemann 2007; Peurala 2005; Pohl 2007; Saltuari 2004; Tong 2006; Werner 2002) measured walking velocity (metres per second, m/s) at study end. The use of electromechanical devices in gait rehabilitation did not increase the walking velocity significantly. The pooled mean difference (random-effects model) for walking velocity was 0.08 m/s (95% CI -0.01 to 0.17; $P = 0.08$; level of heterogeneity $I^2 = 60.7\%$). Patients who were unable to walk were handled as having a walking velocity of zero metres per second. No definitive conclusion can be drawn for a longer lasting effect of the use of electromechanical devices for walking velocity.

Comparison 01.04: Walking velocity (m/s) at follow up

Data from only one study, which used a follow up after study end, were available (Pohl 2007).

Comparison 01.05: Walking capacity (metres walked in six minutes) at the end of intervention phase

Three trials with a total of 216 patients (Peurala 2005; Pohl 2007; Saltuari 2004) measured walking capacity (metres walked in six minutes) at study end. The use of electromechanical devices in gait rehabilitation significantly increased the walking capacity of patients after stroke. The pooled MD (fixed-effect model) for walking capacity was 33.97 metres walked in six minutes (95% CI 8.28 to 59.66; $P = 0.01$; level of heterogeneity $I^2 = 0\%$). No definitive conclusion can be drawn for a longer lasting effect of the use of electromechanical devices for walking capacity.

Comparison 01.06: Walking capacity (metres walked in six minutes) at follow up

Data from only one study, which used a follow up after study end, were available (Pohl 2007).

Comparison 01.07: Acceptability of use of electromechanical-assisted gait training devices during intervention phase: drop outs

All trialists provided information about the rate of patients who dropped out from all causes during the trial period. The drop-out rates were between 0% and 13%. The use of electromechanical devices in gait rehabilitation of non-ambulatory patients after stroke did not increase the risk of patients to drop out (OR (fixed) 0.62, 95% CI 0.27 to 1.43, $P = 0.26$; level of heterogeneity $I^2 = 9.6\%$). The reasons for drop outs and all adverse events are described in detail for each trial in the additional table 'Safety and acceptance of interventions: adverse events and drop-out rates' (Table 04).

Comparison 01.08: Death from all causes until the end of intervention phase

All trialists provided information about the number of patients who died from all causes during the trial. Only the largest trial (Pohl 2007) reported any deaths of patients during the intervention period. In this trial one patient in the control group died due to aspiration pneumonia and one patient in the treatment group died due to recurrent stroke. This was the only study that reported any deaths at all. The use of electromechanical devices in gait reha-

bilitation of non-ambulatory patients after stroke did not increase the risk of patients after stroke dying during the intervention period (OR (fixed) 1.01, 95% CI 0.06 to 16.49, $P = 0.99$; test for heterogeneity is not applicable).

Comparison 02: Post hoc sensitivity analysis by trial methodology

To examine the robustness of results, we specified variables in a sensitivity analysis that we believed could influence the size of effect observed (concealed allocation, blinding of assessors, intention-to-treat analysis, and a PEDro total score below seven points and excluding the largest study).

Including only studies with adequate concealed allocation

Seven trials with a total of 403 patients with adequate concealment of allocation were included (Husemann 2007; Peurala 2005; Pohl 2007; Saltuari 2004; Schwartz 2006; Tong 2006; Werner 2002). The use of electromechanical devices in gait rehabilitation of patients after stroke increased the chance to walk independently (OR (fixed) 3.45, 95% CI 2.11 to 5.65, $P < 0.001$; level of heterogeneity, $I^2 = 50.9\%$).

Including only studies with blinded assessors for the primary outcome

Four trials with a total of 241 patients had blinded assessors for the primary outcome (Pohl 2007; Saltuari 2004; Schwartz 2006; Werner 2002). The use of electromechanical devices in gait rehabilitation of patients after stroke increased the chance to walk independently (OR (fixed) 3.75, 95% CI 1.93 to 7.28, $P < 0.001$; level of heterogeneity, $I^2 = 0\%$).

Including only studies with intention-to-treat analysis

Five trials with a total of 291 patients described an intention-to-treat analysis (Dias 2006; Pohl 2007; Saltuari 2004; Tong 2006; Werner 2002). The use of electromechanical devices in gait rehabilitation of patients after stroke increased the chance to walk independently (OR (fixed) 3.96, 95% CI 2.17 to 7.22, $P < 0.001$; level of heterogeneity, $I^2 = 0.0\%$).

Including only studies with a PEDro score of seven points or above

Five trials with a total of 291 patients were rated with a PEDro score equal to seven points or above (Dias 2006; Pohl 2007; Saltuari 2004; Tong 2006; Werner 2002). The use of electromechanical devices in gait rehabilitation of patients after stroke increased the chance to walk independently (OR (fixed) 3.96, 95% CI 2.17 to 7.22, $P < 0.001$; level of heterogeneity, $I^2 = 0\%$).

Including all studies without the largest study

After excluding the largest study (Pohl 2007) seven trials with a total of 259 patients remained in this analysis. The use of electromechanical devices in gait rehabilitation of patients after stroke increased the chance to walk independently (OR (fixed) 2.28, 95% CI 1.11 to 4.68, $P = 0.02$; level of heterogeneity, $I^2 = 50.3\%$).

DISCUSSION

The aim of this review was to evaluate the effect of electromechanical and robotic-assisted gait training devices (with body weight support) for improving walking after stroke. Our aim was to estimate the likelihood or chance of becoming independent in walking as a result of these interventions, which is a main rehabilitation goal for patients after stroke (Bohannon 1988; Bohannon 1991). We included eight trials with a total of 414 patients in this review and found evidence that the use of electromechanical-assistive devices in combination with physiotherapy in rehabilitation settings may improve walking function after stroke. Furthermore, adverse events and drop outs do not appear to be more frequent in those patients who received electromechanical or robotic-assisted gait training. This indicates that the use of electromechanical-assisted gait training devices might be safe and acceptable to most patients included in the trials which this review analysed.

A risk of publication bias is present in all systematic reviews. However, we searched extensively for relevant literature in databases and handsearched conference abstracts. Additionally we contacted and asked authors, trialists and experts in the field for other unpublished and ongoing trials. No statistical or graphical evidence for publication bias has been found.

Methodological issues

There was heterogeneity between the trials in terms of trial design (two arms, three arms, parallel group or crossover trial, duration of follow up, selection criteria for patients), characteristics of the therapy interventions (especially duration of intervention), participant characteristics (length of time since stroke onset, stroke severity at baseline). There were also methodological differences in the mechanism of randomisation and allocation concealment methods used, blinding of primary outcomes and the presence or use of intention-to-treat analysis.

After examination of the effect of methodological quality on the odds of independence in walking we found that the benefits were robust when trials with unclear allocation procedures, unclear blinding, unclear intention-to-treat analysis and studies with a total PEDro score below seven points were removed. However, we found that the odds of independence in walking were slightly slower after removing the largest included study (Pohl 2007: $N = 155$), but a benefit for patients could still be observed.

While the methodological quality of the included trials was generally moderate to very good (PEDro score ranged from six to eight with a median of seven), the trials investigating electromechanical and robotic-assisted gait training devices are subject to potential methodological limitations. These limitations include inability to blind the therapist and patients, so-called contamination (provision of the intervention to the control group) and cointervention (when the same therapist unintentionally provides additional care to either treatment or comparison group). All these potential methodological limitations introduce the possibility of the so-

called performance bias. However, as discussed above, this was not supported in our sensitivity analyses by methodological quality.

