

Effect of ankle-foot orthoses on functional outcome measurements in individuals with stroke: A systematic review and meta-analysis

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Author contributions

A.D. and T.K. drafted the study protocol, developed the search strategy, and wrote the initial draft. S.Y, SM.L, M.O, and A.A. revised the content. All authors were involved for revising, drafting the final review, and approving the final manuscript. A.D. conducted all analyses and takes responsibility for the precision of findings.

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Abstract:

Purpose: To determine and compare the effect of ankle-foot orthosis (AFOs) types on functional outcome measurements in individuals with (sub)acute or chronic stroke impairments.

Methods: PubMed, Web of Knowledge, Embase, Scopus, ProQuest, and Cochrane were searched from inception until September-2020. Methodological quality assessment of 30 studies was conducted based on the Downs and Black checklist. Functional indices were pooled according to their standardized mean difference (SMD) and 95% confidence intervals (CI) in a random-effect model. A narrative analysis was performed where data pooling was not feasible.

Results: Overall pooled results indicated improvements in favor of AFOs versus without for the Berg Balance Scale (SMD:0.54, CI:0.19 to 0.88), timed-up and go test (SMD:-0.45, CI:-0.67 to -0.24), Functional Ambulatory Categories (SMD:1.72, CI:1.25 to 2.19), 6-Minute Walking Test (SMD:0.91, CI:0.53 to 1.28), Timed Up-Stairs (SMD:-0.35, CI:-0.64 to 0.05), and Motricity Index (SMD:0.65, CI:0.38 to 0.92). Heterogeneity was non-significant for all outcomes ($I^2 < 50\%$, $p > 0.05$) except the Berg Balance Scale and Functional Ambulatory Categories. Additionally, there was not sufficient evidence to determine effectiveness of specific orthotic designs over others.

Conclusions: An AFO can improve ambulatory function in stroke survivors. Future studies should explore long-term effects of rehabilitation using AFOs and compare differences in orthotic designs.

Word count:200

Keywords: Orthosis, Cerebrovascular Accident, Walking, Mobility, Function, Gait

Abbreviations: 6MWT: 6-minute walking test; AFO: ankle-foot orthosis; AFO-PS: hinged plastic or metal AFO with plantarflexion stop and dorsiflexion free; BBS: berg balance scale; FAC: functional ambulatory categories; FIM: functional independence measure; FRT: functional

reach test; PLS-AFO: posterior leaf spring AFO; mEFAP: modified Emory Functional Ambulation Profile; TDS: timed down stairs; TUG: timed-up and go test; TUS: timed up stairs

1. Introduction

Strokes are a common neurological impairment resulting in reduced functional mobility due to postural and dynamic instability, slow gait velocity, low self-efficacy, and decreased independence during activities of daily living (ADLs) [1,2]. The improvements of gait stability and physical function are primary goals of rehabilitation following a stroke [3,4]. Ankle-foot orthoses are frequently prescribed to improve ambulatory function and efficiency during stroke rehabilitation[5].

A wide variety of mobility tests exist to evaluate individuals post stroke[6,7]. Some highly technical tests, such as computerized gait analysis can provide detailed information about gait kinematics and kinetics that can be used to guide specific treatment choices, including orthotic design characteristics[8,9]. Metabolic testing is another mobility test that provides detailed information about the energy cost associated with ambulation post stroke, and can provide information about the effectiveness of a specific intervention[10,11]. However, both of these methods are focused primarily on gait biomechanics, and although implying the potential to ambulate effectively, do not directly quantify an individual's ambulatory function and independent mobility in real world settings. In contrast to these technical mobility tests, clinical mobility tests have been developed that can be more rapidly applied in the clinic setting, and if these tests have acceptable reliability and validity, can be used to guide treatment decisions, and evaluate treatment outcomes. Clinical measurements may have higher ecological validity for functional outcome assessments because they are designed to assess the performance of activities that better reflect ADLs or have more real-world relevance in contrast to the straight ahead single

speed walking most often used in the computerized gait analysis [6,11]. Moreover, clinical outcome measurements are designed to evaluate functional ability by mimicking real world tasks, such as sit-to-stand up and reaching out, and they could be used to evaluate the potential for improvement with rehabilitation interventions including specific AFO prescriptions and gait retraining [12]. Hence, understanding clinical outcome measurements during ambulation is important for evaluating the general effects of AFOs on patients' functional performance and activities in their daily life.

Previous systematic reviews have evaluated AFO performance using different types of mobility tests [8-10,13,14]. However, only one review addressed the effects of AFOs on selected functional outcomes evaluated by clinical tests in individuals with a history of a stroke [13]. The previous review was completed in 2013 and focused more on computerized laboratory tests. Moreover, the analysis did not compare different designs of AFOs in individuals who had suffered a stroke. Thus, the aim of this study was to systematically review the evidence for the impact of AFOs and their designs on clinical outcome measurements in individuals with post-stroke hemiplegia.

2. Methods

2.1. Search strategy

The protocol of present systematic review was already registered in the PROSPERO database (registration no. CRD42020179330). The search strategy was conducted by the population intervention comparison outcome (PICO) method. We identified all relevant papers published from inception until September 2020. After paper identification, the process followed the PRISMA guideline (Fig. 1). The following databases were searched: PubMed, ISI web of

knowledge, Embase, Scopus, ProQuest, and Cochrane. First, a search strategy for PubMed was established, which was then adapted for other databases (Supplemental Appendix 1). The search procedure was performed by an investigator (A.D.). After removing duplicates by Endnote X7 software, the titles, and abstracts were independently reviewed for eligibility by two researchers (A.D. and T.K.); the full texts of the papers were then acquired. Two investigators (A.D. and T.K.) initiated the paper selection process based on the eligibility criteria. Any disagreement in selection procedure was resolved by discussion between the two investigators and if needed, consultation of the third investigator (S.Y.) was also conducted.

2.2. Study types

The review consisted of clinical trials (including paired sample, parallel or crossover designs, unblinded or blinded) without any language limitation, which compared (1) outcomes with and without an AFO (barefoot or with shoes) (Intervention); (2) outcomes between different types or designs of AFOs (Intervention); (3) outcomes of patients with hemiplegia secondary to stroke (chronic or (sub)acute) (Population); and (4) applied outcome measures of functional tests in a clinical setting (Outcome measure). Studies that used other orthotic devices, such as powered orthoses and air-pressure splints, were excluded since those are not necessarily suitable for daily use. Thus, only passive orthoses were included. Passive AFOs are generally grouped into two types: non-articulated and articulated orthoses. The passive non-articulated AFOs include different designs, such as a posterior leaf spring AFO (PLS-AFO), rigid AFO, carbon fiber AFO, dynamic supramalleolar AFO, and an anterior AFO [15]. The passive articulated AFOs have a variety of joint designs, which stop or resist plantarflexion and/or dorsiflexion movement. These AFOs include options of custom plastic or metal AFOs with plantarflexion stop, dorsiflexion free, and plantarflexion resistance designs, as well as a Chignon AFO (an

double-stopped custom-made AFO with posterior joint made out of molded carbon fiber) [15]. We also excluded the knee-ankle-foot orthoses (KAFOs) studies because the mobility subscales of KAFO users are significantly lower than that of AFO users.

2.3. Assessment of methodologic quality

The methodological quality assessment of the included studies was conducted based on the Downs and Black checklist, which consisted of the sections of reporting, external validity, bias, confounding, and power [16]. For the present review, we modified this checklist to 17 items, because giving a score to some items was not possible due to the non-conformity of the items in the included papers. Each answered question received “unable to determine” (score 0), “no” (score 0), or “yes” (score 1). Table 1 lists the Downs and Black scales for the selected papers.

2.4. Data extraction

Two investigators (A.D. and T.K.) carried out the data extraction. The following data were extracted from the selected trials indicated in Table 2: first author’s name with publication year, trial design, sample size, population recruited (age, gender, time from stroke), stroke phase, inclusion and exclusion criteria, intervention delivered, adaptation time with an AFO, outcomes measured, walking velocity, and quality status. If required, we contacted the authors for clarification or missing data.

2.5. Statistical analysis

Regarding the meta-analysis (quantitative analysis), the mean and standard deviation (SD) of parameters were extracted. If mean and SD were not reported, we

contacted the authors by email to obtain their unpublished data. When we did not receive a response from the authors, we followed the methods suggested by Wan et al. to calculate mean and SD based on median and interquartile range (IQR) [17]. Where possible, the effect size across the studies was calculated by standardized mean difference (SMD; Cohen's d) and 95% confidence intervals (CI) using a random-effects model. For a better interpretation of pooled analyses, SMD of 0.2, 0.5, 0.8, and >0.8 were chosen to correspond to small, medium, large, and very large change, respectively.

We represented the findings for every comparison in forest plots. When studies reported the effects of two different AFOs, the data from both orthoses were included in the analysis. The heterogeneity was evaluated using I-square (I^2). The degree of heterogeneity was categorized into low, medium, and high based on the I^2 -values of < 25%, 25%–50%, and 50%–100%, respectively. If the number of papers for each comparison was more than 10, a funnel plot was planned in order to evaluate the publication bias [18]. In case the number of papers was less than 10, Begg's and Egger's tests were used to evaluate publication bias [19,20]. Subgroup analyses were conducted for time from stroke (“<6 months,” “> 6 months,” or “mixed”), AFO type (non-articulated or articulated), follow-up period (immediate, <3 months, > 3 months), walking speed (without orthosis: household, <0.4 m/s; limited community, 0.4-0.8 m/s; community, >0.8 m/s) [21], and methodological quality of the studies (poor, fair, and good). A narrative analysis was performed where data pooling was not feasible (<4 studies). Stata software 11.0 (Stata-Corp LP, USA) was used for all analyses.

2.6. Outcome measures

Based on the literature selected for analysis, independence of walking was assessed using the Functional Ambulation Categories (FAC); walking ability (endurance) with the 6-Minute Walking Test (6MWT); functional mobility with the Timed Up and Go test (TUG), stairs tests (Timed Going Up (TUS) or Down (TDS)), and modified Emory functional ambulation profile (mEFAP). Balance was assessed with Berg Balance Scale (BBS) and Functional Reach Test (FRT). In every study selected for the analysis, the tests related to walking were performed at the participant's self-selected gait velocity. Other outcome measures used for the analysis included Functional Independence Measure (FIM) subscores related to mobility and locomotion (stair-climbing and walk/wheelchair); plantarflexor spasticity, evaluated by the Modified Ashworth scale; the Motricity Index, which assesses isometric contraction and selective muscle control; and the Barthel Index and Rivermead Mobility Index, which evaluate mobility during ADLs. Since a recent systematic review addressed the effect of AFOs on walking speed [22], we did not include walking speed measured by clinical tests for the present review. We did, however, consider it as a factor of sub-group analysis.

3. Results

3.1. Description of studies

In total, 30 studies (29 articles and 1 thesis) involving 669 participants were included for final evaluation (Figure 1). A list of excluded studies with their exclusion reason has been presented in Supplemental Appendix 2. The quality status of the studies had a scientific rigor of 11 (medium or fair) out of 17 and ranged from 8 (low or poor) to 13 (high or good) (Tables 1 and 2). All studies failed in the items which evaluated the adequacy of population representation, and

the blinding of patients or therapists. A non-randomized, one-group clinical design (quasi-experimental) was included in 10 papers in which functional tests without an AFO were defined as the control trials without a randomization for the order of tests [23-32]. A randomized, one-group clinical design (quasi-experimental) was included in 13 papers in which functional tests without an AFO were the control trial with a randomization for the order of tests [33-45]. A randomized, parallel-group controlled design (RCT) was included in six papers in which one group of the patients used an AFO and the control group was evaluated with only shoes or other AFOs [46-51]. One study included a non-randomized parallel-group trial in which participants were not assigned randomly to two groups [52]. Seven papers evaluated the immediate effect of an AFO (without adaptation)[27,29,33,36,40,43,49], and other studies assessed the short-term (< 3 months) [24,26,28,30,31,35,37,38,40-42,44,48,50,52] or long-time effects (> 3 months) [23,34,39,46,47,50,51] of an orthosis. Most studies had small sample sizes (4-61 subjects), and a sample size calculation (power) was reported in five studies [36,42,45,46,49]. Most studies recruited participants with chronic impairments post stroke (>6 months) that did not undergo rehabilitative care (rehabilitative care refers to inpatient or non-hospitalized patients who are undergoing rehabilitation programs in hospitals or rehabilitation centers), except one [45] which recruited patients in this phase with gait training using an AFO. Other studies involved individuals in the early subacute (7 days to 3 months) and late subacute (<6 months) stages who were undergoing rehabilitative care (8 papers) [25,36,42-44,47,48,50]. Two papers did not state whether subjects were receiving rehabilitative care or were not in the subacute phase [33,43]. Three studies evaluated the mixed group of subacute and chronic hemiparetic patients [26,35,38], and two of them recruited patients with rehabilitative care[26,35]. Most papers utilized a non-articulated AFO for all participants, while seven studies used an articulated AFO

[24,25,27,35,40,42,50]. Five studies did not distinguish between articulated orthoses and non-articulated orthoses (mixed group) [29,31,34,37,39].

3.2. Comparison of AFO versus without AFO

The results of Berg Balance Scale (BBS), Timed Up and Go test (TUG), Functional Ambulation Categories (FAC), 6-minute walking test (6MWT), Timed Up Stairs (TUS) and Motricity Index were analyzed quantitatively by a meta-analysis, while the results of Timed Down Stairs (TDS), Functional Reach Test (FRT), Modified Ashworth Scale, Functional Independence Measure (FIM), the modified Emory Functional Ambulation Profile (mEFAP), Barthel Index, and Rivermead Mobility Index were analyzed qualitatively by a narrative analysis.

3.2.1. Results of quantitative analyses

Berg Balance Scale (BBS): This test is utilized to determine static and dynamic balance abilities using 14 list items. Each of the 14 assessment items of BBS ranges from 0 to 4, with 0 representing the lowest level of function and 4 the highest level of function. The effect of AFOs on BBS was reported in 11 trials. Overall pooled results were reported in Figure 2 (a). Pooled SMD demonstrated a moderate and significant improvement (SMD: 0.54, CI: 0.19 to 0.88) in favor of orthotic intervention compared with no orthosis by combining all trials. However, statistical heterogeneity was detected to be high (I^2 : 72.9%). Subgroup analyses based on stroke phase (Supplemental Figure 1(a)), adaptation time (Supplemental Figure 1(b)), study quality (Supplemental Figure 1(c)), and walking speed (Supplemental Figure 1(d)) were also presented. For AFO type, subgroup analysis was not applicable because the subgroups contained only a single study that used either an articulated orthosis or both non-articulated and articulated orthoses (mixed group).

Timed Up and Go test (TUG): This test is an assessment of person's mobility in which the time taken by an individual to stand up from a chair, walk 3 meters, turn, walk back, and sit down again is measured. Fifteen trials compared this mobility test with and without an AFO. Overall pooled SMD (Figure 2 (b)) demonstrated a moderate and significant difference (SMD:-0.45, CI:-0.67 to -0.24) between walking with and without an orthosis for the TUG test with a low level of statistical heterogeneity (I^2 : 21.7%). Subgroup analyses based on stroke phase (Supplemental Figure 2(a)), orthosis type (Supplemental Figure 2(b)) adaptation time (Supplemental Figure 2(c)), study quality (Supplemental Figure 2(d)), and walking speed (Supplemental Figure 2(e)) were also presented.

Functional Ambulation Categories (FAC): The FAC performance is categorized from 0 (needing support from 2 people) to 5 (can walk anywhere without supervision). We excluded one study for meta-analysis because IQR for FAC had not been reported, and we did not receive any responses from authors by email [51]. Fourteen trials compared this function with and without an orthotic intervention. Pooled results of an all trials combination identified a rate of 1.72 (95% CI 1.25 – 2.19) with a significant improvement using an AFO compared to without one (Figure 3 (a)). However, a significant heterogeneity was found (I^2 : 78.0%). Subgroup analyses based on stroke phase (Supplemental Figure 3(a)), orthosis type (Supplemental Figure 3(b)) adaptation time (Supplemental Figure 3(c)), and study quality (Supplemental Figure 3(d)) were also presented. For walking speed, subgroup analysis was not applicable.

6-Minute Walking Test (6MWT): We excluded one study for meta-analysis because SD value for 6MWT had not been reported, and we did not receive any responses from authors by email[26]. Thus, the effect of AFOs on the test performance was reported in seven trials. Pooled SMD demonstrated a large to very large and significant improvement (SMD: 0.91, CI:

0.53 to 1.28) in favor of orthotic intervention compared with no orthosis (Figure 3 (b)). The statistical heterogeneity was moderate (I^2 : 34.4 %). Subgroup analyses based on stroke phase (Supplemental Figure 4(a)), adaptation time (Supplemental Figure 4(a)), study quality (Supplemental Figure 4(a)), and walking speed (Supplemental Figure 4(a)) were also presented. For orthosis type, subgroup analysis was not applicable because all trials included a non-articulated orthosis.

Timed Up-Stairs (TUS): Subjects were timed going up 10 steps, 5 steps in the mEFAP, and 7 steps in Ashburn test. Eight trials compared the performance of the test with and without an AFO. Pooled results of an all trials combination showed a low to moderate improvement (SMD:-0.35, CI:-0.64 to 0.05) and low heterogeneity (I^2 : 17.0%) in the TUS using an AFO compared to no AFO (Figure 4(a)). Subgroup analyses based on stroke phase (Supplemental Figure 5(a)), adaptation time (Supplemental Figure 5(a)), study quality (Supplemental Figure 5(a)), and walking speed (Supplemental Figure 5(a)) were also presented. For orthosis type, subgroup analysis was not applicable because the subgroups contained only a single study that used either an articulated orthosis or both articulated and non-articulated orthoses (mixed group).

Motricity Index: We excluded one study for meta-analysis because values for Motricity Index had not been reported, and we did not receive any responses from authors by email [51]. Eight trials included in two studies were involved in a meta-analysis for the effect of AFOs on Motricity index. Pooled results of an all trials combination identified a Motricity Index of 0.651 (95% CI 0.381– 0.922) with a significant improvement (SMD: 0.65, CI:0.38 to 0.92) and very low heterogeneity (I^2 : 0.0%) after using an orthosis in comparison with before using the orthosis

(Figure 4(b)). Subgroup analyses based on adaptation time (Supplemental Figure 6(a)) and study quality (Supplemental Figure 5(b)) were also presented.

3.2.2. Results of qualitative analyses

For the following outcomes, a meta-analysis was not applicable because of the limitation in the number of studies for each parameter. Thus, we conducted a narrative analysis for these indices.

Timed Down-Stairs (TDS): Total time taken to go down 10 steps from the top of the stairs was recorded (in seconds). The effect of an AFO on this test between an orthotic intervention and a non-orthotic intervention was measured in only one study. Erel et al. reported no difference between wearing a dynamic supramalleolar AFO (13.29 ± 11.21) and a control group wearing only tennis shoes (15.36 ± 8.37) for the TDS test after a 3 month follow-up ($p > 0.05$) [46].

Functional Reach Test (FRT): This test measures the maximum distance a person can reach forward or to the side while standing in a fixed position. Only two papers evaluated the effect of using an AFO on this test. Rao et al. indicated that the mean maximal reaching distance in all the directions (forward, right, and left) was improved in subjects who have suffered a stroke, when provided with a non-articulated orthosis [30]. Another study reported that the outcome in the forward direction did not significantly change in the group wearing dynamic supramalleolar orthosis and tennis shoes (33.43 ± 9.59 cm) compared with the control group wearing only tennis shoes (28.46 ± 4.40 cm) [46].

Modified Ashworth scale: Only two studies reported spasticity after receiving an AFO along with training during the subacute stage. Sankaranarayan et al. reported that Modified

Ashworth scale (plantar flexors) did not significantly change ($p=0.822$) pre to post after an intervention including 14 training sessions (2 weeks) of activity based rehabilitation using rigid AFOs [26]. De Sèze et al. measured tricipital and quadricep spasticity on the modified Ashworth scale at day 0, day 30, and day 90 in two orthotic groups. The results indicated a significant improvement in spasticity after a 3-month follow-up for the group with the Chignon AFO ($p<0.05$), but not for the group with the PLS-AFO [50].

Functional Independence Measure (FIM): Only two studies reported this function after receiving an AFO along with training during the subacute stage. One paper showed that the mean mobility scores of the FIM were significantly high at discharge than at admission for those who used an orthosis (26.0 ± 4.7 vs. 18.9 ± 6.6 , $p<0.001$) [26]. Another paper in a randomized-controlled trial reported that FIM scores significantly improved after receiving PLS-AFO and Chignon AFO at 30 days of follow-up ($p<0.05$) [50].

The modified Emory Functional Ambulation Profile (mEFAP): The mEFAP comprises five timed tasks with different terrains: floor, carpet, TUG, obstacles and stairs. Only one study evaluated the effect of using an AFO on mEFAP in chronic stroke patients. The subscores of time in floor ($p<0.001$) and carpet ($p = 0.013$) trials significantly decreased with an orthotic intervention; no significant difference was observed in stair ($p =0.067$) and obstacle ($p = 0.092$) trials [29].