Potential benefit

The exclusion of certain patient groups, such as older patients (more than 80 years of age), patients with unstable cardiovascular conditions, patients with cognitive and communication deficits and patients with a limited range of motion in the lower limb joints at the start of the intervention, may limit the general applicability of the findings. However, using the results from the primary outcomes, it is possible to explore the apparent effectiveness of electromechanical-assistive devices for regaining walking ability. One hundred and two out of 225 patients in the treatment group (45%) regained independent walking at the end of intervention phase. We used the primary outcome of recovery of independent walking at the end of intervention phase for all included patients (OR 3.06) to calculate the number needed to treat to benefit (NNTB). Together with our control event rate of 27% (51 out of 189 control patients regained independent walking) we calculated a NNTB of four (with a 95% CI 3 to 5) (Sackett 1996). This means that every fourth dependency in walking ability after stroke could be avoidable if electromechanical-assistive devices are used. What remains unclear is the optimum amount of electromechanical-assisted gait training (optimal frequency, optimal duration in the use of assistive technologies, and timing of application).

AUTHORS' CONCLUSIONS

Implications for practice

This systematic review provides evidence that the use of electromechanical-assisted gait training devices in combination with physiotherapy increases the chance of regaining independent walking ability for patients after stroke. The results could be interpreted as preventing one patient remaining dependent in walking after stroke for every four (95% CI 3 to 5) treated. This apparent benefit for patients is, however, not supported by all secondary variables. Gait training devices were not associated with improvements in walking velocity.

Implications for research

There is still a need for well-designed large-scale multicentre studies to evaluate benefits and harms of electromechanical-assisted

gait training on walking after stroke, especially for non-ambulatory patients. Future research should include estimates of the costs (or savings) due to electromechanical gait training. Further analyses should include outcome measures in the activities of daily living and quality of life domains.

POTENTIAL CONFLICT OF INTEREST

Marcus Pohl and Jan Mehrholz were authors of one included trial (Pohl 2007). Cordula Werner was an author of two included trials (Pohl 2007; Werner 2002) and of one excluded trial (Hesse 2001). They did not participate in the quality assessment and data extraction of these studies.

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*Indicates the major publication for the study

TABLES**Characteristics of included studies**

Study	Dias 2006
Methods	Randomised controlled trial Method of randomisation: not stated Blinding of outcome assessors: not stated Adverse events: none Deaths: none Drop outs: none ITT: yes
Participants	Country: Portugal 40 patients (20 in treatment group, 20 in control group) Ambulatory at study onset Mean age: 52 years Inclusion criteria: first ever stroke patients > 12 month after stroke, age > 18 and < 80 years; cognitive (Mini-Mental State > 19) and communication capacities of understanding the treatment; absence of cardiac, psychological and orthopaedics contra-indications Exclusion criteria: not stated
Interventions	Two arms: (1) control group used the Bobath method, 5 times a week for 5 weeks; (2) experimental group used the Gait Trainer (REHA-STIM) for the same time and frequency

Characteristics of included studies (Continued)

Outcomes	Outcomes were recorded at baseline and after 4 weeks and three months later: <ul style="list-style-type: none">- Motricity Index- Toulouse Motor Scale- modified Ashworth Scale- Berg Balance Scale- Rivermead Motor Score- Fugl-Meyer Stroke Scale (Lower Limb and Balance)- Functional Ambulation Category- Barthel Index- 10 metre walking test and gait cycle parameters- Time up and Go test- 6 minutes walking distance test- Step test. After the study end and at follow up patients rated satisfaction and efficiency of treatment with a self questionnaire (Likert scale)
Notes	Unpublished data, provided by the authors
Allocation concealment	B – Unclear

Study **Husemann 2007**

Methods	Randomised controlled trial Method of randomisation: opaque envelopes, stratified by side of paresis and etiology Blinding of outcome assessors: no Adverse events: 2 (one in experimental group, one in control group) Deaths: none Drop outs: 2 (one in experimental group, one in control group) ITT analysis: not provided for all drop outs
Participants	Country: Germany 32 patients (17 in treatment group, 15 in control group) Non-ambulatory at study onset Mean age: not provided by the authors Inclusion criteria: not provided by the authors Exclusion criteria: not provided by the authors
Interventions	Two arms: (1) robotic gait trainer (Locomat), 30 minutes per weekday for 4 weeks; (2) conventional physiotherapy, 30 minutes per day for 4 weeks Both groups received additional 30 minutes of physiotherapy daily
Outcomes	Outcomes were recorded at baseline and after 4 weeks - Functional Ambulation Category
Notes	Unpublished data, provided by the authors
Allocation concealment	A – Adequate

Study **Peurala 2005**

Methods	Randomised controlled trial Method of randomisation: an investigator not involved in the study randomised the patients to groups with the help of concealed envelopes Blinding of outcome assessors: no Adverse events: no Deaths: none Drop outs: none
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Characteristics of included studies (Continued)

	ITT analysis: not stated
Participants	<p>Country: Finland</p> <p>45 patients (15 in treatment group A, 15 in treatment group B, 15 in control group)</p> <p>Ambulatory and non-ambulatory at study onset</p> <p>Mean age: 52 years</p> <p>Inclusion criteria: first supratentorial stroke with a duration of illness longer than 6 month, aged under 65 years, slow or difficult walking, no unstable cardiovascular disease, no severe malposition of joints, no severe cognitive or communicative disorders, written informed consent</p> <p>Exclusion criteria: not stated</p>
Interventions	<p>Three arms:</p> <p>(1) gait trainer exercise without functional electric stimulation</p> <p>(2) gait trainer exercise with functional electric stimulation</p> <p>(3) walking overground</p> <p>All patients practiced gait for 15 sessions over 3 weeks (each session lasting 20 minutes) and received an additional 55 minutes daily physiotherapy</p>
Outcomes	<p>Outcomes were recorded at baseline, after 2 and 3 weeks and after 6 months</p> <ul style="list-style-type: none"> - 10-metre walk test - Six-minute walk test - lower-limb spasticity - muscle force - postural sway tests - Modified Motor Assessment Scale - Functional Independence Measure instrument scores
Notes	Published and unpublished data, provided by the authors
Allocation concealment	A – Adequate

Study	Pohl 2007
Methods	<p>Randomised controlled trial</p> <p>Method of randomisation: lots, indicating A or B, had been prepared in sealed envelopes</p> <p>Blinding of outcome assessors: primary outcomes were evaluated by blinded assessors</p> <p>Adverse events: 4 (3 in experimental group , one in control group)</p> <p>Deaths: 2 (one in experimental group, one in control group)</p> <p>Drop outs: 11 (5 in experimental group, 6 in control group)</p> <p>ITT analysis: yes</p>
Participants	<p>Country: Germany</p> <p>155 patients (77 in treatment group, 78 in control group)</p> <p>Non-ambulatory at study onset</p> <p>Mean age: 63 years</p> <p>Inclusion criteria: first supratentorial stroke (ischemic or hemorrhagic), age between 18 to 79 years, interval between stroke and study onset less than 60 days, able to sit unsupported (i.e. without holding onto supports such as the edge of the bed), with feet supported, could not walk at all, or required the help of one or two therapists irrespective of the use of an ankle-foot orthosis or a walking aid (Functional Ambulation Category 3 or less), understanding the meaning of the study and following instructions, written informed consent of participation in the study approved by the local ethical committee</p> <p>Exclusion criteria: unstable cardiovascular condition, following a 12-lead electrocardiogram and examined by a cardiologist, restricted passive range of motion in the major lower limb joints (extension deficit of > 20° for the affected hip or knee joints, or a dorsiflexion deficit of > 20° for the affected ankle, tested while lying supine and on the non-affected side, prevalence of other neurological or orthopaedic diseases impairing walking ability</p>
Interventions	Two arms:

Characteristics of included studies (Continued)

	(1) 20 minutes locomotor training with a GaitTrainer in combination with 25 minutes physiotherapy every week day for four weeks (2) 45 min physiotherapy every week day for four weeks
Outcomes	Outcomes were recorded at baseline, after 4 weeks and after 6 months Primary outcomes: - gait ability (Functional Ambulation Category 0 to 5) - Barthel Index (0 to 100) Responders to the therapy were defined as ambulatory (Functional Ambulation Category 4 or 5) or reach a Barthel Index of > 75 Secondary outcomes: - walking velocity - walking endurance - mobility (Rivermead Mobility Index) - leg power (Motricity Index)
Notes	Published and unpublished data, provided by the authors
Allocation concealment	A – Adequate

Study	Saltuari 2004
Methods	Cross-over randomised controlled trial Method of randomisation: by random numbers Blinding of outcome assessors: unclear Adverse events: none Deaths: none Drop outs: none ITT: yes
Participants	Country: Austria 16 patients (8 in treatment group, 8 control group) Ambulatory and non-ambulatory at study onset Mean age: 61 years Inclusion criteria: not provided by the authors Exclusion criteria: not provided by the authors
Interventions	Two arms (A = Lokomat, B = Physiotherapy): (1) 3 weeks A, 3 weeks B, 3 weeks A (2) 3 weeks B, 3 weeks A, 3 weeks B
Outcomes	Outcomes were recorded at baseline and after 3 weeks (additionally after 6 and 9 weeks, but only the first phase were included in this review)
Notes	Unpublished data, provided by the authors
Allocation concealment	A – Adequate

Study	Schwartz 2006
Methods	Randomised controlled trial (ongoing) Method of randomisation: block sampling method (each block contained 6 patients: 4 experimental group and 2 control group) Blinding of outcome assessors: unclear Adverse events: 5 (3 in experimental group, 2 in control group) Deaths: none Drop outs: 6 ITT: unclear

Characteristics of included studies (Continued)

Participants	Country: Israel 46 patients (at October 2006) (28 in treatment group, 18 in control group) Non-ambulatory at study onset Mean age: 60 years Inclusion criteria: first stroke, until 3 month after stroke Exclusion criteria: not provided by the authors
Interventions	Two arms: (1) Lokomat three times a week for nine weeks (2) Physiotherapy three times a week for nine weeks
Outcomes	Outcomes were recorded at baseline and after 3, 6 and after 9 weeks - National Institutes of Health Stroke Survey - Stroke severity Scale - Functional Reach Test
Notes	Preliminary unpublished data, provided by the authors Study is still ongoing; the aim is to recruit 64 patients
Allocation concealment	A – Adequate

Study **Tong 2006**

Methods	Randomised controlled trial Randomisation was done by computer-generated random numbers Blinding of outcome assessors: no (except for Barthel Index and Functional Independence Measure Scores which were performed by nurses who were blinded in this study) Adverse events: 2 (none in experimental group, 2 in control group) Deaths: none Drop outs: 4 (none in experimental group, 4 in control group) ITT: yes
Participants	Country: China, Hong Kong 50 patients (15 in treatment group A, 15 in treatment group B, 20 in control group) Non-ambulatory at study onset Mean age: 68 years Inclusion criteria: diagnosis of first ischemic brain injury or intracerebral hemorrhage shown by magnetic resonance imaging or computed tomography less than 6 weeks after the onset of stroke, sufficient cognition to follow simple instructions and understand the content and purpose of the study (Mini-Mental State Examination score > 21), the ability to stand upright, supported or unsupported, for 1 minute, significant gait deficit (Functional Ambulation Category score < 3), no skin allergy to electric stimulation Exclusion criteria: recurrent stroke, other neurological, medical or psychological deficit or condition that would affect ambulation ability or compliance with the study protocol (such as Parkinson's Disease, major depression, pain, cardiac arrhythmias), aphasia with an inability to follow 2 consecutive step commands or a cognitive deficit; or severe hip, knee, or ankle contracture that would preclude passive range of motion of the leg
Interventions	Three arms: (1) gait trainer (2) gait trainer + functional electrical stimulation (3) conventional physiotherapy alone The study consisted of 1 training session per weekday for 4 weeks Experimental Groups (1) and (2) underwent gait training for 20 minutes with body weight support by an electromechanical gait trainer; Group (2) also received functional electrical stimulation to the paretic lower limb during gait training Participants in Group (3) received physiotherapy overground gait training based on the principles of proprioceptive neuromuscular facilitation and Bobath concepts

Characteristics of included studies (Continued)

Outcomes	<ul style="list-style-type: none">- 5-metre walking speed test- Elderly Mobility Scale- Berg Balance Scale- Functional Ambulatory Category- Motricity Index leg subscale- Functional Independence Measure instrument score- Barthel Index score
Notes	Published and unpublished data, provided by the authors No follow up after study end described; however, information provided by the authors indicate that follow up is planned
Allocation concealment	A – Adequate

Study	Werner 2002
Methods	Cross-over randomised controlled trial Method of randomisation: participants randomised to groups (group allocation in envelopes that were drawn by an independent person) Blinding of outcome assessors: yes Adverse events: none Deaths: none Drop outs: none ITT: yes
Participants	Country: Germany 30 patients (15 in treatment group, 15 in control group) Non-ambulatory at study onset Mean age: 60 years Inclusion criteria: first stroke, supratentorial lesion, 4 to 12 weeks post stroke, aged less than 75 years, not able to walk (Functional Ambulation Category of 2 or less), able to sit unsupported on the edge of a bed, able to stand for at least 10 seconds with help, written informed consent Exclusion criteria: hip and knee extension deficit of more than 20 degrees, passive dorsiflexion of the affected ankle to less than a neutral position, severe impairment of cognition or communication, evidence of cardiac ischemia, arrhythmia, decompression or heart failure, feeling of 'overexertion' or heart rate exceeding the age-predicted maximum (ie, 190 beats/minute minus age) during training, resting systolic blood pressure exceeding 200 mmHg at rest or dropping by more than 10 mmHg with increasing workload
Interventions	Two arms: (1) 2 weeks A, 2 weeks B, 2 weeks A (2) 2 weeks B, 2 weeks A, 2 weeks B Treated as inpatients for 5 15 to 20 minute sessions per week for 2 weeks A = treadmill training with body weight support: participants walked on a treadmill with partial body weight support provided by a harness B = gait trainer with body weight support: participants walked on a GaitTrainer with partial body weight support provided by a harness
Outcomes	Outcomes were recorded at baseline and after 2 weeks (additionally after 4 and 6 weeks, but only the first phase was included in this review) <ul style="list-style-type: none">- Functional Ambulation Category- fast walking speed over 10 metres with personal assistance and gait aids if required- Rivermead Motor Assessment Scale- ankle spasticity (modified Ashworth Scale)
Notes	We used the first treatment phase only Published and unpublished data, provided by the authors 0% dropouts at the end of first treatment phase (data were analysed as intended to treat)

Allocation concealment A – Adequate

ITT: intention to treat

Characteristics of excluded studies

Study	Reason for exclusion
Caldwell 2000	Did not investigate electromechanical and robotic-assisted gait training devices as stated in the protocol of this review: bicycle training versus treadmill walking versus variable surface training were investigated
David 2006	Did not meet inclusion criteria of this review: not a randomised controlled trial
Gong 2003	Did not investigate electromechanical and robotic-assisted gait training devices as stated in the protocol of this review: no electromechanical assistive devices were compared
Hesse 2001	Did not meet inclusion criteria of this review: not a randomised controlled trial
Pitkanen 2002	Did not meet inclusion criteria of this review: the study describes preliminary findings of an initial sample of 9 patients, the experimental group received treadmill training or gait trainer
Richards 1993	Did not meet inclusion criteria of this review: the experimental group received a specialised locomotor training including early intensive physiotherapy with tilt table, limb load monitor, resistance exercises and treadmills to promote functional recovery. After discussion the review authors reached consensus to exclude this study
Richards 2004	Did not meet inclusion criteria of this review: the experimental group received a specialised locomotor training including early intensive physiotherapy with tilt table, limb load monitor, resistance exercises and treadmills to promote functional recovery. After discussion the review authors reached consensus to exclude this study