Barthel Index, and Rivermead Mobility Index: These indexes were measured using an AFO in two papers examining subacute stroke patients [47,48] and one paper examining patients in the chronic phase [45]. In a randomized-controlled trial, Nikamp evaluated an early versus delayed provision of a non-articulated orthosis (PLS-AFO or rigid AFO). A positive effect of

using the AFO was found on these indices for both early and delayed groups after two weeks of orthotic use [48]. In another study by Nikamp, the six-month clinical effects of providing AFOs in early versus delayed groups were evaluated. Patients with early provision of orthotics demonstrated a general trend towards earlier independence (about 12 weeks), but this difference was not statistically significant [47]. Everaert et al. reported that the Rivermead Mobility Index significantly increased over the 12 weeks of orthotic use ($P < 0.001$) [45].

3.3. Comparing among different types or designs of AFO or shoes:

Orthotic types or designs used in each study were different from each other. Therefore, a meta-analysis based on the comparison between different types (non-articulated or articulated) of AFO was not possible. Seven studies compared effects of different orthoses or shoes on functional mobility. In Farmani's study, the TUG significantly improved when patients walked with a rigid AFO in a rocker shoe compared to a rigid AFO with a standard shoe [49]. Eckhardt et al. also reported that temporary high orthopaedic shoes with a stiff upper portion, made of carbon fiber, improved TUG score compared to normal shoes (22%; $p < 0.001$) [44]. De Sèze et al. evaluated FAC at initial wearing time (day 0) and at 30 and 90 days of follow-up. The researchers stated that in the condition without an orthotic, the FAC score tended to be higher in the PLS-AFO group compared to Chignon AFO group, at 90-day follow-up. The difference did not reach significance in the condition with an orthosis. No significant differences were found between the two orthotic groups concerning the FIM, Motor index, and spasticity scores [50]. Slijper et al. reported that wearing an AFO that stopped plantarflexion resulted in significantly faster stair climbing ($p=0.005$) and longer walking distance in the 6MWT ($p=0.016$) compared to walking with a carbon fiber AFO [24]. Also, a pilot study by Shin reported that FRT and TUG scores improved significantly when wearing an AFO with plantarflexion stop compared with a

rigid orthosis ($p < 0.01$) [27]. In Karakkattil's study, no significant differences were found between the PLS-AFO and the AFO with plantarflexion stop for endurance and gait velocity at both baseline, and after a week of practice during the subacute phase of stroke recovery. However, there was a significant improvement between the baseline measurement and the 1-week practice measurement for both parameters ($p < 0.001$), regardless of the orthotic design [42]. In another study, there were no significant differences between prefabricated AFOs with plantarflexion stop and custom-made AFOs with plantarflexion stop for the TUG test ($p > 0.05$) [40].

3.4. Assessment of publication bias

The findings demonstrated no evidence of potential publication bias ($p > 0.05$) for the trials included in each outcome, except for FAC ($p < 0.05$) (Supplemental Table 7). Funnel plots for the BBS, TUG, and FAC are presented in Supplemental Figure 8. Egger's linear graphs for the 6MWT, TUS, and Motricity Index are illustrated in Supplemental Figure 9.

4. Discussion

In this review, functional outcomes based on clinical measurements such as walking endurance, independence of walking, functional mobility, balance, motor index, mobility during ADLs, and muscle strength were selected. These measures are easy to perform, require little equipment, and appear to be clinically feasible and reliable for providing the evidence of improved functional performance following clinical treatment [11,53]. In addition, wide ranges of walking capacity can be evaluated using these tests, including endurance, velocity, and different walking environments (such as walking over uneven surfaces and stair-climbing), thereby providing a clearer picture of real-life mobility issues.

4.1. Quantitative analyses

4.1.1. Combined analyses

Current overall pooled results suggest that using an AFO provided a significant improvement in all functional outcomes compared with no orthosis. It could be expected that wearing an AFO would result in a greater contribution of the affected lower extremity to stabilize the body during mobility and quiet standing. Although the overall analysis demonstrates statistically significant differences, the clinical significance for some parameters remains uncertain because SMDs were small (a few degrees of movement in the forest plot). It is not clear whether such changes are sufficient at providing a meaningful difference in functional ambulation for individuals who have previously suffered a stroke. Nevertheless, our analysis, which contained many of the same trials, showed improvements in the 6MWT, FAC, BBS, and Motricity Index. These improvements suggested that changes could sufficiently be translated into function ($SMD > 0.5$). Heterogeneity was not significant in the 6MWT, TUG, TUS, and Motricity Index ($I^2 < 50\%$, $p > 0.05$). However, a significant heterogeneity was observed in the BBS and FAC. We attempted to describe the heterogeneity by subgrouping our findings based on included factors. Unfortunately, our ability to describe heterogeneity was restricted because of the non-homogeneity in a number of the subgroup analyses (i.e., subgroups contained only a single trial or a single subgroup included all trials). Moreover, there was a big difference in the number of trials between each subcategory in some of the subgroup analyses. Therefore, the strength of our conclusion depends more on the overall pooled analysis.

4.1.2. Subgroup analyses

Where subgroup analyses were relevant, subgrouping data based on adaptation time revealed that wearing an AFO has demonstrated better results on all outcomes in long-term adaptation, except for the TUG test, which is a substantial finding. In long-term adaptation, besides corrections of foot varus and foot-drop as well as improvements in mediolateral stability by computerized laboratory analyses reported in previous studies[8,9], functional ambulation improved as the patients' familiarization with the AFO increased. Regarding the quality in subgroup analyses, better results were revealed for trials with good quality, except for the TUG test. Moreover, subgrouping data based on patient walking velocity before the use of an AFO indicated that most trials which recruited patients in the subacute phase had walking speeds in the household ambulation category (<0.4 m/s). On the other hand, most papers evaluating the rehabilitation care of training while using an AFO recruited participants in the subacute recovery phase, but not in the chronic post stroke phase. This finding suggests that early mobility training with an AFO is effective possibly in view of the very active functional and neurological recovery occurring during this time. Subgrouping data revealed that individuals in the subacute stroke phase, as well as those with walking speeds within the household ambulatory category, would demonstrate better results compared to the limited-community speeds (0.4 - 0.8 m/s) for most of the outcomes, except for the TUG test. Thus, rehabilitative care involving gait training while wearing an AFO could have beneficial effects on the functional outcomes of individuals who have had a stroke and are in an early course of recovery. However, the evaluation of the outcomes for orthotic rehabilitative care in the subacute phase was based on the results of four studies [36,47,48,50] with fair to good quality. Two studies did not state whether subjects were receiving rehabilitation [33,43]. Hence, this finding should be interpreted cautiously. For the TUG subgroup, the findings were different from other parameters in some instances, with better

results in chronic stroke patients and the immediate effect of AFO. This finding suggests that the TUG test is a more complex skill than other functional outcomes requiring more strength and balance, which may be recovered later in the rehabilitation timeline for post-stroke individuals. Although this is a logical conclusion, the rigorous support for this speculation is weak because of a fairly large difference in the number of trials between each subcategory in some of the subgroup analyses (Supplemental table 2). Additional research effort is clearly needed to determine when individuals with post-stroke impairments reacquire walking skills as opposed to more difficult mobility skills, such as rising from a chair, which may require additional strength and balance recovery.

Although various AFO designs could improve functional mobility in some way, subgroup analysis of orthotic types (non-articulated versus articulated) was not possible for four outcomes including the BBS, 6MWT, TUS, and Motricity Index. When subgroup analysis of orthotic type was applied for the TUG and FAC, an articulated AFO demonstrated better results on the TUG test. There was no significant difference found on FAC. This result may be due to the increased dorsiflexion an articulated orthosis can allow, but how an articulated orthosis can improve the TUG test and FAC is not completely understood. It is believed that orthotic types or designs should be determined based on specific clinical problems and adjusted for each individual based on pathomechanics and gait mechanics in the clinical setting. However, there is not sufficient evidence that a certain orthotic type or design is more effective than others in post-stroke individuals. Additionally, several different AFO designs were grouped together in the non-articulated category, ranging from rigid AFOs to dynamic supramalleolar AFOs. Although biomechanical features and restrictions embedded in these AFO designs are very different, it was not possible to make a subgroup within the non-articulated category due to the big difference in

number of trials between potential subcategories. Future studies should investigate how specific types or designs of AFOs can benefit specific categories of deficits to develop an effective clinical treatment paradigm in post-stroke individuals.

In this meta-analysis, we focused on the stroke recovery phase, the orthotic type, the adaptation time with AFOs, quality of studies based on Downs and Black checklist, and walking speeds before using an AFO as sources which may explain heterogeneity. However, other potential factors of heterogeneity could have also been evaluated such as hemiparesis and spasticity, cognitive ability, stroke type, differences in walking ability, gender, history of orthotic use, history of gait training, or the degree of familiarization with AFOs (habituation vs. first-time use). Nevertheless, these factors were not consistently stated in all of the included studies.

The strength in the conclusion of reviewed studies depends on the data completeness. We contacted authors for further data because values for some parameters had not been reported in some papers. Unfortunately, we did not receive a response from some of the authors. Based on the results, however, there was not a potential publication bias in any of the outcomes, except for the FAC.

4.2. Qualitative analyses

4.2.1. Comparison of AFO versus without AFO

Although evidence was largely insufficient for reaching a valid conclusion, the scores of the FIM [26,50], mEFAP [29], spasticity [26,50], Barthel Index [47,48], and Rivermead Mobility Index[45,47,48] were statistically improved using an AFO for the short duration category (up to 3-month follow up). All of the studies, except one [29], included patients concurrently receiving physical rehabilitation training supervised by a physiotherapist. Therefore, the improvements of

functional performance likely reflect the recovery process after a stroke and the effectiveness of rehabilitation care using an AFO. However, divergence in the results of two studies for FRT was revealed with the use of an AFO in chronic stroke patients. One study reported a significant increase in the maximal reaching distance in all directions (forward, right, and left) with an AFO [30]. However, a randomized-controlled trial did not find a significant difference in the forward direction [46]. Reaching activities are associated with a shift in ones center of gravity while remaining inside the respective base of support. The central nervous system utilizes movement strategies by either using a step strategy to make a new base of support or realigning the center of gravity within the current base of support to maintain functional stability. An appropriate movement strategy cannot be achieved in individuals with a history of a stroke who have stability impairments [54]. Although AFOs seem to exert positive effects on the alignment of an ankle-foot complex, it is not clear whether using an AFO can improve reaching activities. Additionally, the relationship between reaching distance and center of gravity on limits of stability using an orthotic intervention requires additional evaluation in future studies before definitive conclusions can be reached.

Finally, although spasticity could be reduced by rehabilitation care and also naturally in the course of recovery, only a few studies with fair to poor quality have addressed this [26,50]. We assume that an AFO might have an indirect effect on spasticity by assisting patients to be more active and allow them to perform more rehabilitation and exercise. However, strong evidence is needed to support this hypothesis. Influence of an AFO on spasticity of the lower-limb joints would be an interesting topic for future studies [55].

4.2.2. Comparing among different types or designs of AFO or shoes

Concerning the comparisons among orthotic types conducted by the narrative analysis, the findings of the evaluated studies suggested that the articulated AFOs resulted in greater improvement in some functional outcomes including the TUG test [27], stair climbing [24], and walking endurance [24] compared to walking with non-articulated orthoses. However, the scientific rigor of this evidence is weak. One study reported no significant differences between the PLS-AFO and AFO with plantarflexion stop for endurance at baseline and after 1-week of practice during the subacute phase of recovery [42]. A previous review reported beneficial orthotic effects of articulated orthoses on gait parameters by providing dorsiflexion assistive force and preventing excessive plantarflexion compared with non-articulated orthoses [8]. On the other hand, despite the Chignon AFO group having a higher walking velocity, one study reported that the FAC score was higher in the PLS-AFO group compared to the Chignon AFO group when not wearing an AFO at day 90 [50]. Such changes over time measured when not wearing an orthosis are referred to as a therapeutic effect. Further studies on the therapeutic effect of an AFO based on training should be encouraged, especially in understanding the characteristics of the patient that might help guide the selection and tuning of an AFO for their specific pathomechanics. Regarding the different shoes used with an AFO, two studies reported improvement of the TUG test with the use of a rocker shoe[49] or an orthopaedic shoe[44] compared with a standard shoe. Nevertheless, the orthosis used in Farmani et al. was rigid and limits some motion for functional benefits. Despite the improvement of functional mobility in these studies, it is not clear whether wearing rocker shoes may disturb patient balance after a stroke.

5. Limitations

The main limitations of the current review were related to the nature of data, as previously mentioned. There was a big difference in the number of trials between each subcategory in many of the subgroup analyses. This issue restricted our conclusions based on the subgroup analysis. Most trials assessed effects of AFOs without gait training and had a small sample size. Risk of bias was high and scientific rigor, weak to fair. They were with high risk of bias and weak to fair in scientific rigor. Blinding is difficult for the patients because of the nature of the intervention. However, investigators should be blinded to the types and designs of orthoses, if possible. Those conducting clinical measurements of functional mobility and processing the data should not know the orthotic condition of the participants. These formal structures to blind investigators were absent for all research designs evaluated in this systematic review. Using an AFO along with gait training in the subacute phase may improve the patients' walking ability, although the long-term effects of an AFO in this phase were reported in only a few studies. Only five papers calculated a power analysis to specify the appropriate sample size for the intervention [36,42,45,46,49]. No trial investigated the efficacy of an AFO with variable plantarflexion resistances on the included variables. Only one trial evaluated the effect of using an AFO on different terrains [29]. Further, the AFO-footwear combination would have different clinical effects on functional ambulation depending on gait patterns [49]. Nevertheless, some studies only investigated gait with an AFO, while others examined walking with footwear in addition to an orthosis. Finally, the comparison among various types or designs of AFOs as well as the comparison between the non-articulated and articulated orthoses on functional mobility after a stroke was investigated in few studies.

6. Recommendations for future research

Based on the findings of this systematic review and meta-analysis, future research should:

- Focus on randomized-controlled trials with low risk of bias, blinding the assessors' during measurements, random assignments, and preventing loss in follow-up;
- Investigate effects of long-term training (6-12 months or more) of wearing AFOs in chronic and (sub) acute stages;
- Compare early or delayed provision of AFOs on the walking ability of individuals with a stroke;
- Compare physical function of patients in chronic phase who continue to use AFOs and who quit using them;
- Evaluate walking over different terrains using an AFO;
- Relationship between reaching distance and center of gravity using an AFO during daily activities;
- Evaluate a comparison among different types or designs of orthotics on functional outcomes;
- Evaluate the effects of AFOs when not wearing them after training (carry-over effects); and
- Investigate the effect of rocker shoes with AFOs on walking balance after a stroke.

7. Conclusion

This systematic review and meta-analysis supports that an AFO can improve functional performance and ambulation in survivors of strokes and that an AFO is more effective on functional outcomes with long-term adaptation. Wearing an AFO in rehabilitation care during the subacute phase may have beneficial effects on clinical outcomes measured in individuals with a history of a stroke. There was insufficient evidence to conclude which effects different types or designs of orthotics had on functional outcomes. A number of areas in research methodologies need to be addressed in future studies in order to provide further evidence as to the effects of AFOs on functional outcome measures.

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Table 1. Modified Downs and Black Quality Index Results and Total Score

	Report								Extern al Validit y	Internal Validity- Bias				Internal Validity – Confounding			Power	Total
Quality Items	Q1	Q2	Q3	Q4	Q6	Q7	Q9	Q10	Q11	Q14	Q15	Q18	Q20	Q22	Q23	Q26	Q27	17 possible
	Hy pot hesi s/Ai m	Ma in Out comes in Me th/ Intro	Incl usion /Ex clus ion Cri teri a	Des cri ption of Int erv entions	Mai n Find ings	Ran dom Vari ability	Los t to Foll ow-up	Act ual Prob ability Val ues	Represe ntative of the Entire Populati on	Blin d Stu dy Sub ject s	Blind those meas uring	Statis tical Tests Appr opria ted	Outc ome Meas ures Used Accu rate	Sam e Peri od of time	Ran dom Allo cati on	Losse s of Patie nts to Follo w-up	Estimate of Statistica l Power	-
Farmani (2016)[49]	1	1	1	1	1	1	1	1	0	0	0	1	1	0	1	1	1	13
Hyun(2015)[33]	1	1	1	1	1	0	1	1	0	0	0	1	1	0	0	1	0	10
Maeda(2015)[23]	1	1	1	1	1	0	1	0	0	0	0	1	1	0	0	1	0	9
Erel(2011)[46]	1	1	1	1	1	0	1	1	0	0	0	1	1	0	1	1	1	12
Slijper(2012)[24]	1	1	1	1	1	1	1	1	0	0	0	1	1	0	0	1	0	11
Simons(2009)[34]	1	1	1	1	1	0	1	1	0	0	0	1	1	0	0	1	0	10
Tyson(2009)[36]	1	1	1	1	1	1	1	1	0	0	0	1	1	0	0	1	1	12
Doğan(2011)[25]	1	1	1	1	1	1	1	1	0	0	0	1	1	0	0	1	0	11
Abe(2009)[37]	1	1	1	1	1	0	1	1	0	0	0	1	1	0	0	1	0	10

Tyson(2001)[35]	1	1	1	1	1	1	1	1	0	0	0	1	1	0	0	1	0	11
Assawa palange hai(2017)[38]	1	1	1	1	1	1	1	1	0	0	0	1	1	0	0	1	0	11
de Sèze(2011)[50]	1	1	1	1	1	0	1	1	0	0	0	1	1	0	1	1	0	11
Pavlik(2008)[39]	1	1	1	1	1	1	1	1	0	0	0	1	1	0	0	1	0	11
de Wit(2004)[51]	1	1	1	1	1	1	1	1	0	0	0	0	1	1	1	1	0	12
Pardo(2015)[40]	1	1	1	1	1	1	1	0	0	0	0	0	1	0	0	1	0	9
Sankara narayan(2016)[26]	1	1	1	1	0	0	1	1	0	0	0	1	1	1	0	1	0	10
Yue(2013)[56]	1	1	1	1	1	1	1	0	0	0	0	1	1	0	0	1	0	10
Nkamp(2017)[47]	1	1	1	1	1	1	1	1	0	0	0	1	1	1	1	1	0	13
Nikamp(2017)[48]	1	1	1	1	1	1	1	1	0	0	0	1	1	1	1	1	0	13
Shin(2017)[27]	1	1	1	1	0	1	1	0	0	0	0	1	1	0	0	1	0	9
Karakka ttil(2018)[42]	1	1	1	1	1	1	1	1	0	0	0	1	1	0	0	1	1	12
Hale(2013)[32]	1	1	1	1	1	0	1	0	0	0	0	0	1	0	0	1	0	8
Cakar(2010)[28]	1	1	1	1	1	1	1	1	0	0	0	1	1	0	0	1	0	11
Wang(2005)[43]	1	1	1	1	1	1	1	1	0	0	0	1	1	0	0	1	0	11

Sheffler (2006)[29]	1	1	1	1	1	1	1	1	0	0	0	1	1	0	0	1	0	11
Rao (2016)[30]	1	1	1	1	1	1	1	1	0	0	0	1	1	0	0	1	0	11
Eckhardt (2011)[44]	1	1	1	1	1	0	1	1	0	0	0	1	1	0	0	1	0	10
Tomioka (2017)[31]	1	1	1	1	1	0	1	0	0	0	0	1	1	0	0	1	0	9
Everaert (2013)[45]	1	1	1	1	1	1	1	1	0	0	0	1	1	0	1	1	1	13
Nevisipour (2019)[52]	1	1	1	1	1	1	1	1	0	0	0	1	1	0	0	1	0	11

1=YES, 0= NO, 0= Unable to determine

Table 2: Characteristics of the Studies on the Effect of AFOs on Functional Outcome Measurements