Characteristics of ongoing studies

Study	Brissot 2006
Trial name or title	Efficacy of a mechanical gait repetitive training technique compared with a usual rehabilitation program on gait recovery in hemiparetic stroke patients
Participants	Country: France Inclusion criteria: men or women aged 18 years or more; hemiplegia secondary to stroke; interval between stroke and study inclusion of 2 month or less; first time supratentorial stroke; non ambulatory patient (Functional Ambulatory Category Stage 0); being able to sit unsupported at the edge of the bed; no severe impairment of cognition or communication; written informed consent Exclusion criteria: orthopaedic or rheumatological disease impairing mobility or both; other neurological associated disease; history of myocardial infarction or deep venous embolism or pulmonary embolism less than 3 months before study inclusion; chronic pulmonary disease; intolerance to stand up
Interventions	4 week rehabilitation program associating physiotherapy and gait trainer therapy or physiotherapy alone
Outcomes	Primary outcomes: walking speed (time needed to walk 10 metres) after the 4 week rehabilitation program Secondary outcomes: Functional Ambulatory Category; walking endurance (6 minute walk); time to self sufficient gait recovery; spasticity (modified Ashworth score); Motricity index; need for mobility and self assistance (Barthel score, PMSI-SSR scores, need for physical assistance); economic evaluation (healthcare requirements, rehabilitation unit length of stay)
Starting date	March 2006
Contact information	Principal investigator: Régine Brissot MD Service de Médecine Physique et Réadaptation, Hôpital Pontchaillou, Rennes, 35033, France Tel: +33 2 9928 4219; Email: regine.brissot@chu-rennes.fr

Characteristics of ongoing studies (Continued)

Notes	Expected total enrolment: 122 Sponsored by: Rennes University Hospital Information derived from: ClinicalTrials.gov Identifier: NCT00284115
Study	MARS 2006
Trial name or title	Gait restoration in hemiparetic stroke patients using goal-directed, robotic-assisted treadmill training
Participants	Country: USA Patients in the sub-acute stage following stroke (less than 6 months post stroke), randomly assigned to 1 of 2 experimental groups
Interventions	The first (control) group will receive one hour of conventional gait training, with appropriate physical assistance and feedback as necessary The second group will receive body-weight supported treadmill training with robotic-assistance using the Lokomat® System (Hocoma Inc, Zurich, Switzerland) Both groups will be trained for 24 sessions over a 10-week period, 3 times per week, with 1 hour allocated for all training paradigms
Outcomes	The re-acquisition of natural gait patterns and lower limb motor function will be evaluated at weeks 0, 4, and 8 of the intervention, as well as during a follow-up exam 3 months after study completion, and will be based on numerous measures, including the speed and variability of unassisted walking, step lengths and cadence, postural balance, assessment of spasticity, and strength measures
Starting date	2003
Contact information	Principal Investigators: Joseph Hidler PhD and George Hornby PhD, PT
Notes	Expected completion: end of 2007 Information derived from personal communication ClinicalTrials.gov Identifier: NCT00075283

Study	Sivenius 2006
Trial name or title	Body-weight supported therapy using gait trainer versus traditional gait-oriented physiotherapy in the acute phase of stroke. The effectiveness of gait training and brain networks using Navigating Brain Stimulation
Participants	Country: Finland Patients with acute stroke Ages eligible for study: 18 to 85 years Genders eligible for study: both Inclusion criteria: supratentorial stroke within 8 days of onset Barthel index 25 to 75 Exclusion criteria: severe cognitive disorder; severe cardiac disease
Interventions	Gait-oriented traditional physiotherapy Patients in physiotherapy group will have 75 minutes of physiotherapy daily every workday This includes 20 minutes walking exercises in the traditional group and 20 minutes of gait trainer therapy in the gait trainer group
Outcomes	The evaluation of the effectiveness of therapy in each group is made after 3 weeks' therapy and at 6 months Primary outcomes: improvement in motor function among patients in each group Secondary outcomes: Modified Motor Assessment Scale; Rivermead Motor Assessment Scale; Rivermead Mobility Index; 10 metre walking time; 6 minute walking distance; Barthel index; National Institutes of Health Stroke Scale
Starting date	May 2003
Contact information	Principal investigator: Prof Juhani Sivenius

Characteristics of ongoing studies (Continued)

Tel: +358 50 5614874; Email: juhani.sivenius@fimnet.fi,
Sinikka Peurala, PhD, Tel: +358 500 362623; Email: sinikka.peurala@sport.jyu.fi

Notes	<p>Expected completion: end of 2006 At November 2006 43 patients had already performed the 21-day training period, and 2 patients left to complete the 3 month follow-up visit Data entry closure: December 2006 Results shall be published probably early 2007 Information derived from personal communication with Prof J Sivenius ClinicalTrials.gov Identifier: NCT00307762</p>
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ADDITIONAL TABLES

Table 01. Patient characteristics in studies

Study ID	Age, mean (SD) EXP	Age, mean (SD) CON	Time post stroke EXP	Time post stroke CON	Gender EXP	Gender CON	Side paresis EXP	Side paresis CON
Dias 2006	not provided by the authors	not provided by the authors	more than 1 year poststroke	more than 1 year poststroke	not provided by the authors	not provided by the authors	not provided by the authors	not provided by the authors
Husemann 2007	60 (13) years	57 (11) years	79 (56) days	89 (61) days	11 male, 5 female	10 male, 4 female	12 right, 4 left	11 right, 3 left
Peurala 2005	52 (8) years	52 (7) years	2.5 (2.5) years	4.0 (5.8) years	26 male, 4 female	11 male, 4 female	13 right, 17 left	10 right, 5 left
Pohl 2007	62 (12) years	64 (11) years	4.2 (1.8) weeks	4.5 (1.9) weeks	50 male, 27 female	54 male, 24 female	36 right, 41 left	33 right, 45 left
Saltuari 2006	62 (13) years	60 (19) years	3.6 (4.6) month	1.9 (0.8) month	4 male, 4 female	2 male, 6 female	not provided by the authors	not provided by the authors
Schwartz 2006	not provided by the authors	not provided by the authors	not provided by the authors	not provided by the authors	not provided by the authors	not provided by the authors	not provided by the authors	not provided by the authors
Tong 2006	71 (14) years	64 (10) years	2.5 (1.2) weeks	2.7 (1.2) weeks	19 male, 11 female	12 male, 8 female	13 right, 17 left	7 right, 13 left
Werner 2002	60 (9) years	60 (9) years	7.4 (2.0) weeks	6.9 (2.1) weeks	8 male, 7 female	5 male, 10 female	8 right, 7 left	8 right, 7 left
EXP = experimental group	CON = control group	SD = standard deviation						

Table 02. PEDro scores

PEDro score	Dias 2006	Husemann 2007	Peurala 2005	Pohl 2007	Saltuari 2004	Schwartz 2006	Tong 2006	Werner 2002
Random allocation	yes	yes	yes	yes	yes	yes	yes	yes
Concealed allocation	unclear	yes	yes	yes	yes	yes	yes	yes
Baseline comparability	yes	yes	yes	yes	unclear	yes	yes	yes
Blind subjects	no	no	no	no	no	no	no	no
Blind therapists	no	no	no	no	no	no	no	no
Blind assessors	yes	no	no	yes	yes	no	no	yes
Adequate follow up* (drop-out rate)	yes (0%)	yes (6%)	yes (0%)	yes (6%)	yes (13%)	yes (13%)	yes (8%)	yes (0%)
Intention-to-treat analysis	yes	no	no	yes	yes	unclear	yes	yes
Between-group comparisons	yes	yes	yes	yes	yes	yes	yes	yes
Point estimates and variability	yes	yes	yes	yes	yes	yes	yes	yes
Total PEDro score	7 (10)	6 (10)	6 (10)	8 (10)	7 (10)	6 (10)	7 (10)	8 (10)