Author / Year	Study design	Samples	Stroke phase	Adaptation time for AFO use or shoe	AFO Design	Outcome Measures	Walking speed (m/s) in mean (SD): no AFO and with AFO	Quality status
Farmani (2016)[49]	Randomized, parallel-group controlled design (RCT)	30 individuals (M: 19, F: 11) with chronic stroke, were able to walk independently without assistive devices, mean age:59.3 years, mean time from stroke: 29.1 months, MAS:3 Group I (n:15): SS +RAFO Group II (n:15): RS+RAFO	Chronic	Not adopted (Immediate)	RAFO	-TUG (s) -Stairs (TUS and TDS) (s)	-Group I: AFO+SS: 0.64 (0.14) -Group II: AFO+RS: 0.71 (0.32)	good
Hyun(2015)[33]	Randomized clinical trial (quasi-experimental)	15 individuals (M:12, F:3) with subacute stroke, the ability to walk at least 3 minutes with or without an aid, but without standby assistance, mean age: 62.1 years, time from stroke: 34.4days, ankle dorsiflexor muscle weakness grade of “less than fair”, MAS: nr -Not stated whether subjects were undergoing rehabilitation	Subacute	Immediate	RAFO	6MWT (m)	-No AFO: 0.73 (0.23) -With AFO: 0.82 (0.29)	poor
Maeda(2009)[23]	Non-Randomized clinical trial (quasi-experimental)	18 individuals (M: 15, F: 3) with chronic stroke, able to walk without assistance, mean age: 45years, time from stroke: 19 months, MAS: nr BS: 3-5	Chronic	Habituated to walking with a PAFO for 8 months	PAFO	6MWT (m)	- No AFO: 0.38 (0.2) -AFO: 0.48 (0.2)	poor
Erel (2011)[46]	Randomized, parallel-group controlled design (RCT)	28 individuals (M: 18, F: 10) with chronic stroke were classified into 2 groups: CG: mean age:50.64 years, time from stroke: 25.36 months SG: mean age: 42.50 years, time from stroke: 30.21 months, MAS:3, FAC: 3-5 CG (M: 7, F:7): only tennis shoe (n:14) SG (M: 11, F:3): tennis shoe +AFO (n:14)	Chronic	Three months	DAFO (Supramalleolar orthosis) based on tone-inhibiting orthosis	-TUG(s) -Stairs (s) (TUS and TDS) - FRT (cm)	-Initial assessment: CG: 0.65 (0.19) SG: 0.84 (0.40) -After 3 months: CG: 0.72 (0.20) SG: 0.99 (0.45)	fair
Slijper(2012)[24]	Non- clinical trial (quasi-experimental)	12 individuals (M:2, F:10) with chronic stroke, able to walk for at least 6 minutes without personal assistance (walking aid was allowed), mean age:56years, mean time from stroke: 25months, MAS: 0-3	Chronic	-Time with AFO-PS:2.5 months -Time with C-AFO:3 months	- CAFO - AFO-PS	-6MWT(m) -Stairs (s) (TUS)	-CAFO: 0.55 (0.28) -AFO-PS: 0.59 (0.25)	fair

Simons (2009)[34]	Randomized clinical trial (quasi-experimental)	20 individuals (M:14, F:6) with chronic stroke, being able to walk for 10 m with or without an assistive device, mean age:57.2 years, mean time from stroke:39.3months, total Motricity index: 81.7, MAS: nr	Chronic	Worn an AFO in everyday life, mean > for 3 months	-PLS-AFO -RAFO -Metal AFO-PS	-TUG(s) -FAC (score) -BBS (score)	- No AFO: 0.46 (0.21) -AFO: 0.58 (0.24)	poor
Tyson(2009)[36]	Randomized clinical trial (quasi-experimental)	20 individuals (M: nr, F: nr) with subacute stroke undergoing rehabilitation care, able to walk 5m without physical support, mean age: 65.6years, mean time from stroke: 6.5weeks, Motricity index: 48.1, MAS: nr	Subacute	The morning before testing (Immediate effect)	-Cane -PLS-AFO -Slider shoe -A combination of all 3 devices	FAC(score)	-No device: 0.3 (0.14) -Cane: 0.28 (0.15) -AFO: 0.30 (0.12) -Slider shoe: 0.31 (0.13) -All devices: 0.29 (0.14)	fair
Doğan (2011)[25]	Non- clinical trial (quasi-experimental)	51 individuals (M:24, F:27) with subacute stroke, able to ambulate, mean age: 60.7years, mean time from stroke: 69days, MAS: 1-3	Subacute	4 days	AFO-PS	-TUG(s) -Ashburn climbing stairs (7 stairs) (s) -BBS (score)	- No AFO: 0.29 -AFO:0.32	fair
Abe(2009)[37]	Randomized clinical trial (quasi-experimental)	16 individuals (M:11, F:5) with chronic stroke, ability to walk at least 8m, mean age: 55.9years, mean time from stroke: 49.5months, BS:3-4, passive ROM for ankle dorsiflexion: 0-20, FAC: 3-4, MAS: nr	Chronic	At least 2 weeks	-PLS-AFO (n:9) -AFO-PS (n:7)	FAC(score)	- No AFO:0.30 (0.13) -AFO:0.38 (0.11)	poor
Tyson(2001)[35]	Randomized clinical trial (quasi-experimental)	25 individuals (M:16, F:9) with subacute/chronic stroke, ability to weight bear and step with weak leg (but may be unable to have a functional gait pattern), mean age: 49.9 years, mean time from stroke: 8.3months, MAS: nr	Subacute/chronic	Participants wore an AFO in everyday life for at least 1 month before testing	AFO-PS	FAC(score)	- No AFO: 0.18 (0.1) -AFO: 0.25 (0.1)	fair
Assawapalangchai(2017)[38]	Randomized clinical trial (quasi-experimental)	21 individuals (M:13, F:8) with subacute/chronic stroke, able to walk at least 10 meters with intermittent support, but without standby assistance, mean age: 59.8 years, time from stroke: 3-39months, MAS: nr	Subacute/chronic	2-week for familiarization	Flexible AAFO	FAC(score)	- No AFO: 0.13 (0.063) -AFO: 0.13 (0.061)	fair

De Sèze(2011)[50]	Randomized, parallel-group controlled design (RCT)	28 individuals (M: 18, F: 10) with subacute stroke and plantar flexion spasticity undergoing rehabilitation care, able to walk >10 m - SG (Chignon AFO): 13 subjects (M:11, F:2), mean age:56.4 years, mean time from stroke:104.4 days - CG (PLS-AFO): 15 subjects (M:7, F:8), mean age: 53 years, mean time from stroke: 56 days MAS ≥ 3	Subacute	30 and 90 days of follow-up	-Chignon AFO: SG -PLS-AFO: CG	-FAC(score) - Motricity index (score) -Spasticity (score) -FIM (score)	- No AFO in day 0: Chignon AFO group: 0.10*; AFO-PLS group: 0.12* - With AFO in day 30: Chignon AFO group: 0.25*; AFO-PLS group: 0.16* - With AFO in day 90: Chignon AFO group: 0.30*; AFO-PLS group: 0.22*	fair
Pavlik (2008)[39]	Randomized clinical trial (quasi-experimental)	4 individuals (M: 3, F: 1) with chronic stroke, ability to independently ambulate with and without their AFO (the use of other assistive devices was permitted for safety), mean age: 60years, mean time from stroke: 75months, MAS: nr	Chronic	Participants wore an AFO for at least 6 months before study	-RAFO: Right hemiplegia -AFO-PS: left hemiplegia	TUG (s)	- No AFO: 0.33(0.27) -AFO: 0.55(0.39)	poor
de Wit (2004)[51]	Randomized, parallel-group controlled design (RCT)	20 individuals (M:12, F:8) with chronic stroke, ability to walk independently recruited from rehabilitation centers, mean age: 61years, mean time from stroke: 26 months, MAS: nr Group I: walking with AFO (n:10) Group II: walking without AFO (n:10)	Chronic	All wore an AFO in everyday life for at least 6 months	PAFO (PLS-AFO or RAFO)	-TUG (s) -Stairs (TUS and TDS) (s) -Motricity index(score) - FAC(score)	-No AFO:0.44(0.24) -AFO:0.49(0)	fair
Pardo (2015)[40]	Randomized clinical trial (quasi-experimental)	14 chronic stroke subjects (M:9, F:5), able to bear weight and step with the paretic leg, mean age: 55.7years, mean time from stroke: 13.5months, ability to achieve a neutral ankle (at least 0 degrees of dorsiflexion), MAS: nr	Chronic	Current use of a custom-made AFO, time: nr -Prefabricated AFO-PS: immediate	-Custom-made AFO-PS -Prefabricated AFO-PS	TUG(s)	-No AFO:0.53(0.07) -Custom-made AFO-PS: 0.66 (0.08) -Prefabricated AFO-PS: 0.63 (0.07)	poor
Sankaranarayanan(2016)[26]	Non- clinical trial (quasi-experimental)	26 (M:21, F:5) individuals with chronic and sub-acute stroke undergoing rehabilitation care, able to complete the walk tests, mean age: 41.6years, mean time from stroke: 196.7 days (minimum 6 weeks but not more than 1y), MAS:+1	Subacute/chronic	At least 2 weeks to get familiar with an AFO in rehabilitation center	RAFO	-Mobility FIM(score) -6MWT(m) -Spasticity (score)	-No AFO on admission: 0.40 -AFO on discharge: 0.51 - No AFO on discharge: 0.45	poor
Yue (2013)[56]	Randomized clinical trial (quasi-experimental)	20 individuals (M:11, F:9) with sub-acute stroke, ability to walk at least 10 m without assistance, mean age:55.3years, mean time from stroke: 5–15 weeks, BS: 3–5, MAS: nr	Subacute	30-minute sessions, twice a day, for 5 days	Molded plastic PAFO	-FAC(score) -BBS (score)	-No AFO: 0.48(0.19) -AFO: 0.59(0.21)	poor

Nikamp(2017)[47]	Randomized, parallel-group controlled design (RCT)	33 individuals (M:20, F:13) with (sub)acute stroke undergoing rehabilitation care, mean age:57.2years, mean time from stroke:31.4days. -Early group (at inclusion; week 1) :16 -Delayed group (eight weeks later; week 9): 17, MAS: nr	Subacute	Six-month clinical effects of early or delayed provision of an AFO	-PLS-AFO -RAFO	-FAC (score) -TUG(s) -6MWT(m) -Stair (TUS) (s) -BBS (score) -Motricity Index (score) -Barthel Index (score) -Rivermead Mobility Index (score)	-Early: no AFO: 0.16 (0.22), with AFO: 0.70 (0.36) -Delayed: no AFO: 0.22 (0.31), with AFO: 0.66 (0.31)	good
Nikamp(2017)[48]	Randomized, parallel-group controlled design (RCT)	33 individuals (M:20, F:13) with (sub)acute stroke undergoing rehabilitation care, mean age:57.2years, mean time from stroke:31.4days, Motricity index: 30.3 -Early group (at inclusion; week 1) :16 -Delayed group (eight weeks later; week 9): 17, MAS: nr	Subacute	Two weeks clinical effects of early or delayed provision of an AFO	-PLS-AFO -RAFO	-FAC(score) -TUG(s) -6MWT(m) -Stair (TUS) (s) -BBS(score) - Motricity index (score) -Barthel Index (score) -Rivermead Mobility Index (score)	-Early: no AFO: 0.16 (0.22), with AFO: 0.40 (0.31) -Delayed: no AFO: 0.22 (0.31), with AFO: 0.48 (0.25)	good
Shin(2017)[27]	Non- clinical trial (quasi-experimental)	15 individuals (M:9, F:6) with chronic stroke, mean age: 58.53years, mean time from stroke: 10.53months, BS: 3–5, MAS: nr	Chronic	Immediate	-Traditional PAFO -AFO-PS	-TUG (s) -FRT (cm)	-PAFO:0.40* -AFO-PS: 0.53*	poor
Karakatıl(2018)[42]	Randomized clinical trial (quasi-experimental)	20 individuals (M:11, F:9) with subacute stroke, able to walk 20 feet without or with assistive device, mean age: 57.5years, mean time from stroke: 60days, MAS: nr	Subacute	One-week practice	- PLS-AFO -AFO-PS (DA)	6MWT (m)	-Baseline: AFO-PLS: 0.58(0.26), AFO-PS: 0.58(0.26) -After 1 week: PLS:0.66 (0.27), AFO-PS:0.70 (0.29)	fair
Hale(2013)[32]	Non- clinical trial (quasi-experimental)	5 individuals (M: 2, F: 3) with chronic stroke, able to walk at least 10m with supervision or assistive device, mean age: 56years, mean time from stroke: 25.4 months MAS: nr	Chronic	Immediate	Ground reaction design AFO	-TUG (s) -6MWT(m)	- No AFO: 0.53* -AFO: 0.82*	poor

Cakar(2010)[28]	Non- clinical trial (quasi-experimental)	25 individuals (M:17, F:8) with chronic stroke, ability to ambulate without assistive device, mean age: 60.52years, mean time from stroke: 20.32months, MAS:1-2, BS:2-3	Chronic	One week	PLS-AFO	BBS (score)	nr	fair
Wang(2005)[43]	Randomized clinical trial (quasi-experimental)	-42 subjects (M:23, F:19) with short duration stroke (<6 months), able to ambulate for 10m with or without assistive device, mean age: 60.52years, mean time from stroke: 101.0days, MAS:1-2, BS:2-3 -61 subjects (M:51, F:10) with long duration stroke (> 12 months), mean age: 59.9y, mean time from stroke: 1043.6days, MAS:1-2, BS: 2-3 -Not stated whether subjects were undergoing rehabilitation	-Subacute -Chronic	Immediate	RAFO	BBS (score)	-Short duration stroke; No AFO: 0.58 (0.29), With AFO: 0.69 (0.41) -Long duration stroke; No AFO: 0.61 (0.27), With AFO: 0.71(0.34)	fair
Sheffler(2006)[29]	Non- clinical trial (quasi-experimental)	14 individuals (M:9, F:5) with chronic stroke, able to walk at least 30 feet with minimal assistance, mean age: 56.7years, mean time from stroke: 30.8months, MAS: <4/5	Chronic	Immediate	-Prefabricated AFO (n:2) -Hinged AFO (n:4) -Plastic AFO (n:8)	mEFAP subscores (floor, carpet, TUG, obstacles and stairs) (s)	-No AFO: 0.33* -AFO: 0.40*	fair
Rao (2016)[30]	Non- clinical trial (quasi-experimental)	23 individuals (M:11, F:12) with chronic stroke, able to ambulate at least 10m with or without assistive devices, mean age: 60.90 years, mean time from stroke: 7.8months, MAS:>2	Chronic	One month	-PAFO including RAFO (n:12) and PLS-AFO (n:11)	FRT (cm)	nr	fair
Eckhardt (2011)[44]	Randomized clinical trial (quasi-experimental)	19 individuals (M:12, F:7) with subacute stroke, ability to walk minimum 20m in normal shoes with or without assistive device or supervision, mean age: 55 years, mean time from stroke: 3.6months, MAS:1, Motricity index: 53 -subjects were undergoing rehabilitation	Subacute	10 days	-Normal shoes -Orthopaedic shoe	- TUG (s)	-Normal shoes: 0.28 (0.15) -Orthopaedic shoe: 0.37 (0.21)	poor
Tomioka (2017)[31]	Non- clinical trial (quasi-experimental)	27 individuals (M:24, F:3) with chronic stroke undergoing repetitive facilitative exercises, able to walk using a T-cane and/or AFO without an assistance, mean age: 59.3 years, mean time from stroke: 35.7months, BS:4, Motricity index: 53, MAS: nr	Chronic	4 weeks training with an AFO	-RAFO (n:1) -PLS-AFO(n:2) -Hinged AFO (n: 24)	- TUG (s)	- No AFO before training: 0.68 (0.22) -After training with AFO: 0.81 (0.24)	poor
Everaert(2013)[45]	Non- clinical trial (quasi-experimental)	24 individuals (M:16, F:8) with chronic stroke, could ambulate at least 10 m with or without an assistive device, mean age:57years, mean time from stroke: 6.4 months, MAS: nr, FAC ≥4	Chronic	12 weeks	A conventional non-articulated AFO	-Rivermead Mobility Index (score)	-No AFO before training: 0.36 (0.26) -No AFO after training: -With AFO after training:	good

							0.55(0.33)	
Nevisipour(2019) [52]	Non-randomized, parallel-group	32 individuals (18 Non-users, 14 AFO users) with chronic stroke, able to walk 5 minutes without assistance. -Non-users: 18 (M:12, F:6) mean age:54.8years, MAS for soleus: 0.3±0.5 -AFO users: 14 (M:7, F:7), mean age:54.7years, MAS for soleus: 1.0±1.0	Chronic	At least one month	PLS-AFO	- TUG (s) -BBS (score)	-No AFO:1.03 (0.30) -With AFO: 0.96 (0.49)	fair

* Mean walking speed was calculated and estimated using other clinical tests, such as 10-meter walking test (10MWT) and 5-meter walking test (5MWT) because it was not directly reported.

6MWT: 6-Minute Walking Test, AFO: ankle-foot orthosis, AAFO: anterior AFO, AFO-PS: hinged plastic or metal AFO with plantarflexion stop and dorsiflexion free, BS: Brunnstrom stage, BBS: Berg Balance Scale, CAFO: carbon fiber AFO, CG: control group, DA: metal double action joints and metal upright, DAFO: dynamic AFO, F: female, FAC: Functional Ambulatory Categories, FIM: Functional Independence Measure, FRT: Functional Reach Test, PAFO: plastic ankle-foot orthosis, PLS-AFO: posterior leaf spring AFO, PWS: preferred walking speed, M: men, MAS: Modified Ashworth Scale, mEFAP: modified Emory Functional Ambulation Profile, nr: not reported, RAFO: rigid AFO, RS: rocker shoe, SG: study group, SS: standard shoe, TDS: Timed Down-Stairs, TS: Tardieu scale(this scale measures the degree of spasticity), TUG: Timed-Up and Go Test, TUS: Timed Up Stairs,

Figure legends

Figure 1. Flowchart of the articles selection using the PRISMA. AFO: ankle-foot orthosis, FES: functional electrical stimulation

Figure 2. Overall pooled SMD by random-effects model for an AFO versus without an AFO on Berg Balance Scale (a) and Timed Up and Go Test (b). AFO: ankle-foot orthosis, SMD: standardized mean difference. The direction of improvement for Berg Balance Scale is toward positive values and for Timed Up and Go Test is toward negative values

Figure 3. Overall pooled SMD by random-effects model for an AFO versus without an AFO on Functional Ambulation Categories (a) and 6-Minute Walking Test (b). AFO: ankle-foot orthosis, SMD: standardized mean difference. The direction of improvement for both tests is toward positive values

Figure 4. Overall pooled SMD by random-effects model for an AFO versus without an AFO on Timed Up-Stairs (a) and Motricity Index (b). AFO: ankle-foot orthosis, SMD: standardized mean difference. The direction of improvement for Timed Up-Stairs is toward negative values and for Motricity Index is toward positive values

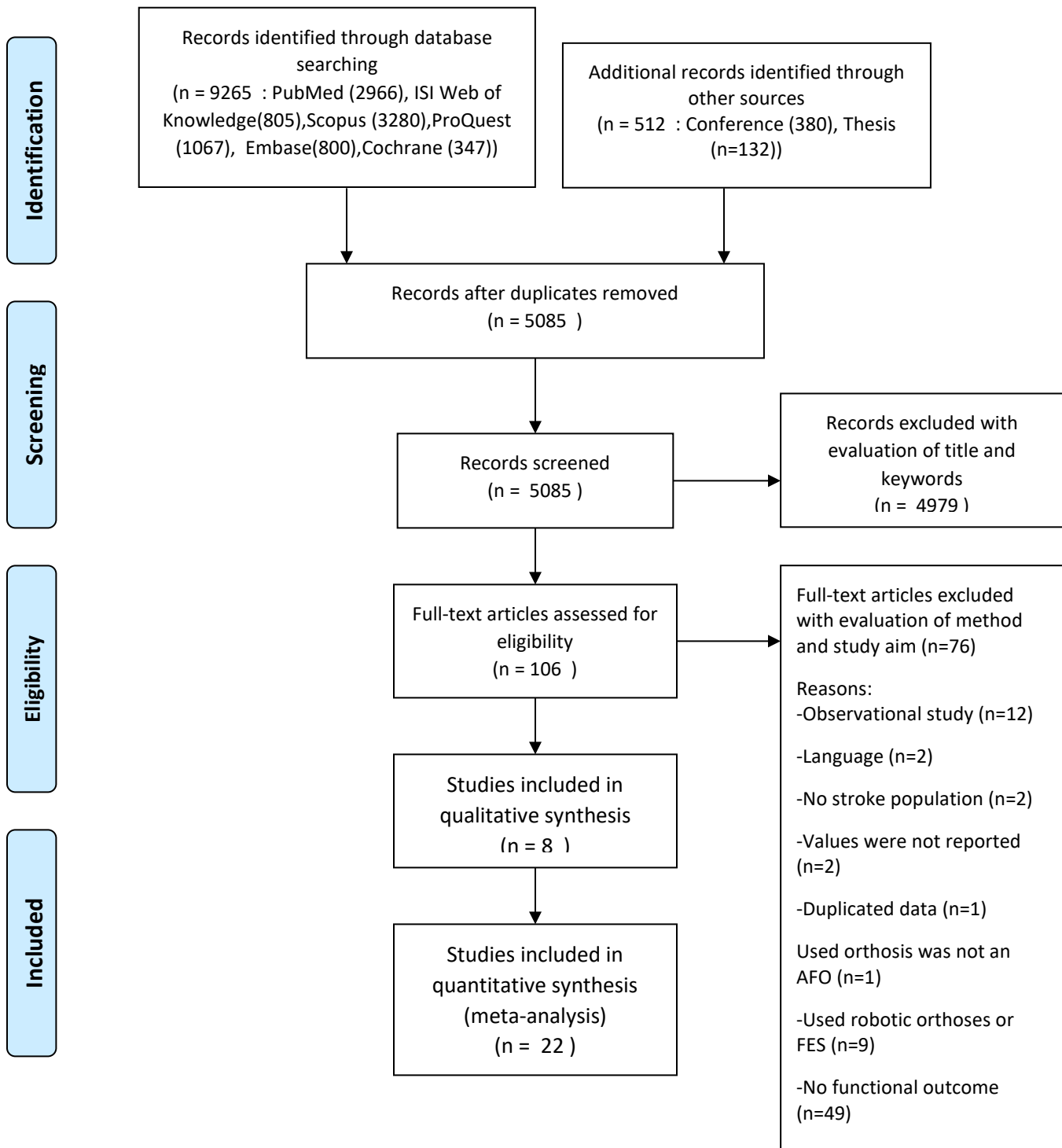


Figure 1. Flowchart of the articles selection using the PRISMA. AFO: ankle-foot orthosis, FES: functional electrical stimulation