*defined as less than 15% drop outs

Table 03. Demographics of studies

Criteria	Dias 2006	Husemann 2007	Peurala 2005	Pohl 2007	Saltuari 2004	Schwartz 2006	Tong 2006	Werner 2002
Mean age, years (SD)	unclear	59 (12)	53 (8)	63 (12)	61 (16)	60 (SD unclear)	68 (12)	60 (9)
Stroke severity	mean Barthel Index 34 points	median Barthel Index 35 points	Scandinavian Stroke Scale 42 points	mean Barthel Index 37 points	unclear	mean NIHSS 11 points	mean Barthel Index 51 points	mean Barthel Index 38 points
Duration of	unclear > 12	12 (8)	163 (195)	4 (2)	12 (14)	subacute	3 (1)	7 (2)

Table 03. Demographics of studies (Continued)

Criteria	Dias 2006	Husemann 2007	Peurala 2005	Pohl 2007	Saltuari 2004	Schwartz 2006	Tong 2006	Werner 2002
illness weeks (SD)	month					phase		
Electromechanical device used	Gait trainer	Lokomat	Gait trainer	Gait trainer	Lokomat	Lokomat	Gait trainer	Gait trainer
Duration of study intervention	4 weeks	4 weeks	3 weeks	4 weeks	2 weeks	9 weeks	4 weeks	2 weeks
Gender ratio (male/female)	unclear	21/9	37/8	104/51	10/6	unclear	31/19	5/10
Etiology (ischemic/hemorrhage)	unclear	22/8	25/20	124/31	unclear	unclear	39/11	3/12
Side of hemiparesis (right/left)	unclear	23/7	22/23	69/86	unclear	unclear	20/30	8/7
Intensity of treatment per day	unclear	5 times a week 30 minutes	5 times a week, 20 minutes for three weeks in addition to rehabilitation treatment	5 times a week 20 minutes	unclear	3 times a week	5 times a week 20 minutes	5 times a week 20 minutes

Table 04. Safety and acceptance of interventions: adverse events and drop-out rates

Study ID	Dias 2006	Husemann 2007	Peurala 2005	Pohl 2007	Saltuari 2004	Schwartz 2006	Tong 2006	Werner 2002
Percentage of drop outs	0%	6%	0%	6%	0%	13%	8%	0%
Drop outs	0 of 40	2 of 32	0 of 45	11 of 155	0 of 16	6 of 46	4 of 50	0 of 30
Reasons for drop out and adverse events in EXP	none	1 patient enteritis	none	2 patients refused therapy, 1 increased cranial pressure, 1 relapsing pancreas tumour, 1	none	2 patients with leg wounds, 1 patient with recurrent CVA, 1 refused therapy	none	none

Table 04. Safety and acceptance of interventions: adverse events and drop-out rates (Continued)

Study ID	Dias 2006	Husemann 2007	Peurala 2005	Pohl 2007	Saltuari 2004	Schwartz 2006	Tong 2006	Werner 2002
Reasons for drop out and adverse events in CON	none	1 patient PE	none	cardiovascular unstable 4 patients refused therapy, 1 patient died, 1 myocardial infarction	none	1 patients with recurrent CVA, 1 with PE as stated by the authors	2 patients discharged before study end, 1 patient readmitted to an acute ward, 1 patient deteriorating condition	none
Source of information	unpublished information provided by the authors	information as provided by the authors	information as published by the authors	information as published by the authors	unpublished information provided by the authors	unpublished information provided by the authors	information as published by the authors	information as published by the authors
EXP = experimental group	CON = control group	CVA = cerebrovascular accident	PE = pulmonary emboli					

ANALYSES

Comparison 01. Electromechanical and robotic assisted gait training plus physiotherapy versus physiotherapy (or usual care)

Outcome title	No. of studies	No. of participants	Statistical method	Effect size
01 Independent walking at the end of intervention phase, all electromechanical devices used	8	414	Odds Ratio (Fixed) 95% CI	3.06 [1.85, 5.06]
02 Recovery of independent walking at follow up after study end	1	155	Odds Ratio (Fixed) 95% CI	4.19 [2.14, 8.21]
03 Walking velocity (metres per second) at the end of intervention phase	6	328	Weighted Mean Difference (Random) 95% CI	0.08 [-0.01, 0.17]
04 Walking velocity (metres per second) at follow up	1	155	Weighted Mean Difference (Fixed) 95% CI	0.17 [0.05, 0.29]
05 Walking capacity (metres walked in six minutes) at the end of intervention phase	3	216	Weighted Mean Difference (Fixed) 95% CI	33.97 [8.28, 59.66]
06 Walking capacity (metres walked in six minutes) at follow up	1	155	Weighted Mean Difference (Fixed) 95% CI	53.40 [9.09, 97.71]

07 Acceptability of electromechanical assisted gait training devices during intervention phase: drop outs	8	414	Odds Ratio (Fixed) 95% CI	0.62 [0.27, 1.43]
08 Death from all causes until the end of intervention phase	8	399	Odds Ratio (Fixed) 95% CI	1.01 [0.06, 16.49]

Comparison 02. Post hoc sensitivity analysis: by trial methodology

Outcome title	No. of studies	No. of participants	Statistical method	Effect size
01 Regaining independent walking ability			Odds Ratio (Fixed) 95% CI	Subtotals only

COVER SHEET

Title	Electromechanical-assisted training for walking after stroke
Authors	Mehrholz J, Werner C, Kugler J, Pohl M
Contribution of author(s)	<p>Jan Mehrholz (JM) contributed to the conception and to the design of the protocol and drafted the protocol. He searched electronic databases and conference proceedings, screened titles and abstracts of references identified by the search, selected and assessed trials, extracted trial and outcome data, guided the analysis and the interpretation of the data, and contributed to and approved the final manuscript of the review.</p> <p>Joachim Kugler (JK) assessed and extracted trial and outcome data, assessed the methodological quality of selected trials, contributed to the interpretation of the data, and contributed to and approved the final manuscript of the review.</p> <p>Cordula Werner (CW) screened titles and abstracts of references identified by the search, located, selected and assessed trials, extracted trial and outcome data, assessed the methodological quality of selected trials, contributed to the interpretation of the data, and contributed to and approved the final manuscript of the review.</p> <p>Marcus Pohl (MP) contributed to the conception and design of the review, drafted the protocol, and assessed the methodological quality of selected trials. He contacted, together with JM, trialists about unpublished data and also entered the data, carried out statistical analysis, helped with the interpretation of the data, drafted the review and approved the final manuscript of the review.</p>
Issue protocol first published	2006/4
Review first published	2007/3
Date of most recent amendment	18 June 2007
Date of most recent SUBSTANTIVE amendment	04 June 2007
What's New	Information not supplied by author
Date new studies sought but none found	Information not supplied by author
Date new studies found but not yet included/excluded	Information not supplied by author
Date new studies found and included/excluded	Information not supplied by author