Figure 2. Overall pooled SMD by random-effects model for an AFO versus without an AFO on Berg Balance Scale (a) and Timed Up and Go Test (b). AFO: ankle-foot orthosis, SMD: standardized mean difference. The direction of improvement for Berg Balance Scale is toward positive values and for Timed Up and Go Test is toward negative values

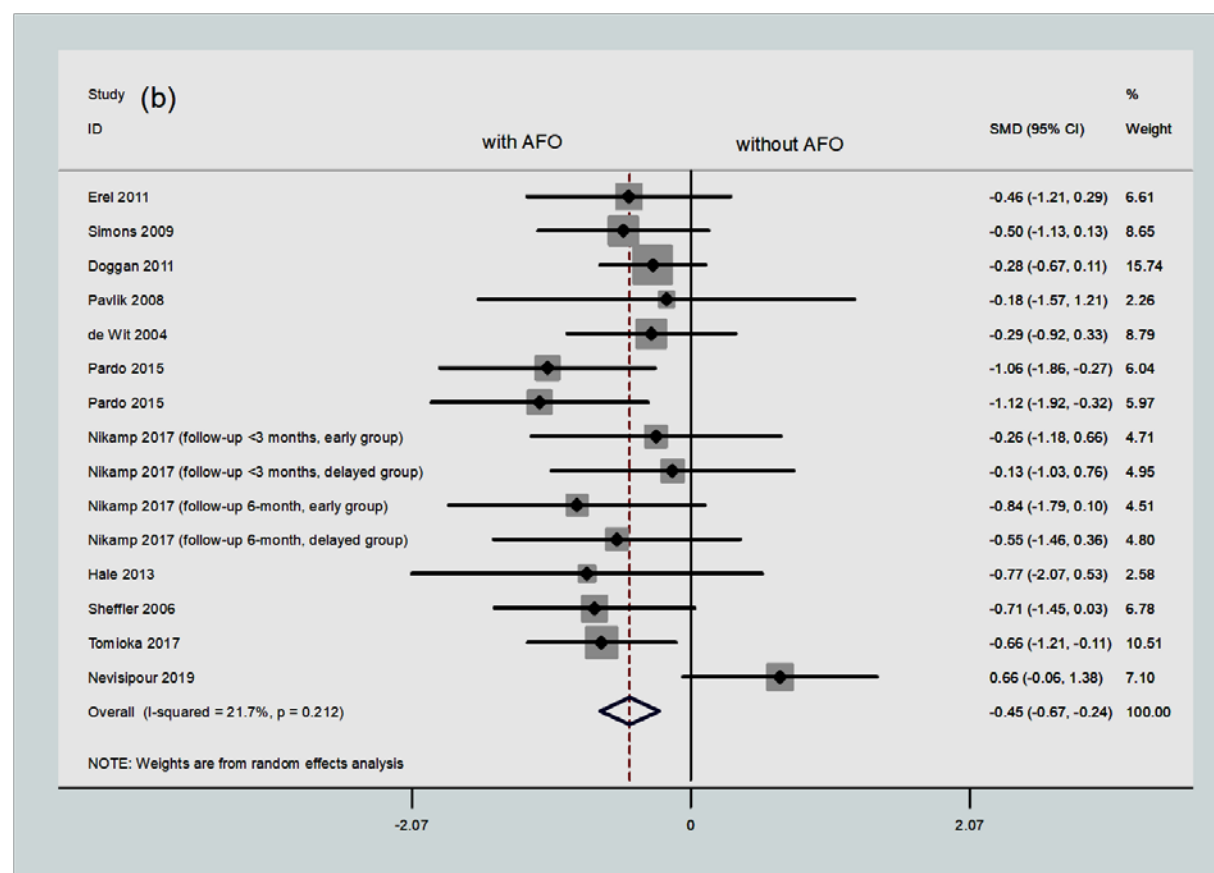
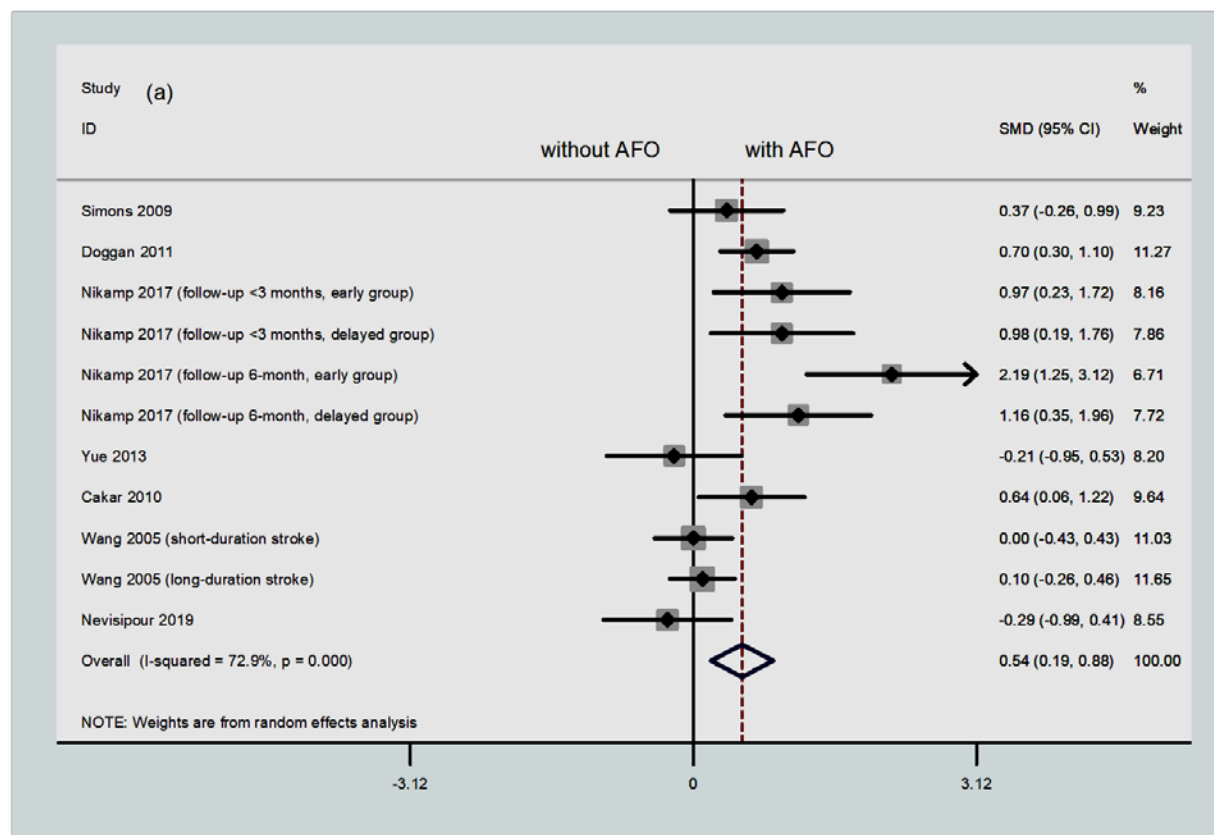


Figure 3. Overall pooled SMD by random-effects model for an AFO versus without an AFO on Functional Ambulation Categories (a) and 6-Minute Walking Test (b). AFO: ankle-foot orthosis, SMD: standardized mean difference. The direction of improvement for both tests is toward positive values

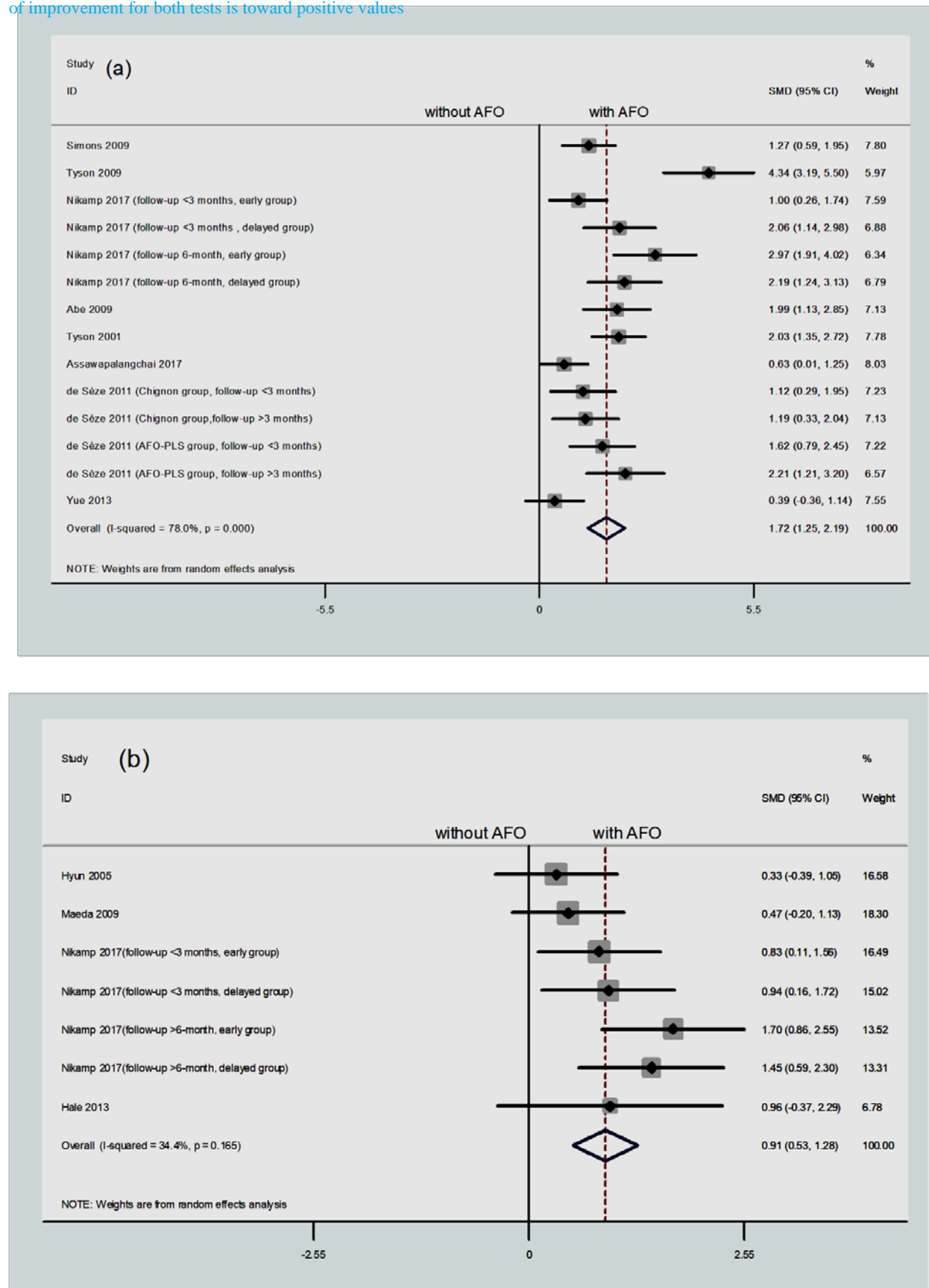
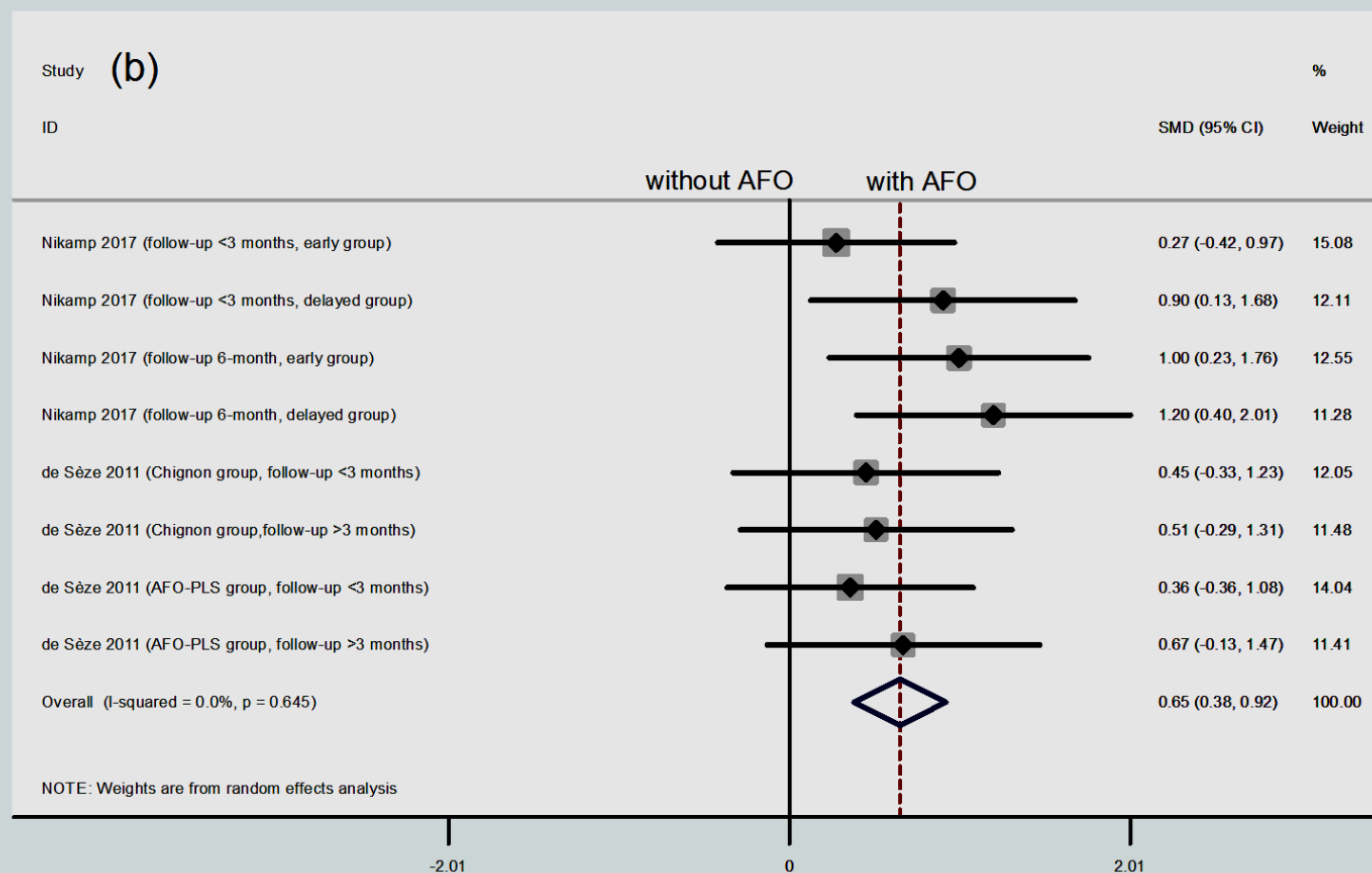
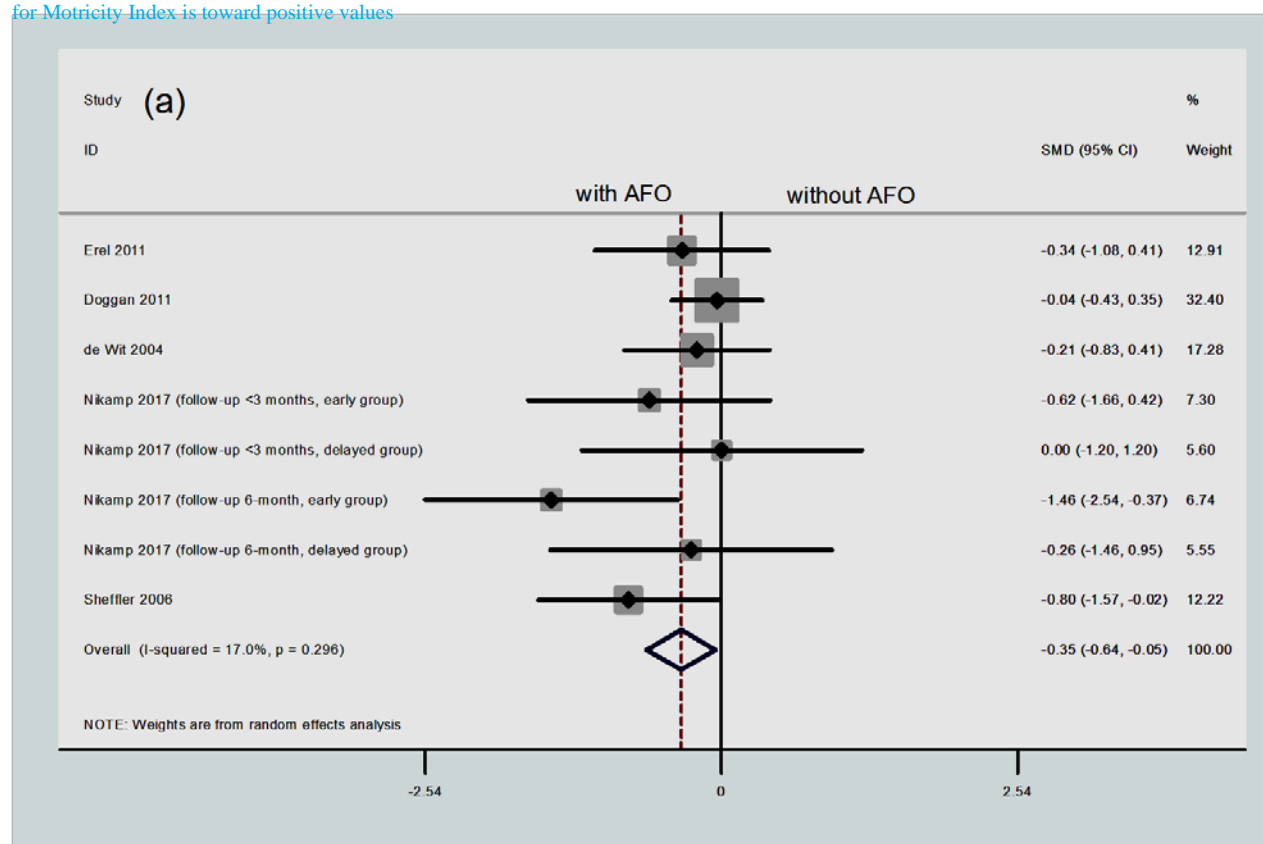


Figure 4. Overall pooled SMD by random-effects model for an AFO versus without an AFO on Timed Up-Stairs (a) and Motricity Index (b). AFO: ankle-foot orthosis, SMD: standardized mean difference. The direction of improvement for Timed Up-Stairs is toward negative values and for Motricity Index is toward positive values



Implications for rehabilitation

- An AFO can improve functional performance and ambulation in survivors of strokes
- Wearing an AFO in rehabilitation care during the subacute phase post stroke may have beneficial effects on functional outcomes measured.
- There was no evidence as to the effectiveness of specific AFO designs over others.