Date authors' conclusions section amended Information not supplied by author

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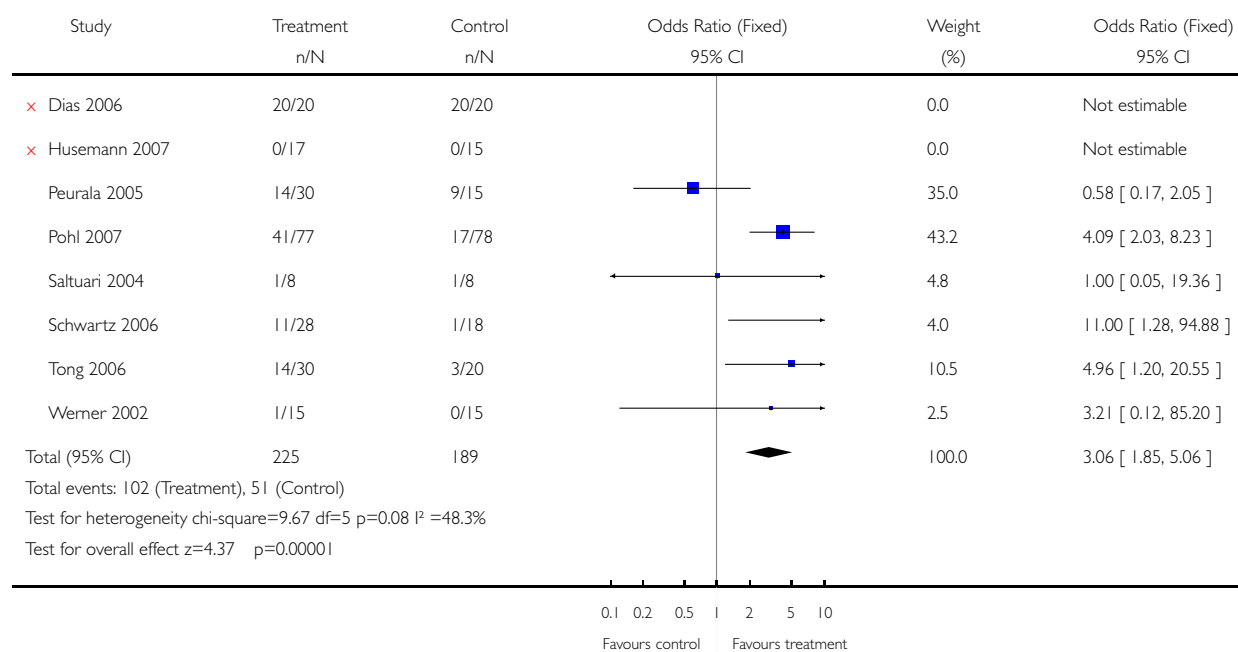
GRAPHS AND OTHER TABLES

Analysis 01.01. Comparison 01 Electromechanical and robotic assisted gait training plus physiotherapy versus physiotherapy (or usual care), Outcome 01 Independent walking at the end of intervention phase, all electromechanical devices used

Review: Electromechanical-assisted training for walking after stroke

Comparison: 01 Electromechanical and robotic assisted gait training plus physiotherapy versus physiotherapy (or usual care)

Outcome: 01 Independent walking at the end of intervention phase, all electromechanical devices used

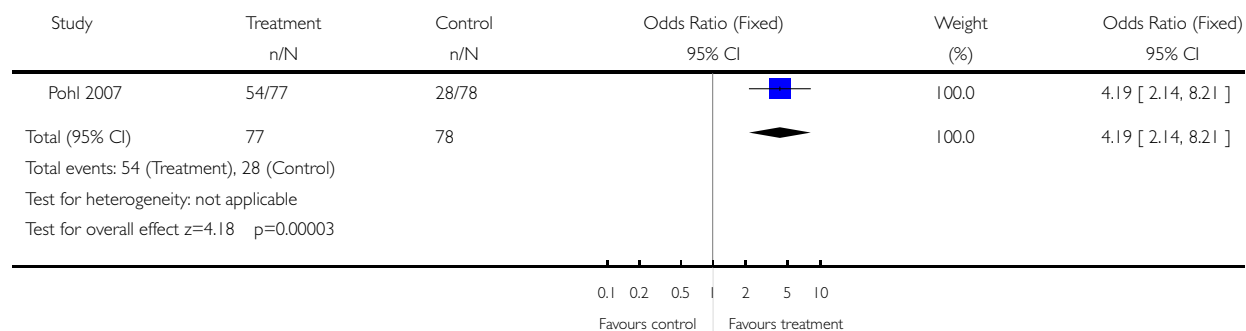


Analysis 01.02. Comparison 01 Electromechanical and robotic assisted gait training plus physiotherapy versus physiotherapy (or usual care), Outcome 02 Recovery of independent walking at follow up after study end

Review: Electromechanical-assisted training for walking after stroke

Comparison: 01 Electromechanical and robotic assisted gait training plus physiotherapy versus physiotherapy (or usual care)

Outcome: 02 Recovery of independent walking at follow up after study end

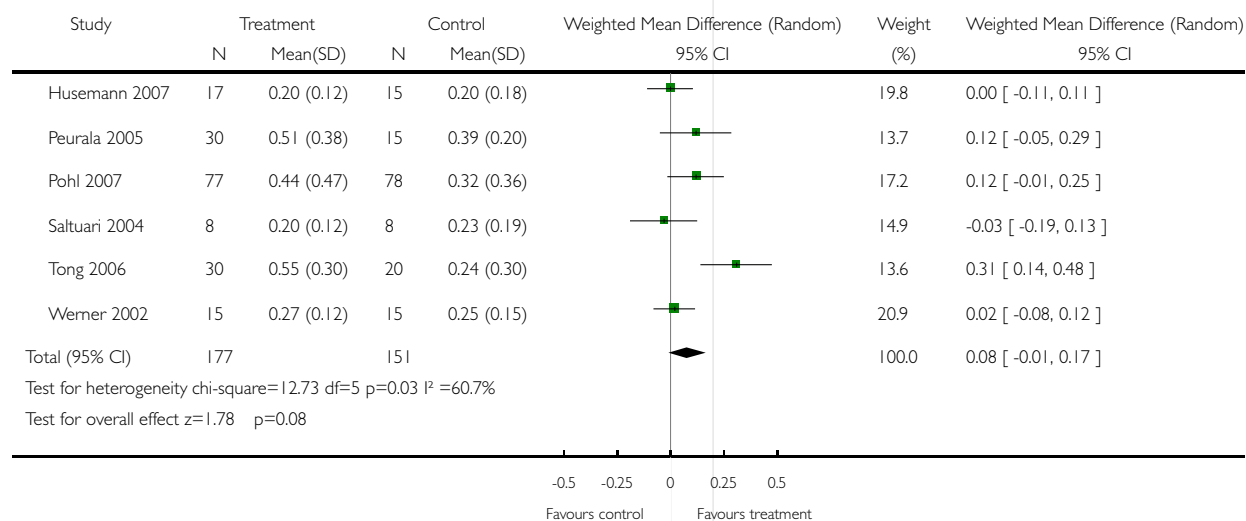


Analysis 01.03. Comparison 01 Electromechanical and robotic assisted gait training plus physiotherapy versus physiotherapy (or usual care), Outcome 03 Walking velocity (metres per second) at the end of intervention phase

Review: Electromechanical-assisted training for walking after stroke

Comparison: 01 Electromechanical and robotic assisted gait training plus physiotherapy versus physiotherapy (or usual care)

Outcome: 03 Walking velocity (metres per second) at the end of intervention phase