Supplementary Material

Supplemental Appendix 1: Search strategies

Search strategy for PubMed

(((((("cerebrovascular") OR "CVA") OR "stroke") OR hemi*)) AND (((orthos*) OR "brace") OR "orthotic") OR "caliper")) AND (((((((((((((((((((("stair") OR "ambulatory function") OR "functional ambulation") OR "walking ability") OR "walking capacity") OR "TUG") OR ("Timed Up and Go") OR "six minute") OR "6 minute") OR "6MWT") OR "Functional Reach") OR "Motricity Index") OR "Emory") OR "Barthel Index") OR "Rivermead Mobility Index") OR "Berg Balance Scale") OR "balance") OR "Functional Ambulation Categories") OR "Functional Independence Measure") OR "Spasticity") OR "walking") OR "Step Test") OR "mobility"))

Search strategy for Scopus

(ALL("stroke") OR ALL("cerebrovascular") OR ALL(hemi*) OR ALL("CVA")) AND (ALL("orthotic") OR ALL(orthos*) OR ALL("AFO") OR ALL("brace") OR ALL("caliper") OR ALL("orthotic device")) AND (ALL("mobility") OR ALL("stair") OR ALL("ambulatory function") OR ALL("walking ability") OR ALL("walking capacity") OR ALL("TUG") OR ALL("Timed Up and Go") OR ALL("6 minute") OR ALL("six minute") OR ALL("6MWT") OR ALL("Functional Reach") OR ALL("Motricity Index") OR ALL("Rivermead Mobility Index") OR ALL("Emory") OR ALL("Berg Balance Scale") OR ALL("Functional Ambulation Categories") OR ALL("step test") OR ALL("walking") OR ALL("balance") OR ALL("Functional Independence Measure"))

Search strategy for Web of Science

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Search strategy for Embase

('cerebrovascular disease'/exp OR stroke OR 'hemiplegia'/exp OR 'hemiparesis'/exp OR hemiparetic) AND ('brace'/exp OR 'orthosis'/exp OR 'orthotics'/exp OR 'ankle foot orthosis'/exp OR 'caliper'/exp OR orthoses OR 'orthotic device') AND (mobility OR stair OR 'ambulatory function' OR 'walking ability' OR 'timed up and go test'/exp OR 'six minute walk test'/exp OR 'functional reach'/exp OR 'motricity index'/exp OR emory OR 'berg balance scale'/exp OR 'functional ambulation categories' OR 'step test'/exp OR 'functional independence measure'/exp OR 'spasticity'/exp OR 'rivermead mobility index'/exp OR 'barthel index'/exp)

ProQuest

("Stroke" OR "Cerebrovascular" OR "hemiplegia" OR "hemiparetic" OR "hemiparesis") AND ("Brace" OR "Orthotic Device" OR "orthosis" OR "orthoses" OR "Orthotic" OR "caliper") AND ("mobility" OR "stair" OR "ambulatory function" OR "walking ability" OR "walking capacity" OR "TUG" OR "Timed Up and Go" OR "6MWT" OR "six minute" OR "6 minute" OR "Functional Reach" OR "Berg Balance Scale" OR "Functional Ambulation Categories" OR "Step Test" OR "Functional Independence Measure" OR "Motricity Index" OR "Rivermead Mobility Index" OR "Barthel Index" OR "balance" OR "walking" OR "Spasticity")

Search strategy for Cochrane Central

(Stroke OR Cerebrovascular OR hemiplegia OR hemiparesis OR hemiparetic) AND (Brace OR Orthotic Device OR orthosis OR orthoses OR Orthotic OR caliper) AND (mobility OR stair OR ambulatory function OR walking ability OR walking capacity OR TUG OR Timed Up and Go OR 6MWT OR six minute OR 6 minute OR Functional Reach OR Motricity Index OR Berg

Balance Scale OR Functional Ambulation Categories OR Step Test OR Functional Independence Measure OR Motricity Index OR Rivermead Mobility Index OR Barthel Index OR balance OR walking OR Spasticity)

Supplemental Appendix 2: List of excluded papers

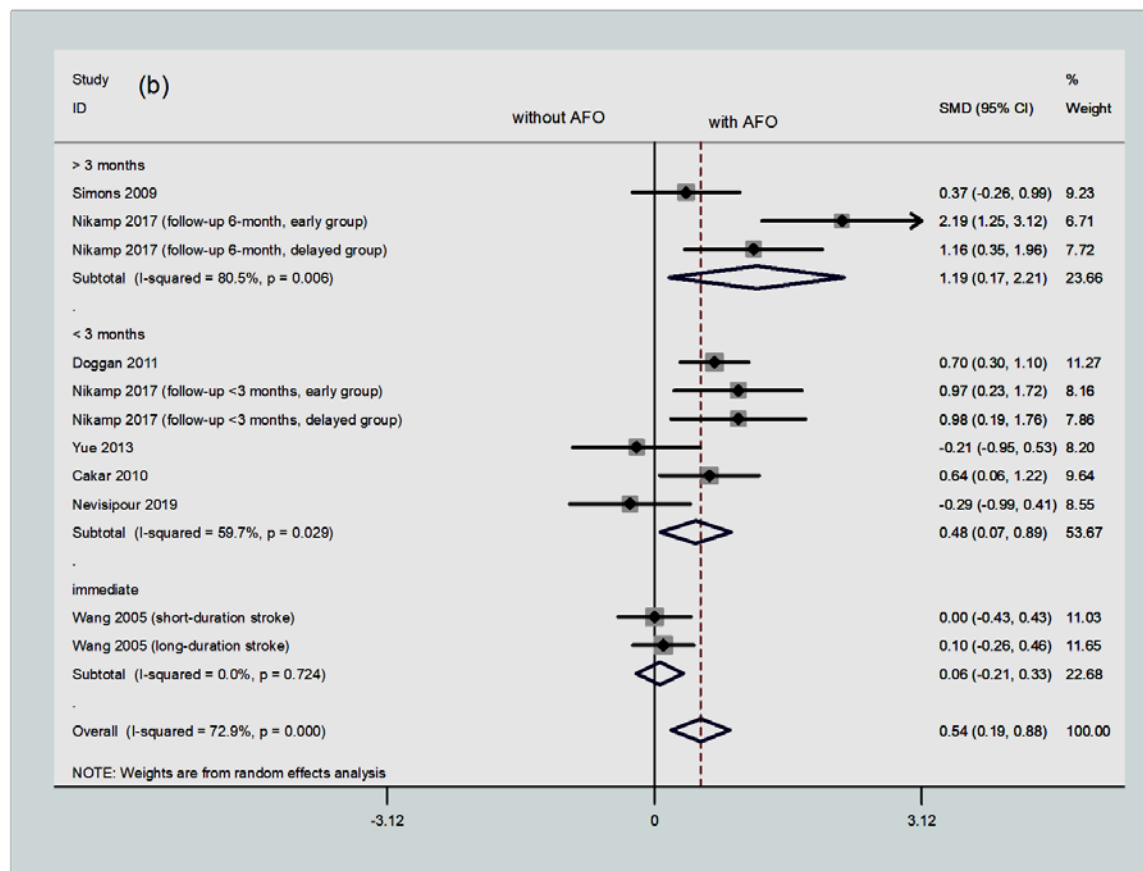
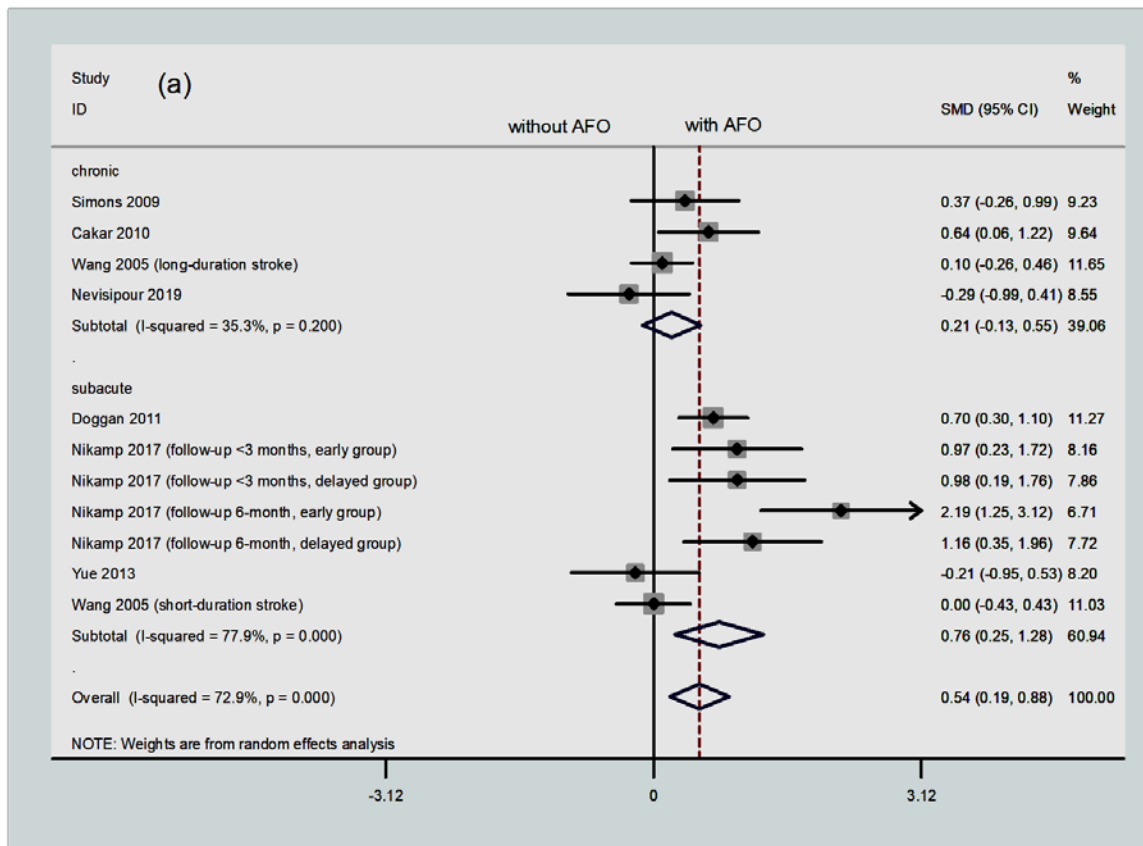
Author (year)	Title	Reason for exclusion
Chen (2014)	Effects of an Anterior Ankle-Foot Orthosis on Walking Mobility in Stroke Patients: Get Up and Go and Stair Walking	Observational study (Retrospective)
Hung (2011)	Long-Term Effect of an Anterior Ankle-Foot Orthosis on Functional Walking Ability of Chronic Stroke Patients	Observational study (Retrospective)
Nolan (2009)	Objective Assessment of Functional Ambulation in Adults with Hemiplegia using Ankle Foot Orthotics after Stroke	Observational study (Retrospective)
BouchaloVál (2016)	The influence of an ankle-foot orthosis on the spatiotemporal gait parameters and functional balance in chronic stroke patients	Observational study (Retrospective)
Maeshima (2017)	Lower Limb Orthotic Therapy for Stroke Patients in a Rehabilitation Hospital and Walking Ability at Discharge	Observational study (Retrospective)
Ota (2018)	Difference in independent mobility improvement from admission to discharge between subacute stroke patients using knee-ankle-foot and those using ankle-foot orthoses	Observational study (Retrospective)
Kesikburun (2017)	Effect of ankle foot orthosis on gait parameters and functional ambulation in patients with stroke	Observational study (Retrospective)
Ota (2018)	Differences in activities of daily living between people with subacute stroke who received knee-ankle-foot and ankle-foot orthoses at admission	Observational study (Retrospective)
Teasell (2001)	Physical and Functional Correlations of Ankle-Foot Orthosis Use in the Rehabilitation of Stroke Patients	Observational study (Retrospective)
Shen (2013)	Early application of front-ankle-foot orthosis affects the walking ability and speed of the patients with hemiplegia after stroke	Observational study (Retrospective)
MURAGUCHI (2013)	The Effect of a Plastic Ankle Foot Orthosis on the Balance and Walking Ability of Community-dwelling Individuals with Chronic Stroke.	Observational study (Retrospective)
Xu (2011)	Effects of Ankle-Foot Orthosis on Gait Stability and Balance Control in Patients With Hemiparetic Stroke	Observational study (Retrospective)
Bregman(2010)	Polypropylene ankle foot orthoses to overcome drop-foot gait in central neurological patients: a mechanical and functional evaluation.	Population (stroke and multiple sclerosis)
DeMeyer (2015)	Effectiveness of a night positioning programme on ankle range of motion in patients after hemiparesis: a prospective randomized controlled pilot study	Population (stroke and brain injury)
McCain (2012)	Ankle-Foot Orthosis Selection to Facilitate Gait Recovery in Adults After Stroke: A Case Series	Values for 6MWT were not reported
Beatrice Janka	Relative influence of orthotic support features within an open frame AFO versus a total contact AFO on function, endurance, and activity level in patients with spastic equinovarus secondary to chronic stroke	Number of patients and values for 6MWT were not reported
Nikamp (2019)	The effect of ankle-foot orthoses on fall/near fall incidence in patients with (sub-)acute stroke: A randomized controlled trial	Duplicated data
Maguire (2012)	How to improve walking, balance and social participation following stroke: a comparison of the long term effects of two walking aids--canes and an orthosis TheraTogs--on the recovery of gait following	Used orthosis was not an AFO

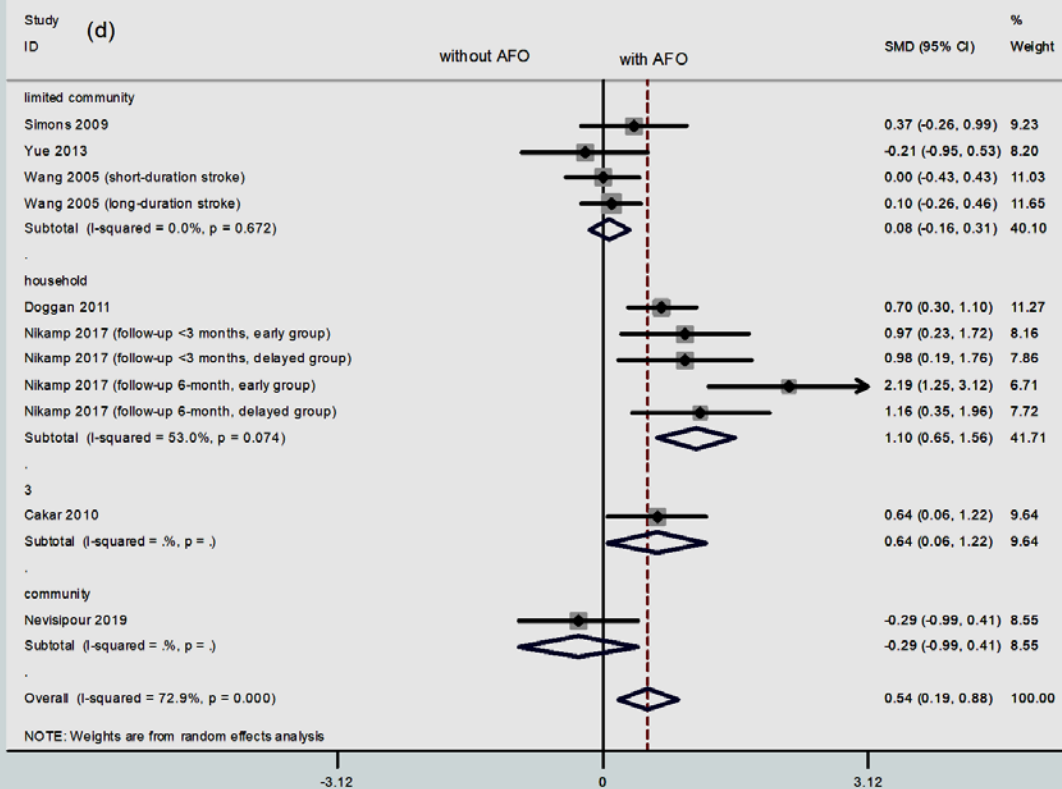
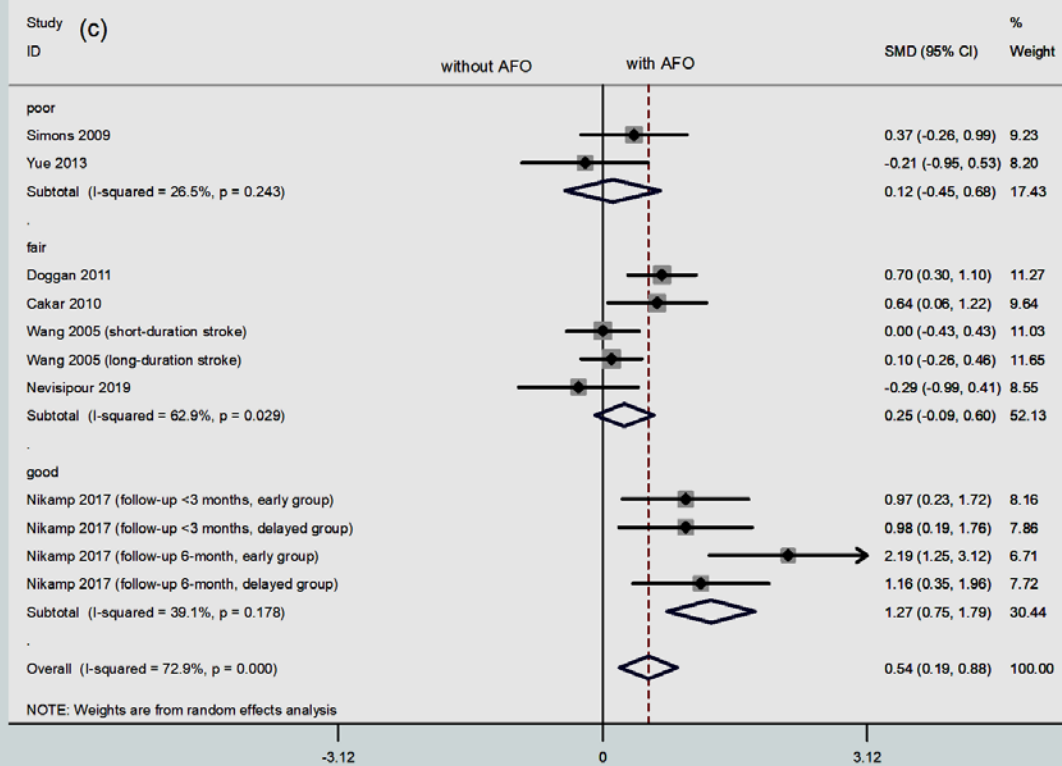
	acute stroke. A study protocol for a multi-centre, single blind, randomised control trial	
Schiemanck(2015)	.Effects of implantable peroneal nerve stimulation on gait quality, energy expenditure, participation and user satisfaction in patients with post-stroke drop foot using an ankle-foot orthosis	Used robotic or FES orthoses
Schiemanck(2015)	peroneal nerve stimulation on gait quality, energy expenditure, participation and user satisfaction in patients with post-stroke drop foot using an ankle-foot orthosis	Used robotic or FES orthoses
Hesse (2012)	Robot-assisted practice of gait and stair climbing in nonambulatory stroke patients	Used robotic or FES orthoses
Rahman(2014)	Asymmetrical Performance and Abnormal Synergies of the Post-Stroke Patient Wearing SCRIPT Passive Orthosis in Calibration, Exercise and Energy Evaluation	Used robotic or FES orthoses
Maeshima(2011)	Efficacy of a hybrid assistive limb in post-stroke hemiplegic patients: a preliminary report	Used robotic or FES orthoses
Ward(2011)	Stroke Survivors' Gait Adaptations to a Powered Ankle Foot Orthosis.	Used robotic or FES orthoses
Stein(2010)	Long-term therapeutic and orthotic effects of a foot drop stimulator on walking performance in progressive and nonprogressive neurological disorders.	Used robotic or FES orthoses
Krewer (2007)	The influence of different Lokomat walking conditions on the energy expenditure of hemiparetic patients and healthy subjects	Used robotic or FES orthoses
Geroïn (2011)	Combined transcranial direct current stimulation and robot-assisted gait training in patients with chronic stroke: a preliminary comparison	Used robotic or FES orthoses
Rao (2014)	The Effects of Two Different Ankle-Foot Orthoses on Gait of Patients with Acute Hemiparetic Cerebrovascular Accident	No functional outcome
Do (2014)	Effect of a Hybrid Ankle Foot Orthosis Made of Polypropylene and Fabric in Chronic Hemiparetic Stroke Patients	No functional outcome
Beckerman (1996)	Walking Ability of Stroke Patients: Efficacy of Tibial Nerve Blocking and a Polypropylene Ankle-Foot Orthosis	No functional outcome
Tyson (2018)	Bespoke versus off-the-shelf ankle-foot orthosis for people with stroke	No functional outcome
Zissimopoulos(2014)	The effect of ankle-foot orthoses on self-reported balance confidence in persons with chronic poststroke hemiplegia	No functional outcome
Iwata (2003)	An Ankle-Foot Orthosis With Inhibitor Bar: Effect on Hemiplegic Gait	No functional outcome
Kobayashi(2015)	The effect of changing plantarflexion resistive moment of an articulated ankle-foot orthosis on ankle and knee joint angles and moments while walking in patients post stroke	No functional outcome
Lewallen (2010)	Effect of three styles of custom ankle foot orthoses on the gait of stroke patients while walking on level and inclined surfaces	No functional outcome
Mehan (2012)	A preliminary study into the immediate effects of ankle foot orthoses of varying design on the walking of people in the early stages of stroke recovery and healthy individuals	No functional outcome
Yamamoto(2011)	Change of rocker function in the gait of stroke patients using an ankle foot orthosis with an oil damper: immediate changes and the short-term effects	No functional outcome
Akezaki (2016)	The Physical Function of Stroke Patients Necessary for an Independent Gait with the Use of an Ankle Foot Orthosis	No functional outcome
CUI(2008)	The effect of ankle-foot orthoses on motor function of the lower extremities about 40 cases of hemiplegic stroke patients	No functional outcome
Kim (2015)	Effect of ankle-foot orthosis on weight bearing of chronic stroke patients performing various functional standing tasks	No functional outcome
Bae (2019)	Effects of dorsiflexor functional electrical stimulation compared to an ankle/foot orthosis on stroke-related genu recurvatum gait	No functional outcome