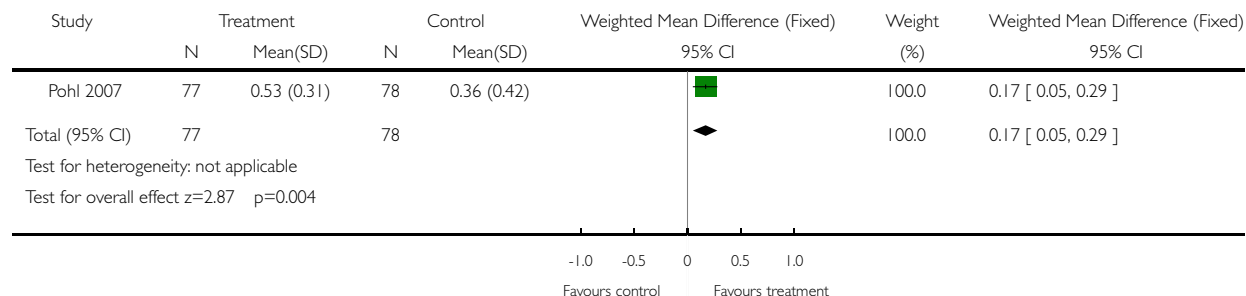


Analysis 01.04. Comparison 01 Electromechanical and robotic assisted gait training plus physiotherapy versus physiotherapy (or usual care), Outcome 04 Walking velocity (metres per second) at follow up

Review: Electromechanical-assisted training for walking after stroke

Comparison: 01 Electromechanical and robotic assisted gait training plus physiotherapy versus physiotherapy (or usual care)

Outcome: 04 Walking velocity (metres per second) at follow up

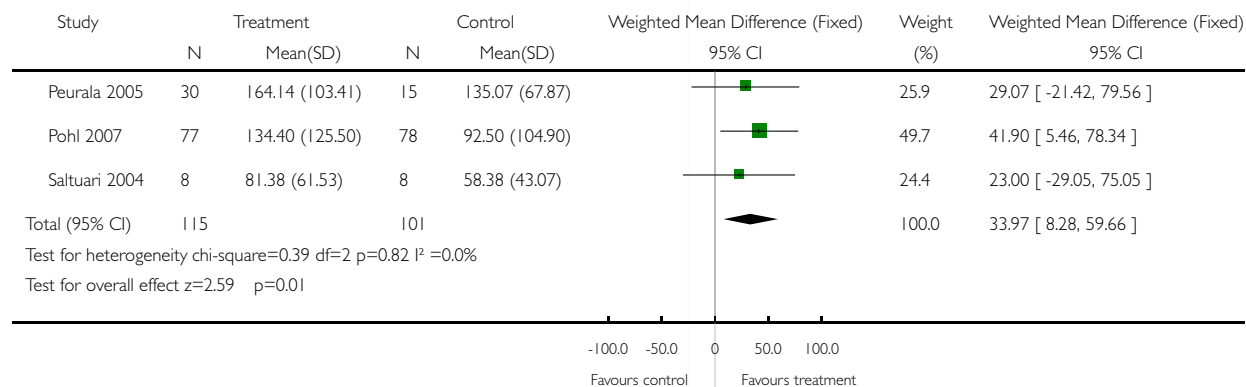


Analysis 01.05. Comparison 01 Electromechanical and robotic assisted gait training plus physiotherapy versus physiotherapy (or usual care), Outcome 05 Walking capacity (metres walked in six minutes) at the end of intervention phase

Review: Electromechanical-assisted training for walking after stroke

Comparison: 01 Electromechanical and robotic assisted gait training plus physiotherapy versus physiotherapy (or usual care)

Outcome: 05 Walking capacity (metres walked in six minutes) at the end of intervention phase

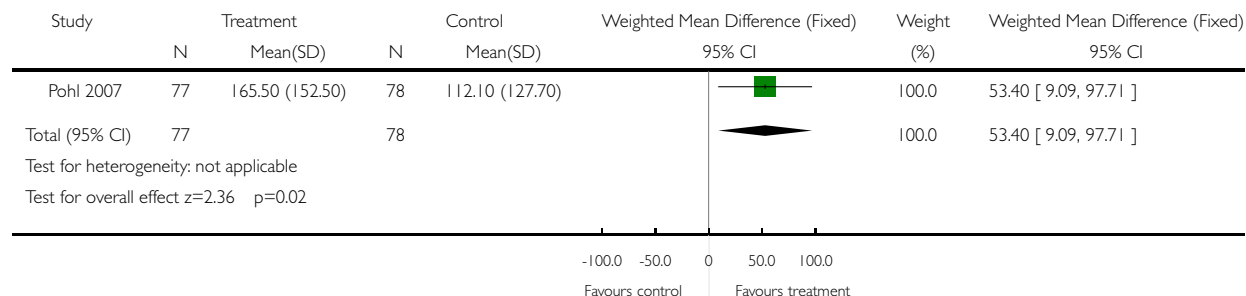


Analysis 01.06. Comparison 01 Electromechanical and robotic assisted gait training plus physiotherapy versus physiotherapy (or usual care), Outcome 06 Walking capacity (metres walked in six minutes) at follow up

Review: Electromechanical-assisted training for walking after stroke

Comparison: 01 Electromechanical and robotic assisted gait training plus physiotherapy versus physiotherapy (or usual care)

Outcome: 06 Walking capacity (metres walked in six minutes) at follow up

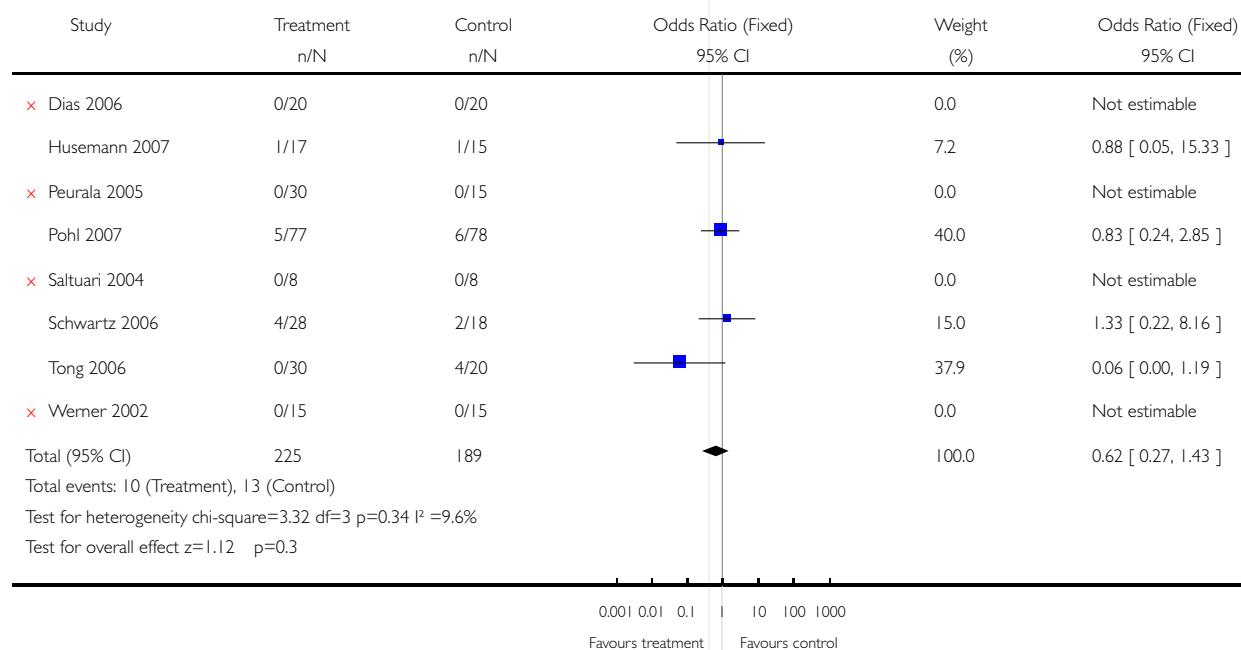


Analysis 01.07. Comparison 01 Electromechanical and robotic assisted gait training plus physiotherapy versus physiotherapy (or usual care), Outcome 07 Acceptability of electromechanical assisted gait training devices during intervention phase: drop outs