Bulley (2011)	User experiences, preferences and choices relating to functional electrical stimulation and ankle foot orthoses for foot-drop after stroke	No functional outcome
Lee (2014)	Effect of Ankle-foot Orthosis on Lower Limb Muscle Activities and Static Balance of Stroke Patients Authors' Names	No functional outcome
Chern (2013)	Static ankle-foot orthosis improves static balance and gait functions in hemiplegic patients after stroke	No functional outcome
Zissimopoulos (2014)	Effects of ankle-foot orthoses on mediolateral foot-placement ability during post-stroke gait	No functional outcome
Lee (2020)	Immediate Effects of Ankle-Foot Orthosis Using Wire on Static Balance of Patients with Stroke with Foot Drop: A Cross-Over Study	No functional outcome
Uutela (2003)	The effect of dynamic ankle-foot orthoses on the balance and gait of stroke patients	No functional outcome
Chang (2007)	The effects of anterior and posterior ankle-foot-orthosis on postural stability in stroke patients	No functional outcome
Bleyenheuft(2008)	Assessment of the Chignon dynamic ankle-foot orthosis using instrumented gait analysis in hemiparetic adults	No functional outcome
MULROY (2010)	Effect of AFO design on walking after stroke: Impact of ankle plantar flexion contracture	No functional outcome
Gök(2003)	Effects of ankle-foot orthoses on hemiparetic gait	No functional outcome
Do KH (2014)	Effect of a Hybrid Ankle Foot Orthosis Made of Polypropylene and Fabric in Chronic Hemiparetic Stroke Patients	No functional outcome
Fatone (2009)	Effect of Ankle-Foot Orthosis Alignment and Foot-Plate Length on the Gait of Adults With Poststroke Hemiplegia	No functional outcome
Zollo (2015)	Comparative analysis and quantitative evaluation of ankle-foot orthoses for foot drop in chronic hemiparetic patients	No functional outcome
Park (2009)	Comparison of Gait Analysis Between Anterior and Posterior Ankle Foot Orthosis in Hemiplegic Patients	No functional outcome
Lairamore (2011)	Comparison of tibialis anterior muscle electromyography, ankle angle, and velocity when individuals post stroke walk with different orthoses	No functional outcome
Yamamoto (2018)	Comparison of ankle-foot orthoses with plantar flexion stop and plantar flexion resistance in the gait of stroke patients: A randomized controlled trial	No functional outcome
Kobayashi (2015)	The effect of changing plantarflexion resistive moment of an articulated ankle-foot orthosis on ankle and knee joint angles and moments while walking in patients post stroke	No functional outcome
Kobayashi (2016)	Reduction of genu recurvatum through adjustment of plantarflexion resistance of an articulated ankle-foot orthosis in individuals post-stroke	No functional outcome
Fatone (2007)	Effect of ankle-foot orthosis on roll-over shape in adults with hemiplegia	No functional outcome
Lee(2018)	A novel hinged ankle foot orthosis for gait performance in chronic hemiplegic stroke survivors: a feasibility study	No functional outcome
Kobayashi(2017)	An articulated ankle-foot orthosis with adjustable plantarflexion resistance, dorsiflexion resistance and alignment: A pilot study on mechanical properties and effects on stroke hemiparetic gait	No functional outcome
Ibuki (2010)	An investigation of the neurophysiologic effect of tone-reducing AFOs on reflex excitability in subjects with spasticity following stroke while standing	No functional outcome
Chen (2010)	Kinematic features of rear-foot motion using anterior and posterior ankle-foot orthoses in stroke patients with hemiplegic gait	No functional outcome
Daryabor (2019)	Design and Evaluation of an Articulated Ankle Foot Orthosis with Plantarflexion Resistance on the Gait: a Case Series of 2 Patients with Hemiplegia	No functional outcome
Farmani (2019)	The Influence of Rocker Bar Ankle Foot Orthosis on Gait in Patients	No functional

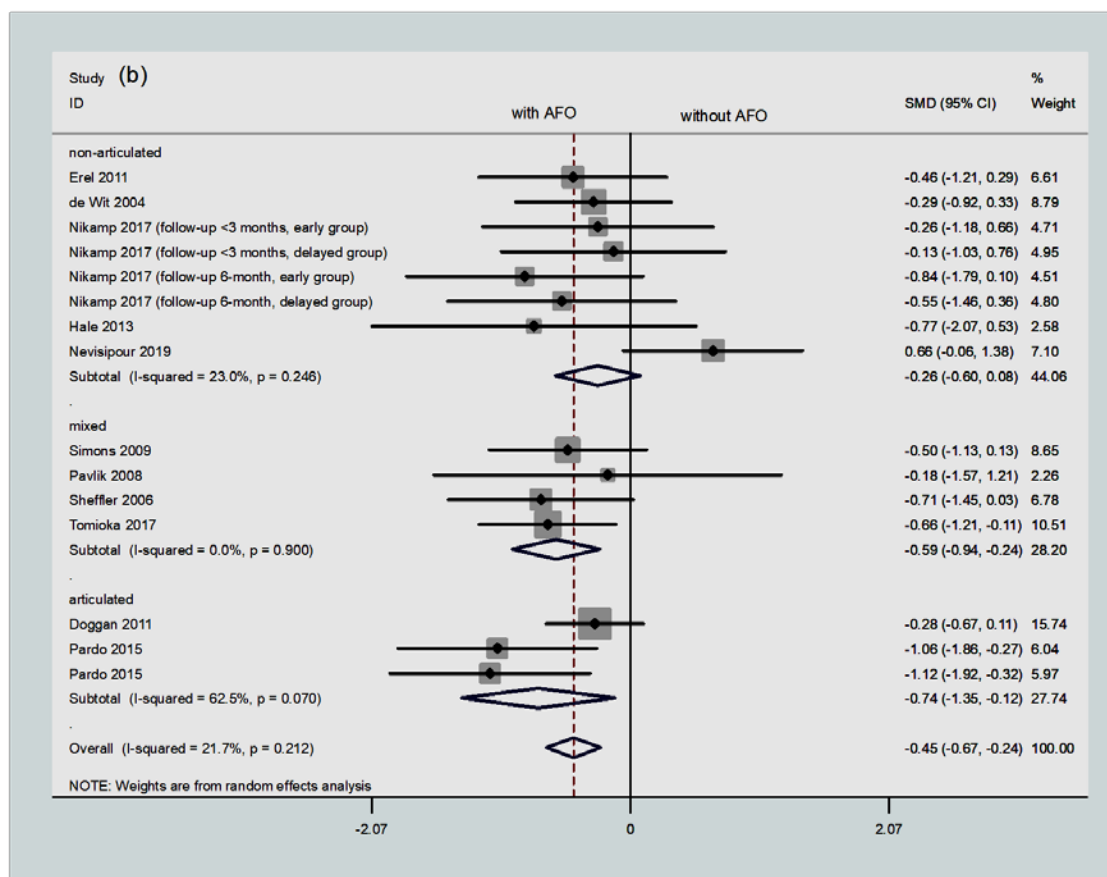
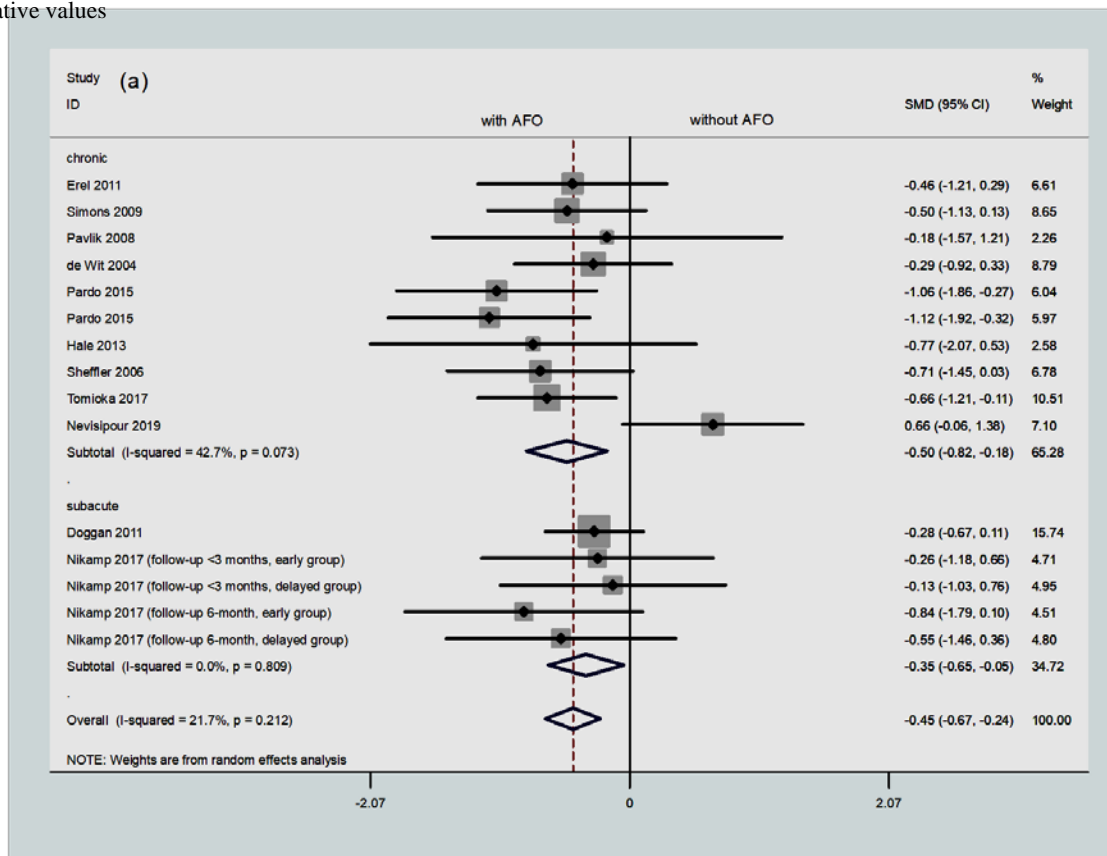
	with Chronic Hemiplegia	outcome
Hesse (1996)	Gait function in spastic hemiparetic patients walking barefoot, with firm shoes, and with ankle-foot orthosis	No functional outcome
Hesse (1999)	Gait function in spastic hemiparetic patients walking barefoot, with firm shoes, and with ankle-foot orthosis	No functional outcome
Jagadamma (2010)	The effects of tuning an ankle-foot orthosis footwear combination on kinematics and kinetics of the knee joint of an adult with hemiplegia	No functional outcome
Nolan (2011)	Weight transfer analysis in adults with hemiplegia using ankle foot orthosis	No functional outcome
Nolan (2011)	Preservation of the first rocker is related to increases in gait speed in individuals with hemiplegia and AFO	No functional outcome
Ohata (2011)	Effects of an ankle-foot orthosis with oil damper on muscle activity in adults after stroke	No functional outcome
Singer (2014)	The effect of ankle-foot orthosis plantarflexion stiffness on ankle and knee joint kinematics and kinetics during first and second rockers of gait in individuals with stroke	No functional outcome
Wang (2007)	Gait and balance performance improvements attributable to ankle-foot orthosis in subjects with hemiparesis	No functional outcome
Yamamoto (2015)	Immediate-term effects of use of an ankle-foot orthosis with an oil damper on the gait of stroke patients when walking without the device	No functional outcome
Yamamoto (2015)	Effects of plantar flexion resistive moment generated by an ankle-foot orthosis with an oil damper on the gait of stroke patients: a pilot study	No functional outcome

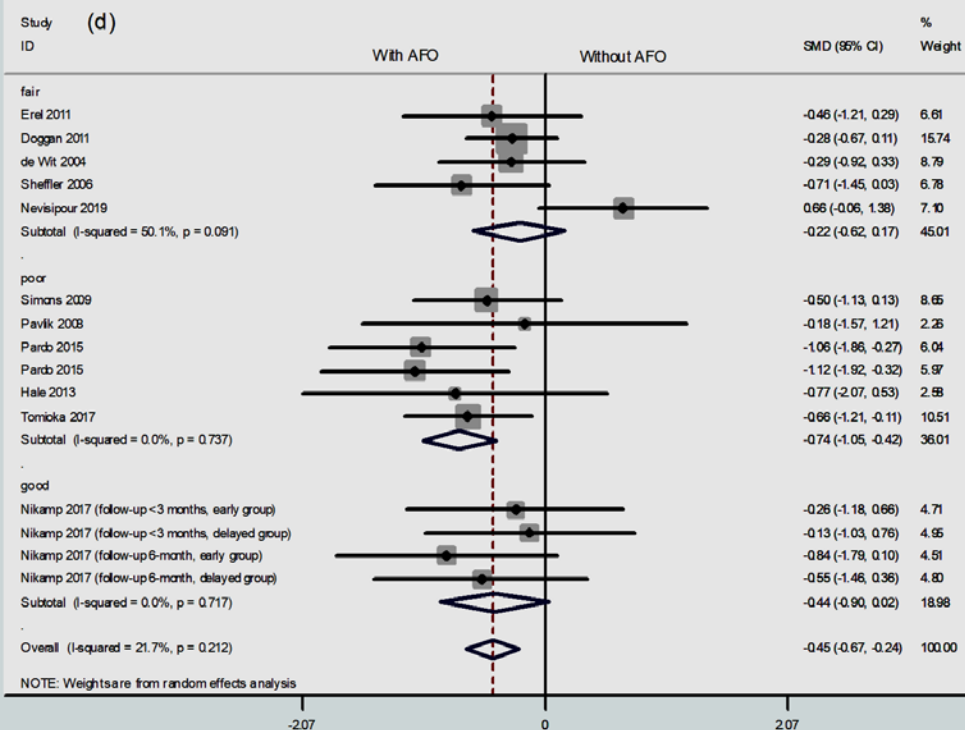
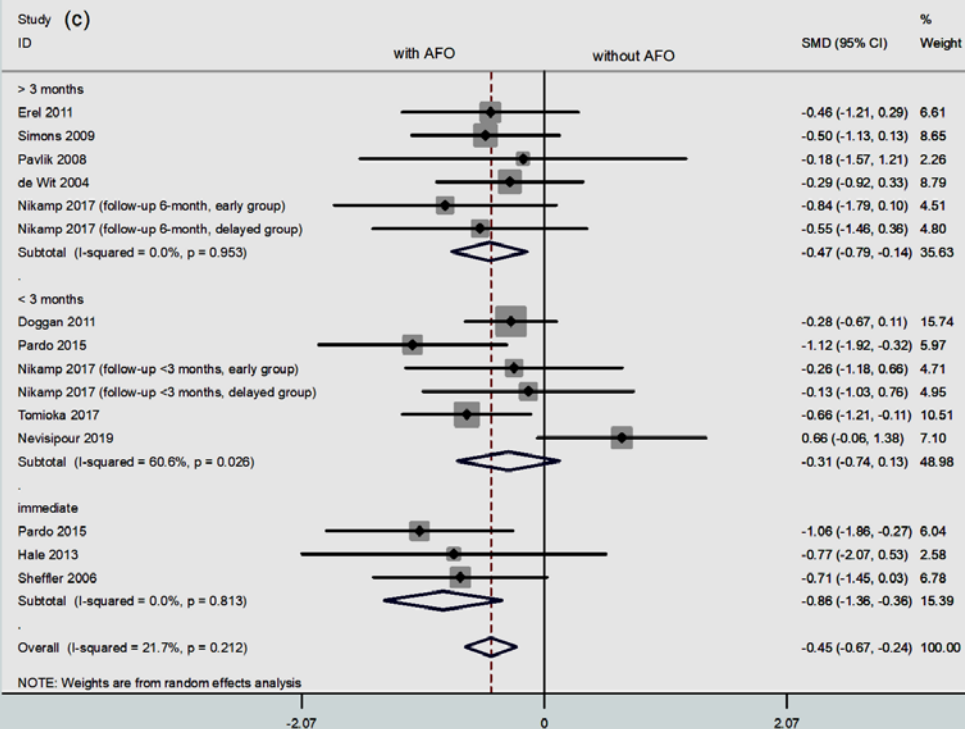
Supplemental Figure 1. Subgroup analysis by random-effects model for an AFO versus without an AFO on Berg Balance Scale: a) stroke phase, b) adaptation time, c) quality status, d) walking speed. AFO: Ankle-Foot Orthosis, SMD: Standardized Mean Difference. The direction of improvement for Berg Balance Scale is toward positive values.



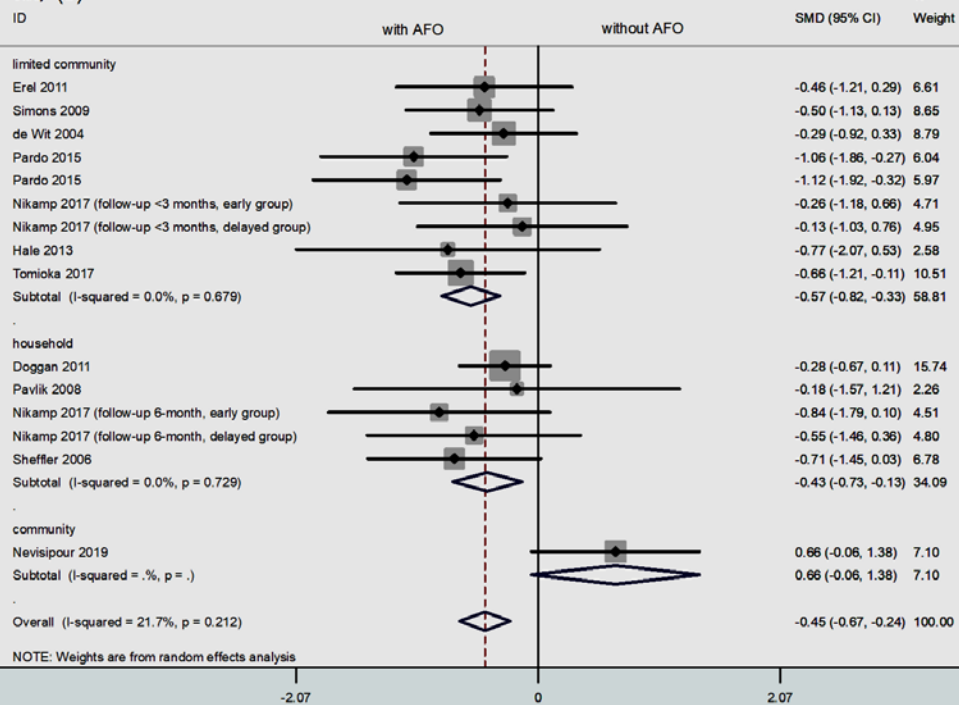


Supplemental Figure 2. Subgroup analysis by random-effects model for an AFO versus without an AFO on Timed Up and Go Test: a) stroke phase, b) AFO type, c) adaptation time, d) quality status, e) walking speed. AFO: Ankle-Foot Orthosis, SMD: Standardized Mean Difference. The direction of improvement for Timed Up and Go Test is toward negative values

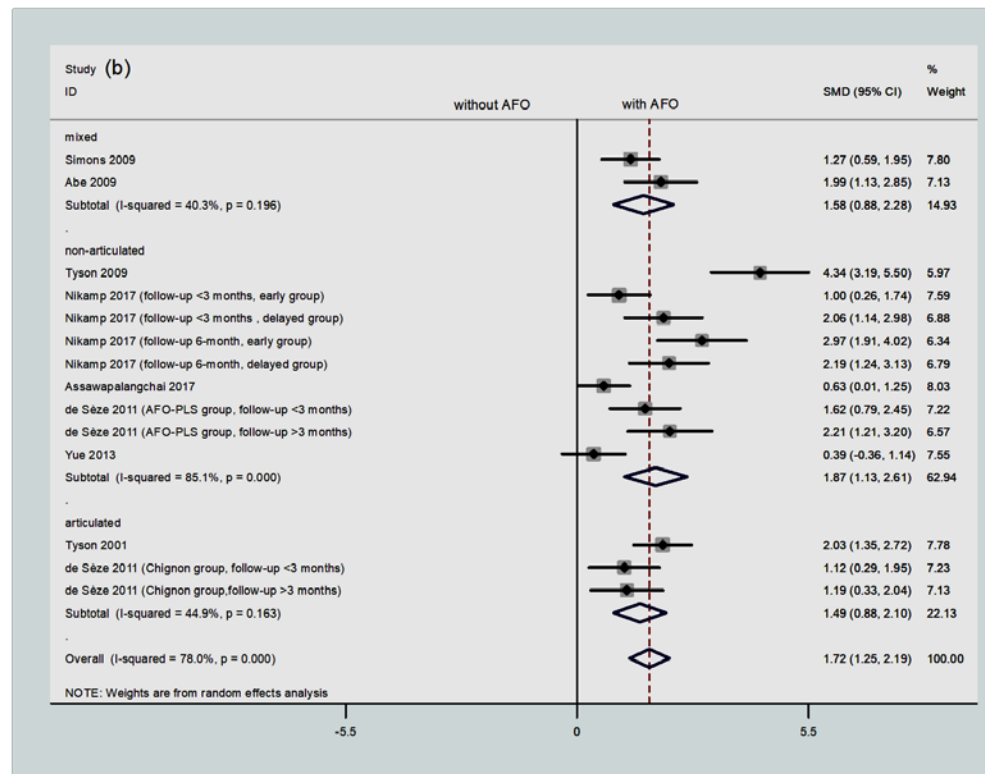
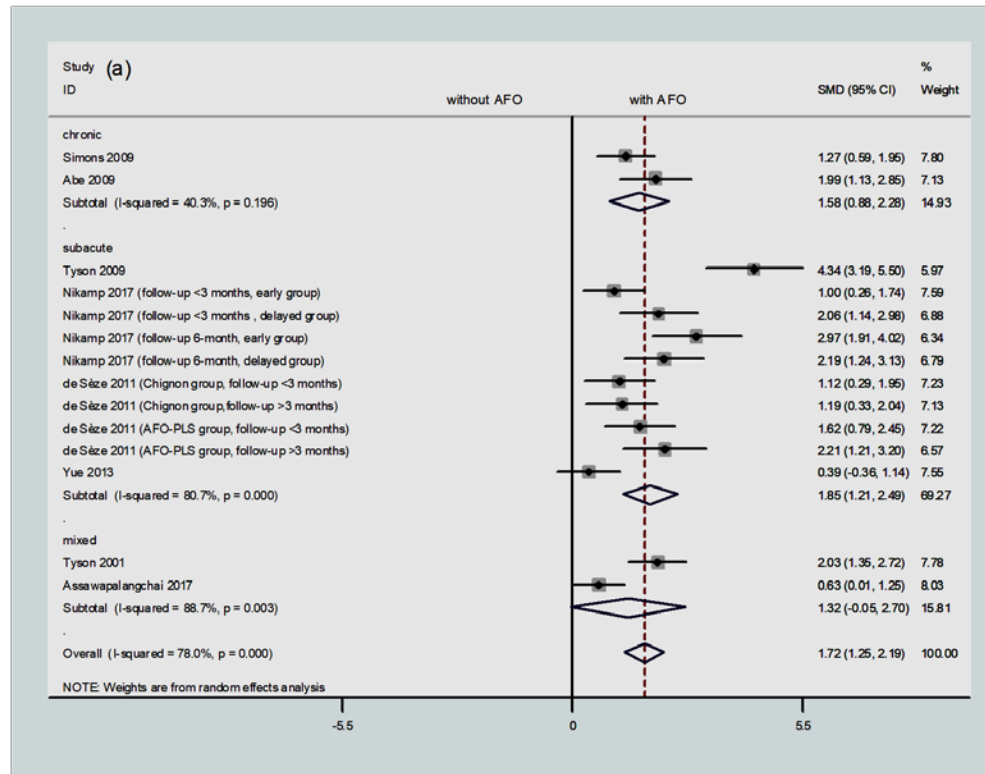




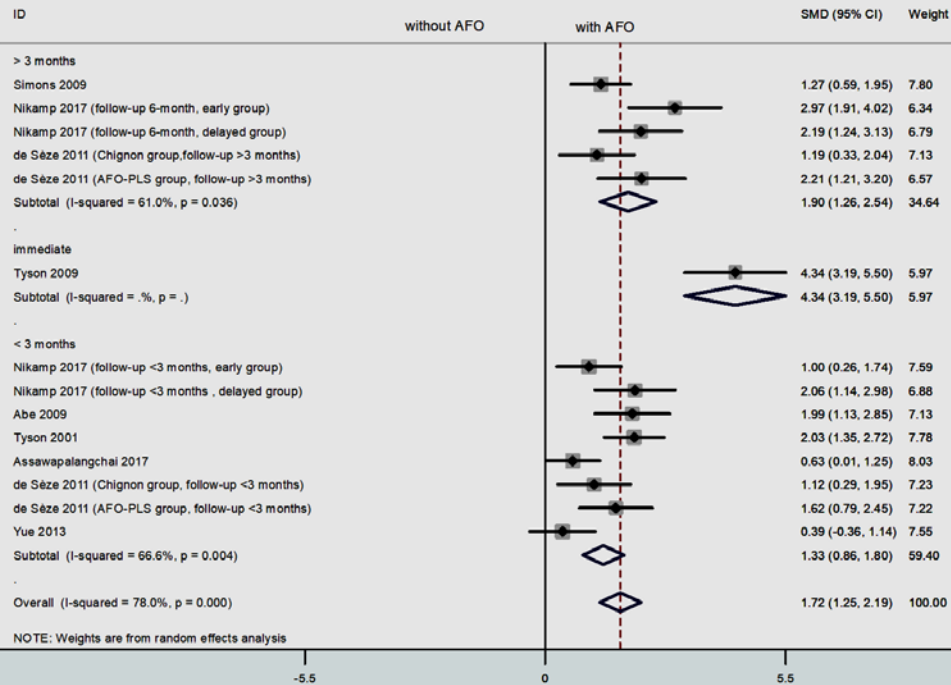
Study (e)



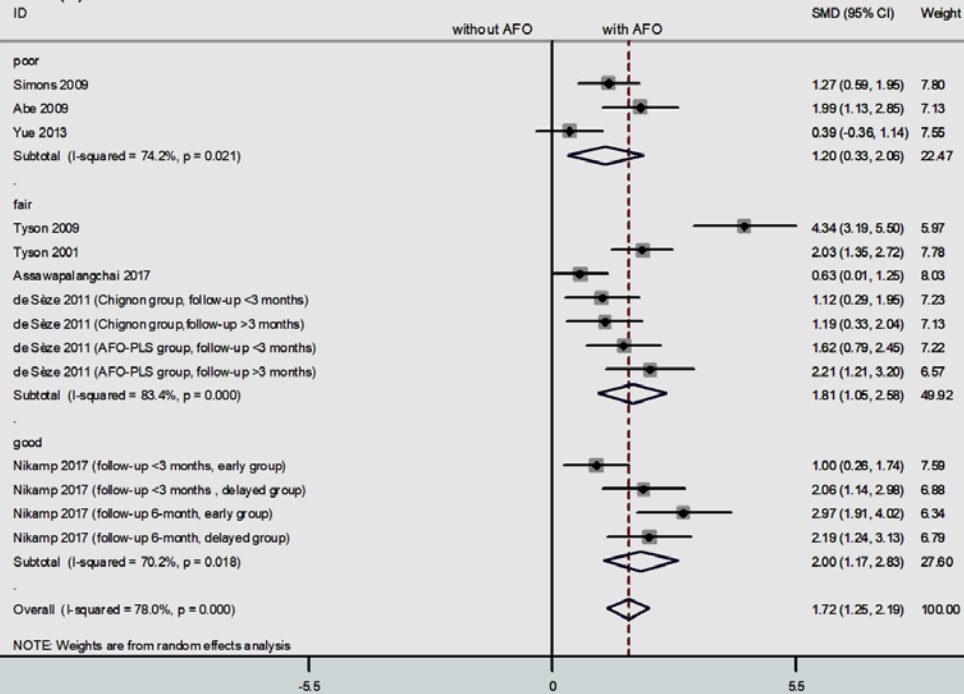
Supplemental Figure 3. Subgroup analysis by random-effects model for an AFO versus without an AFO on Functional Ambulation Categories: a) stroke phase, b) AFO type, c) adaptation time, d) quality status. AFO: Ankle-Foot Orthosis, SMD: Standardized Mean Difference. The direction of improvement for Functional Ambulation Categories is toward negative values.



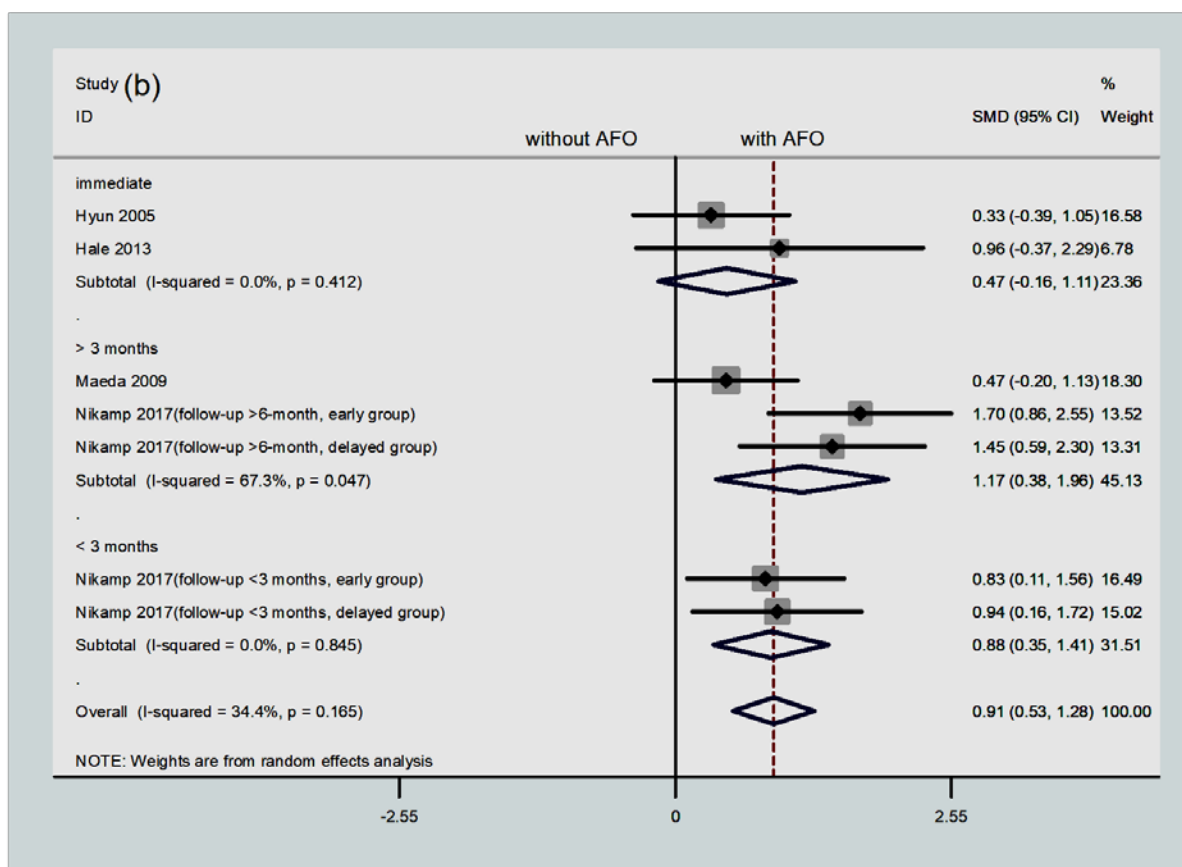
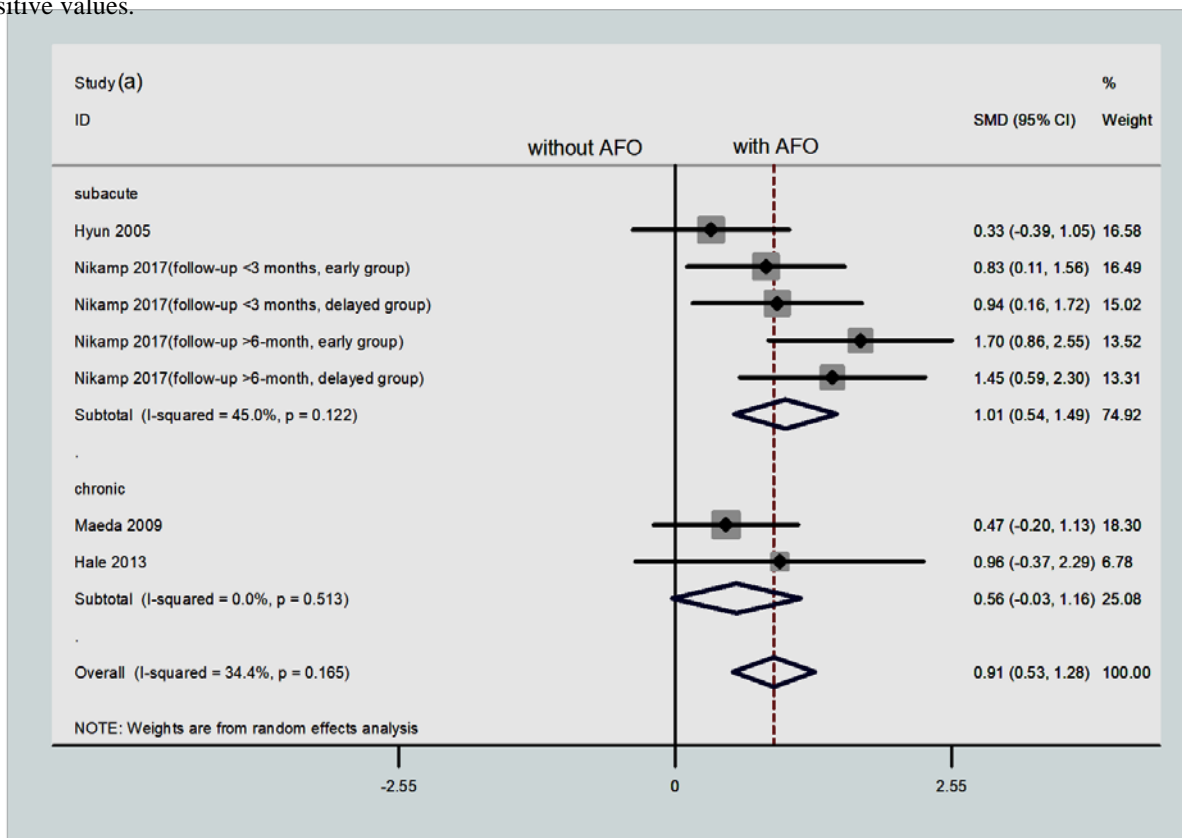
Study (c)

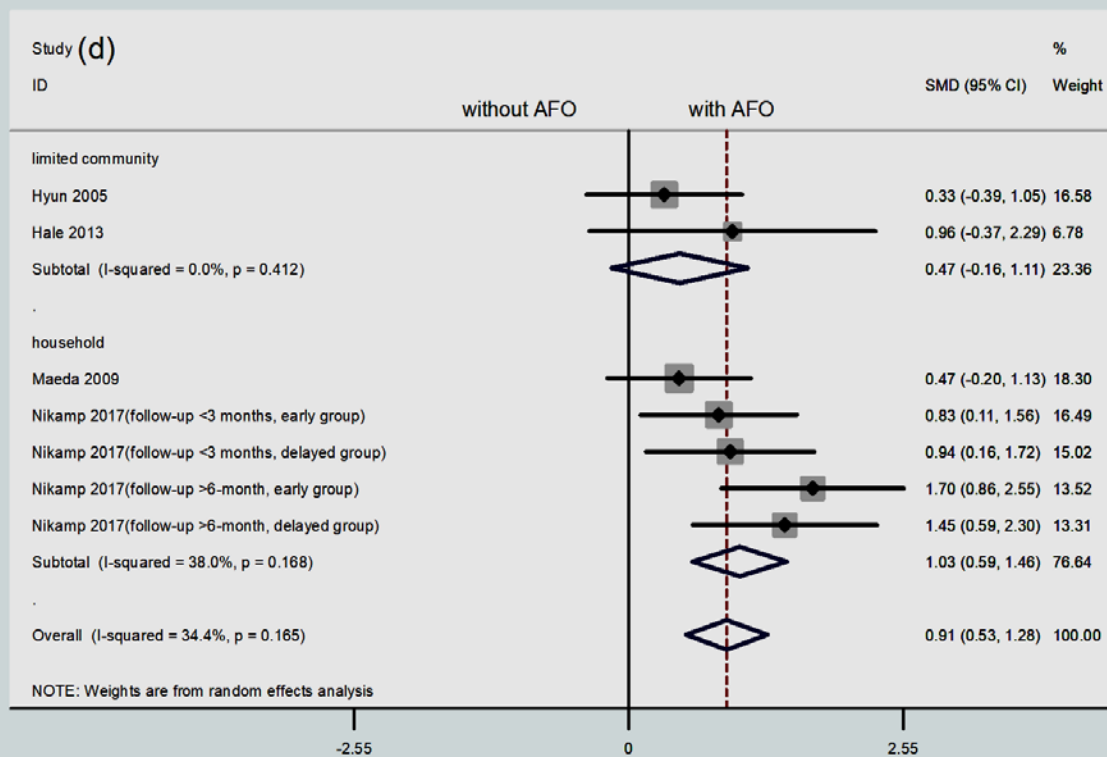
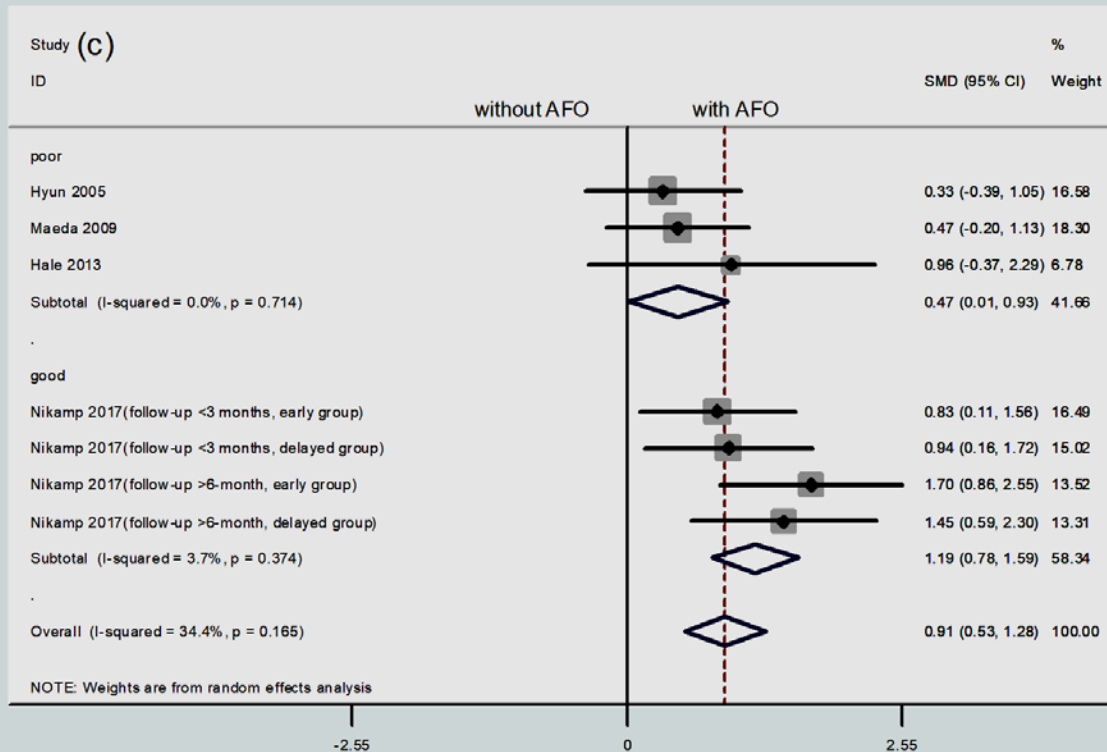


Study (d)