Review: Electromechanical-assisted training for walking after stroke

Comparison: 01 Electromechanical and robotic assisted gait training plus physiotherapy versus physiotherapy (or usual care)

Outcome: 07 Acceptability of electromechanical assisted gait training devices during intervention phase: drop outs

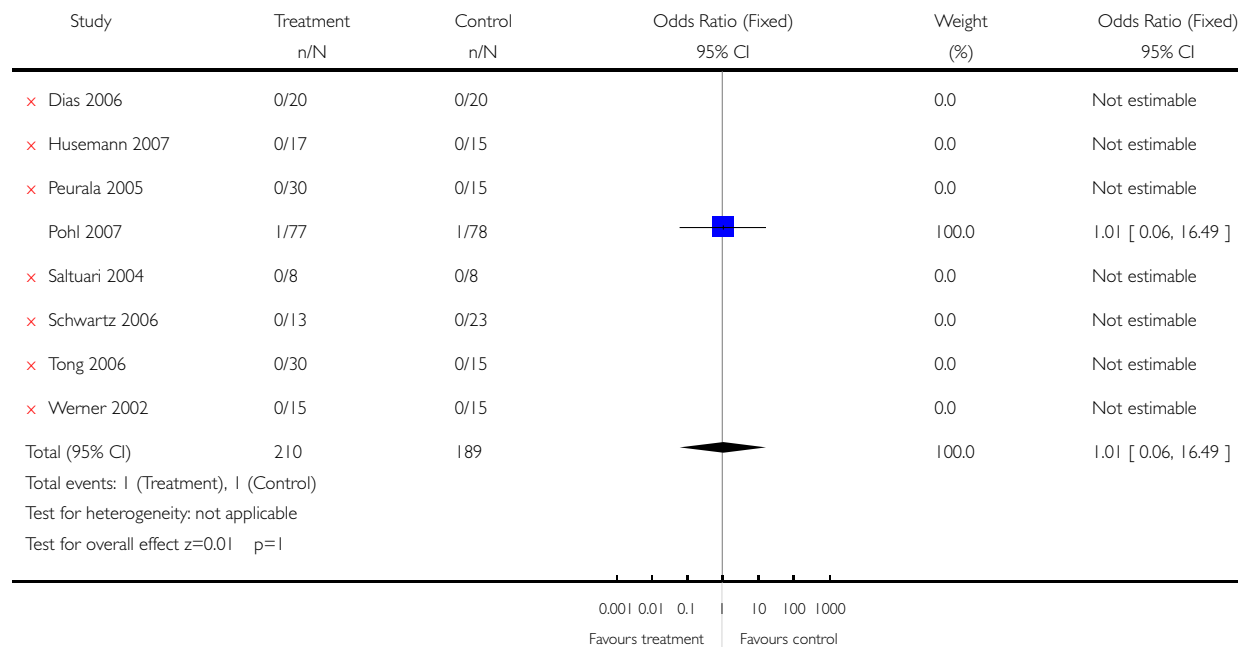


Analysis 01.08. Comparison 01 Electromechanical and robotic assisted gait training plus physiotherapy versus physiotherapy (or usual care), Outcome 08 Death from all causes until the end of intervention phase

Review: Electromechanical-assisted training for walking after stroke

Comparison: 01 Electromechanical and robotic assisted gait training plus physiotherapy versus physiotherapy (or usual care)

Outcome: 08 Death from all causes until the end of intervention phase

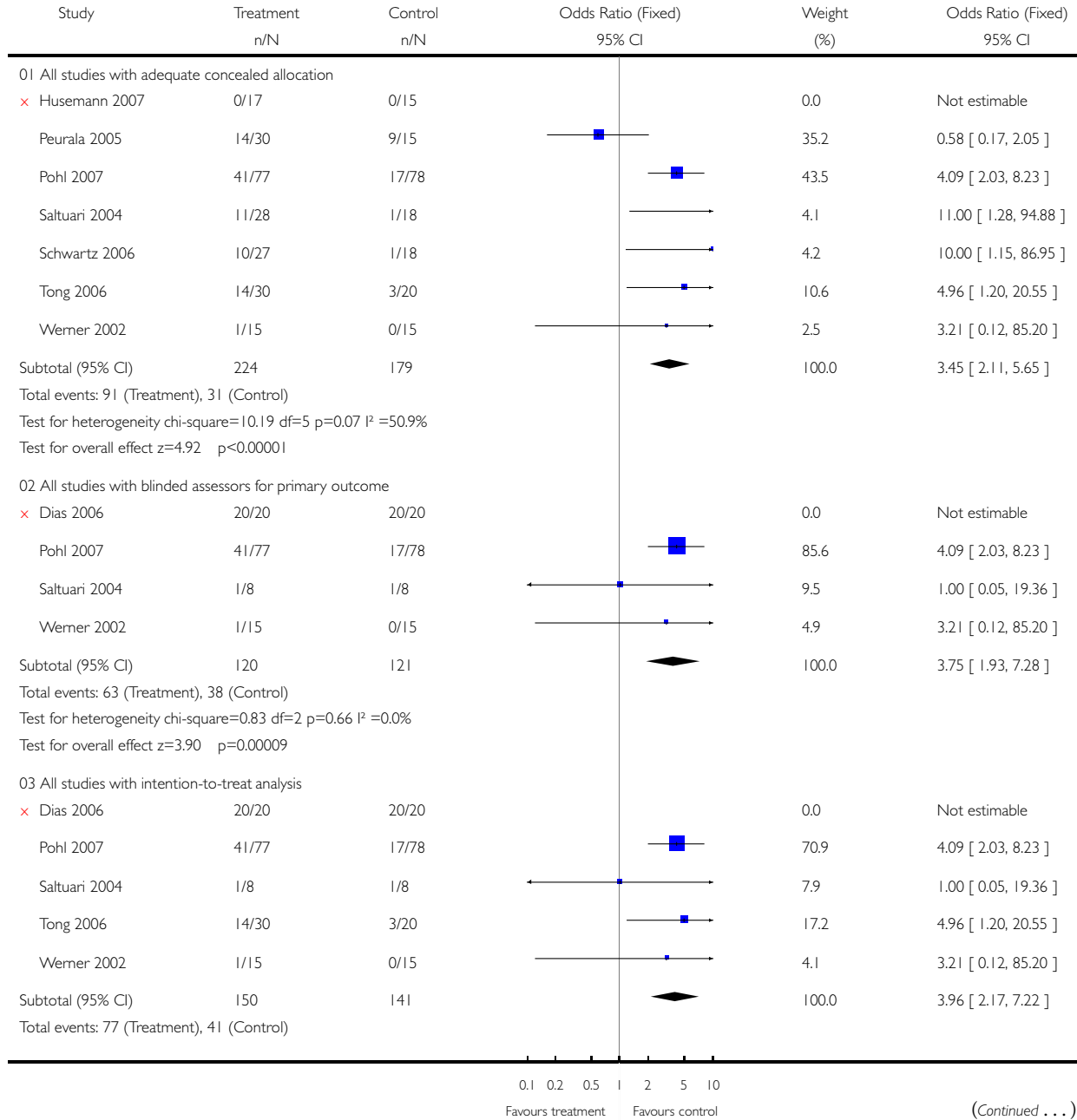


Analysis 02.01. Comparison 02 Post hoc sensitivity analysis: by trial methodology, Outcome 01 Regaining independent walking ability

Review: Electromechanical-assisted training for walking after stroke

Comparison: 02 Post hoc sensitivity analysis: by trial methodology

Outcome: 01 Regaining independent walking ability



(... Continued)