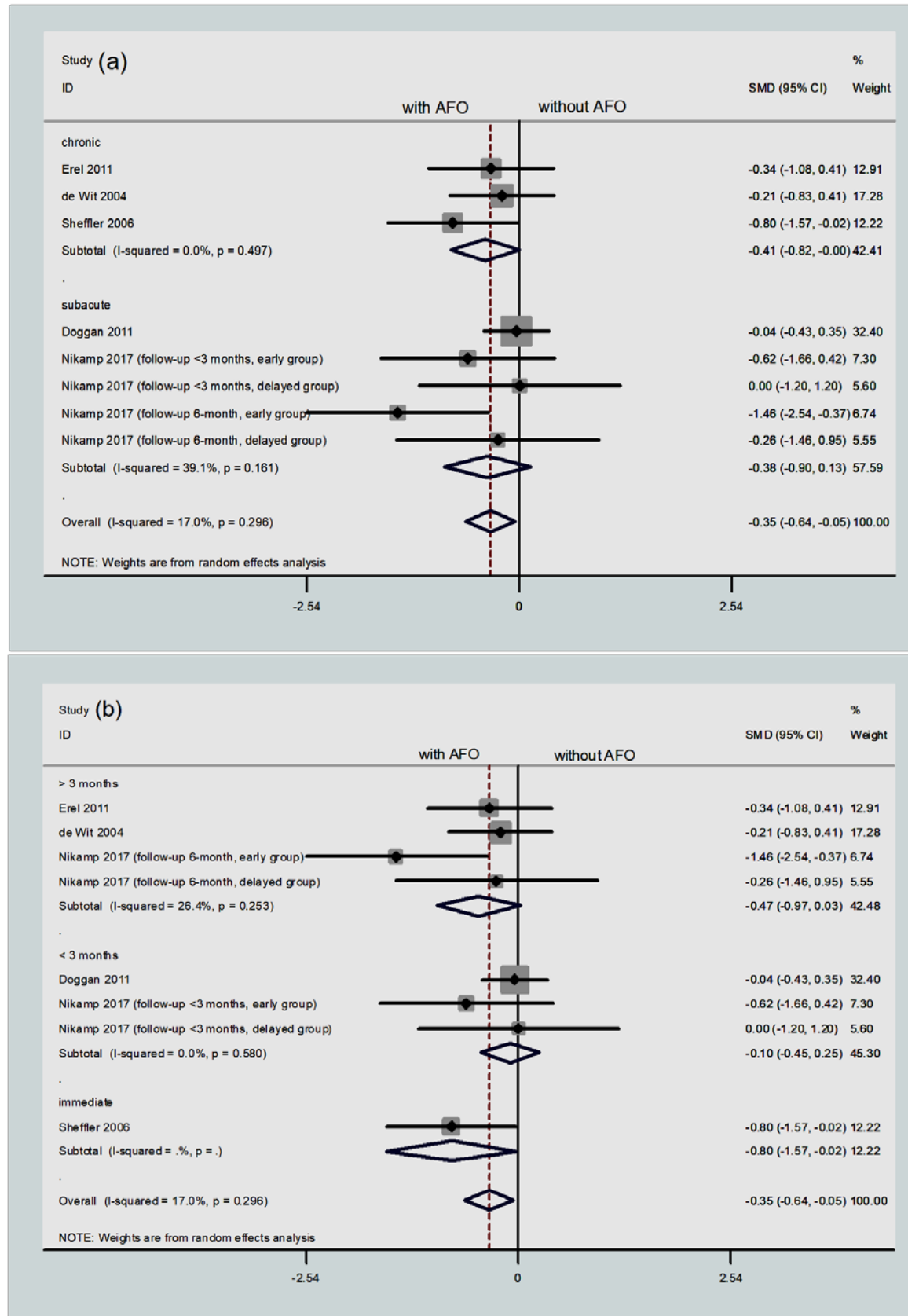


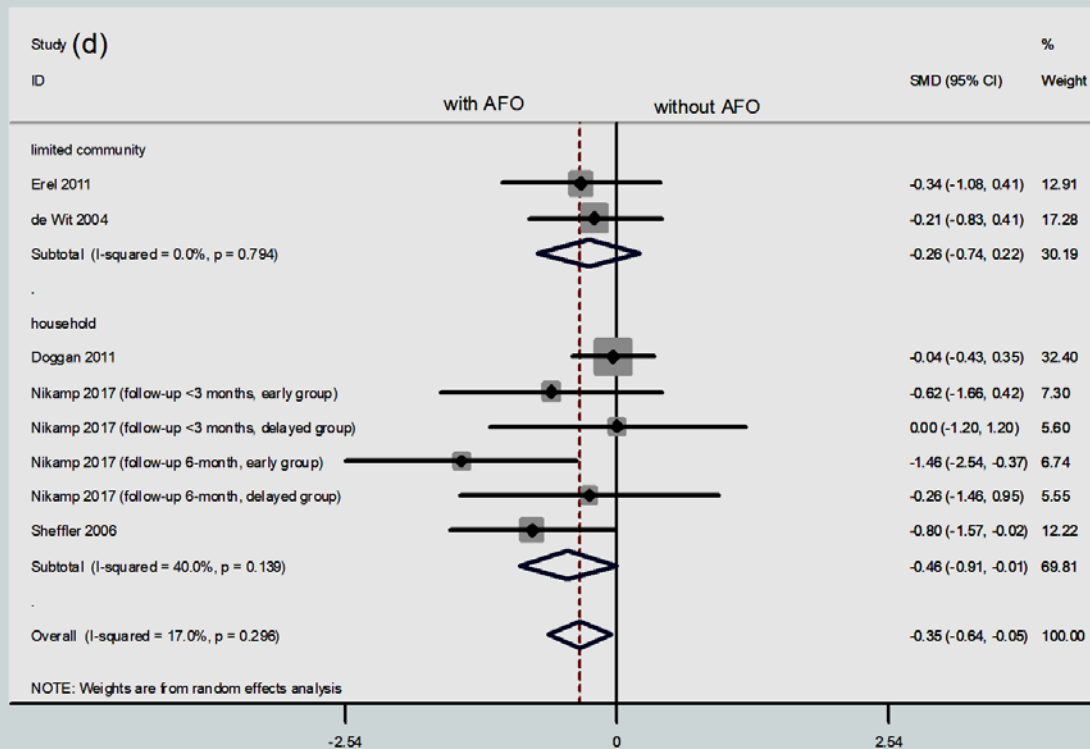
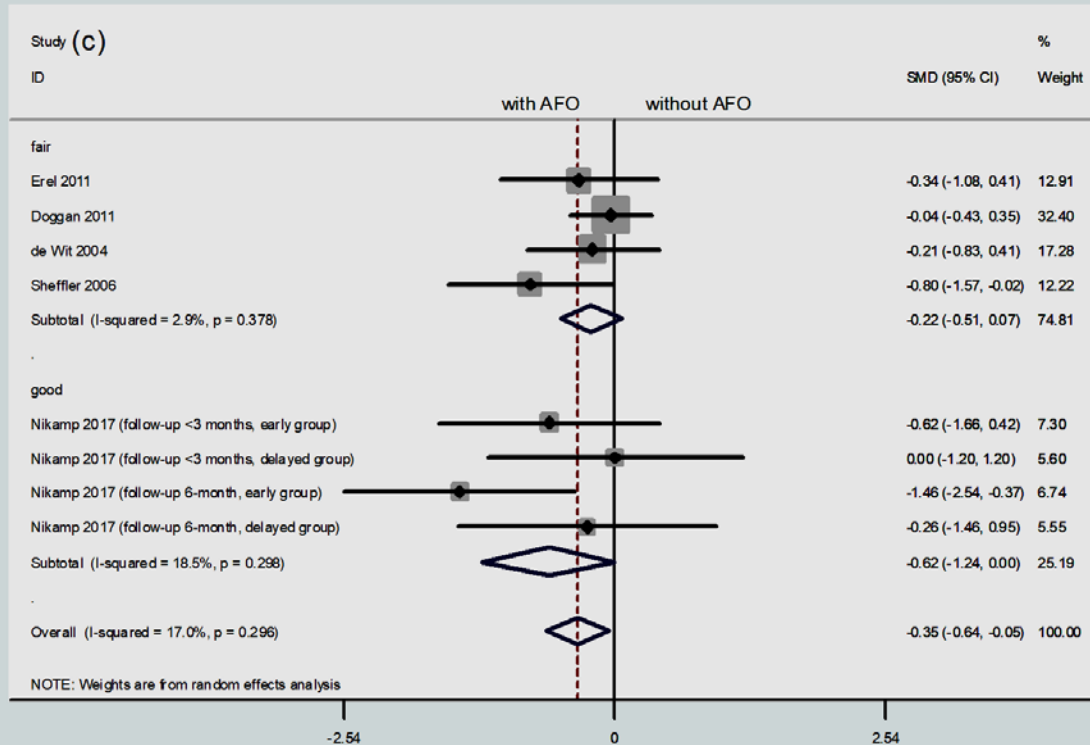
Supplemental Figure 4. Subgroup analysis by random-effects model for an AFO versus without an AFO on 6-Minute Walking Test: a) stroke phase, b) adaptation time, c) quality status, d) walking speed. AFO: Ankle-Foot Orthosis, SMD: Standardized Mean Difference. The direction of improvement for 6-Minute Walking Test is toward positive values.



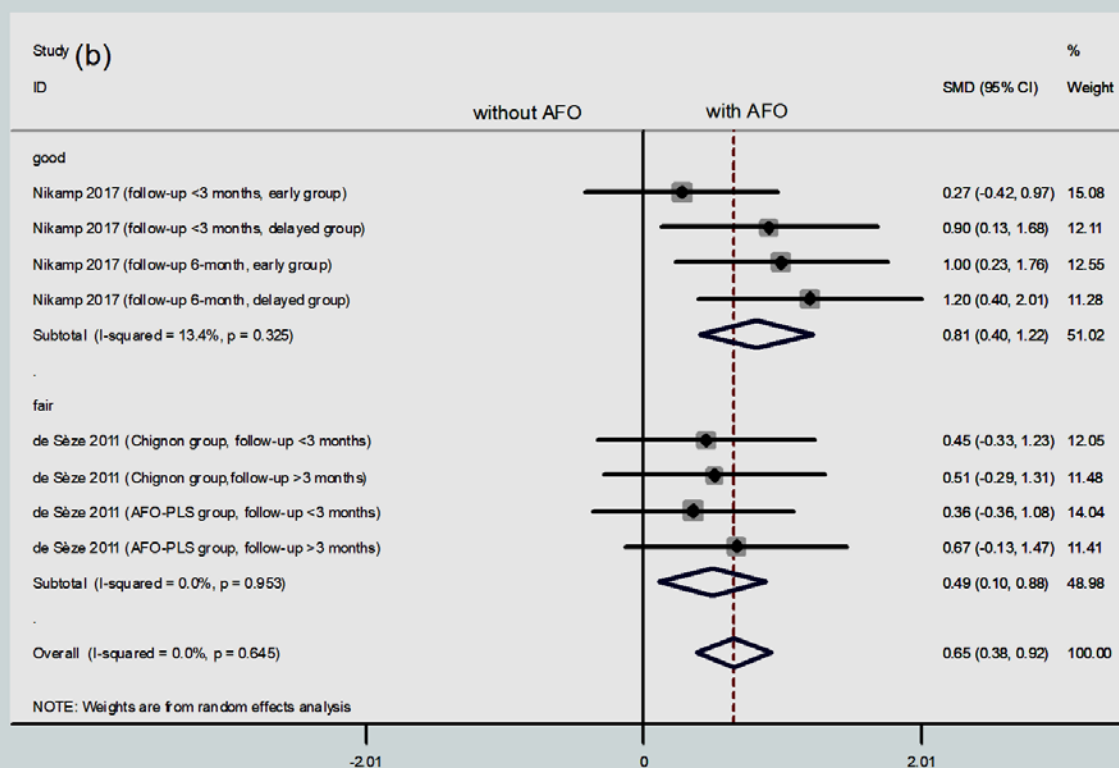
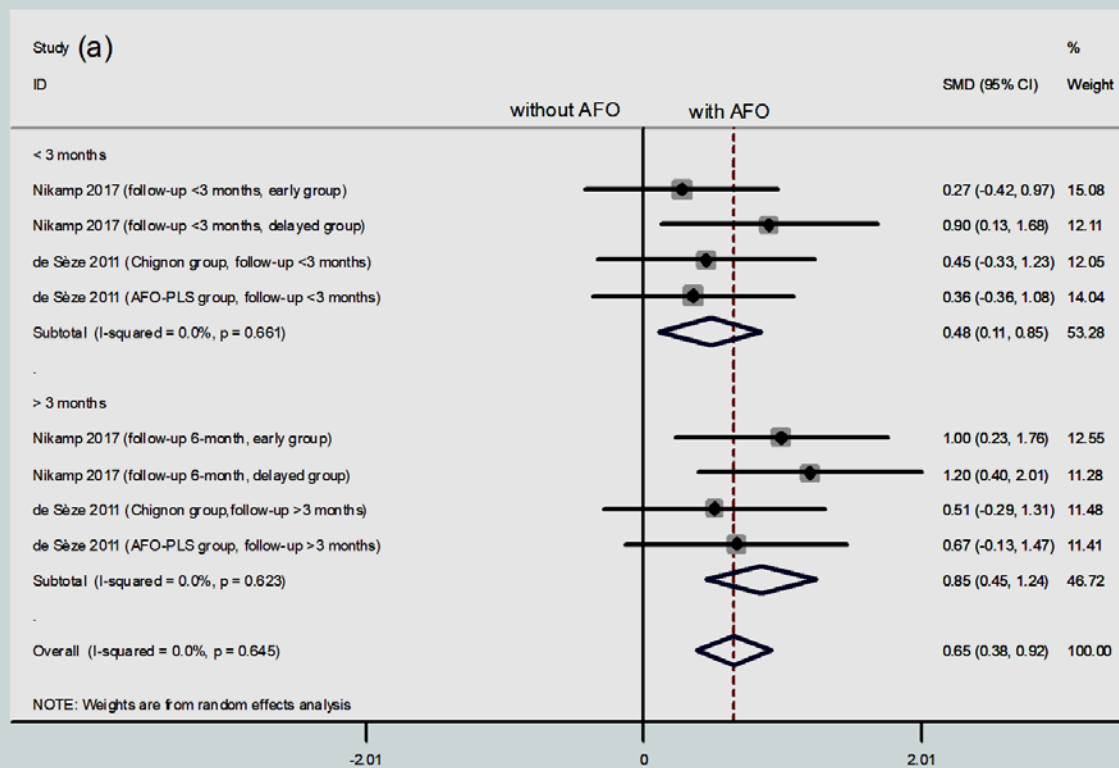


Supplemental Figure 5. Subgroup analysis by random-effects model for an AFO versus without an AFO on Timed Up-Stairs: a) stroke phase, b) adaptation time, c) quality status, d) walking speed. AFO: Ankle-Foot Orthosis, SMD: Standardized Mean Difference. The direction of improvement for Timed Up-Stairs is toward negative values.

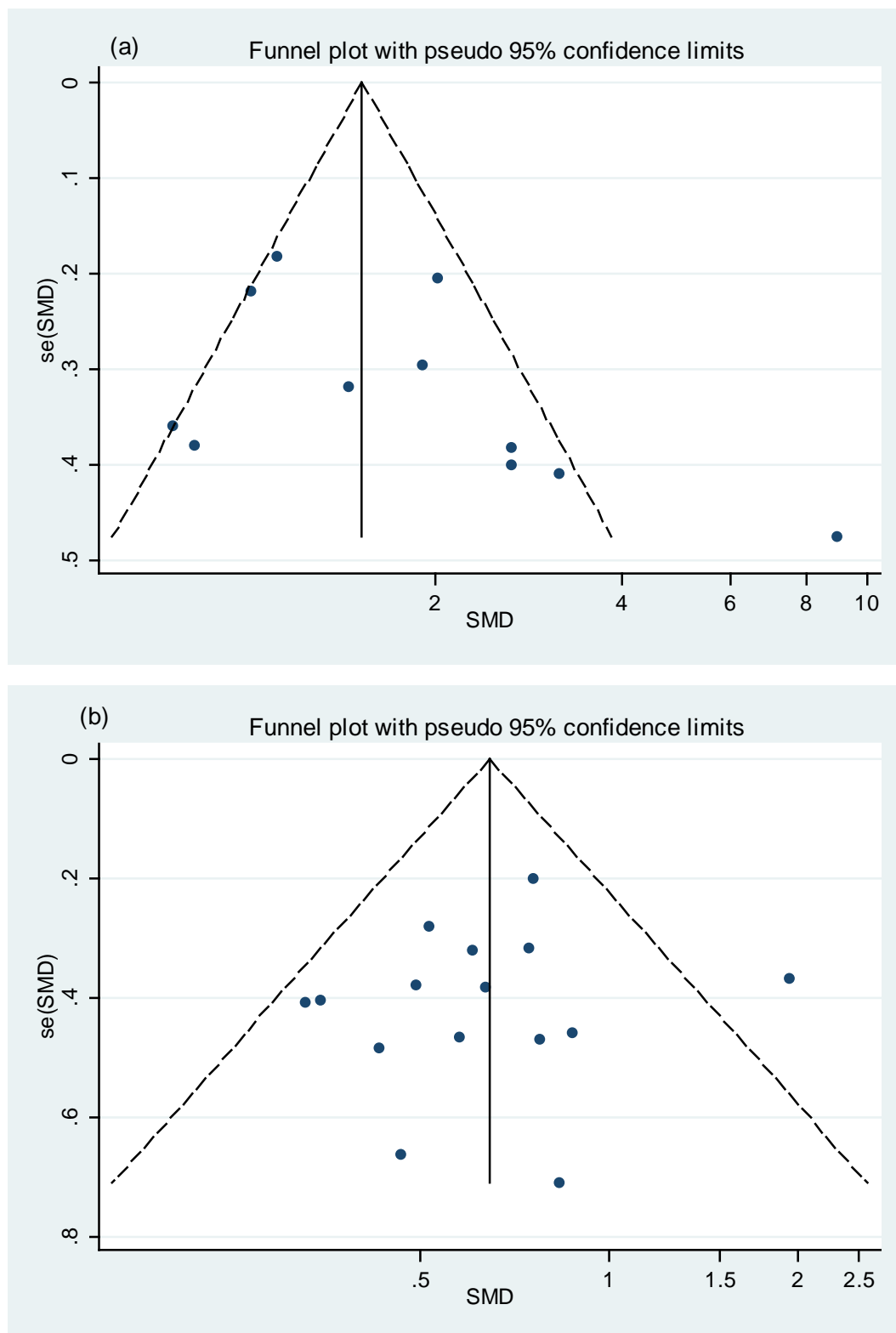


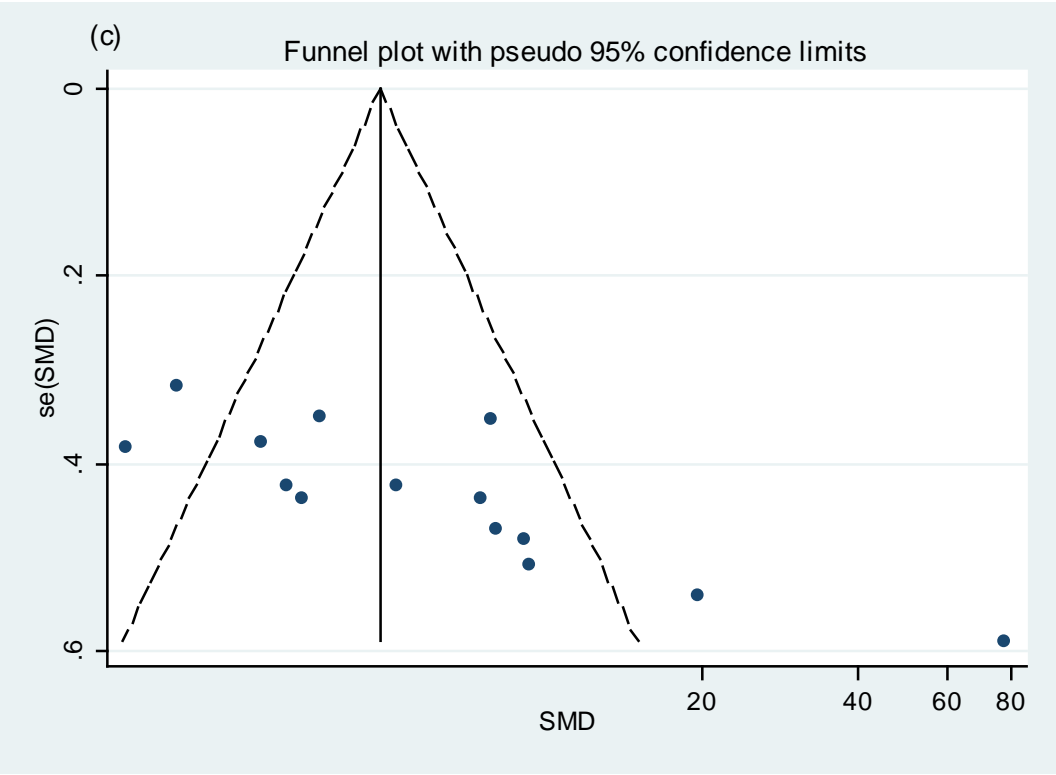


Supplemental Figure 6. Subgroup analysis by random-effects model for an AFO versus without an AFO on Motricity Index: a) adaptation time, b) quality status. AFO: Ankle-Foot Orthosis, SMD: Standardized Mean Difference. The direction of improvement for Motricity Index is toward positive values.

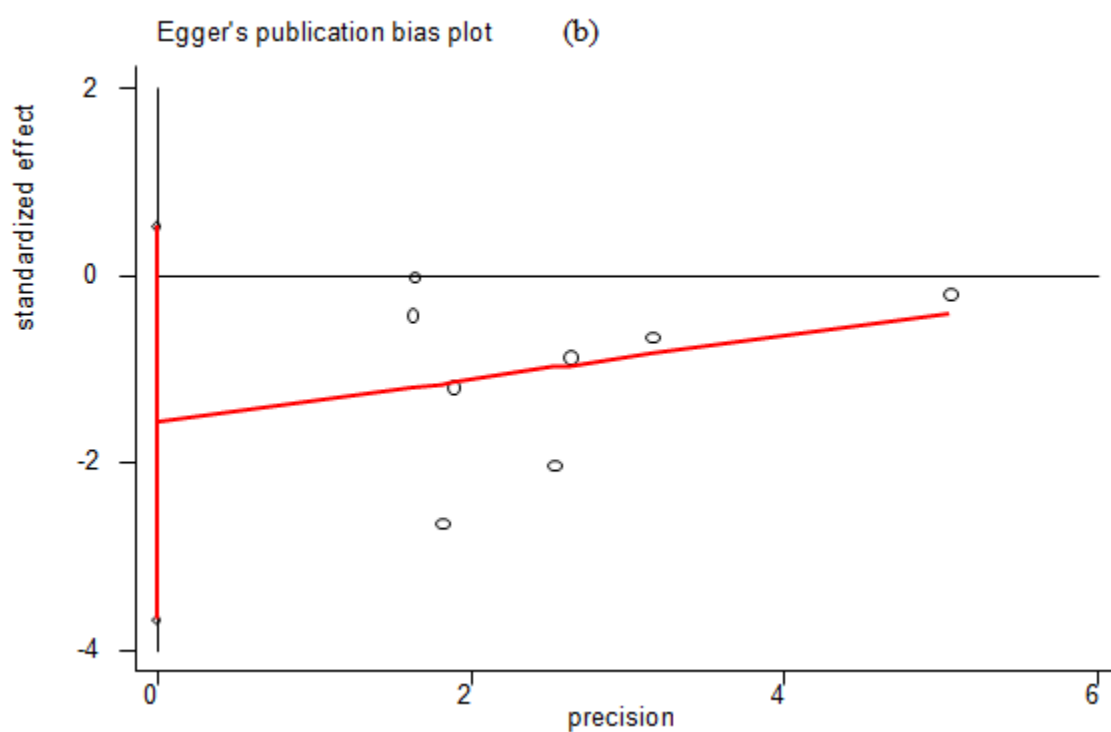
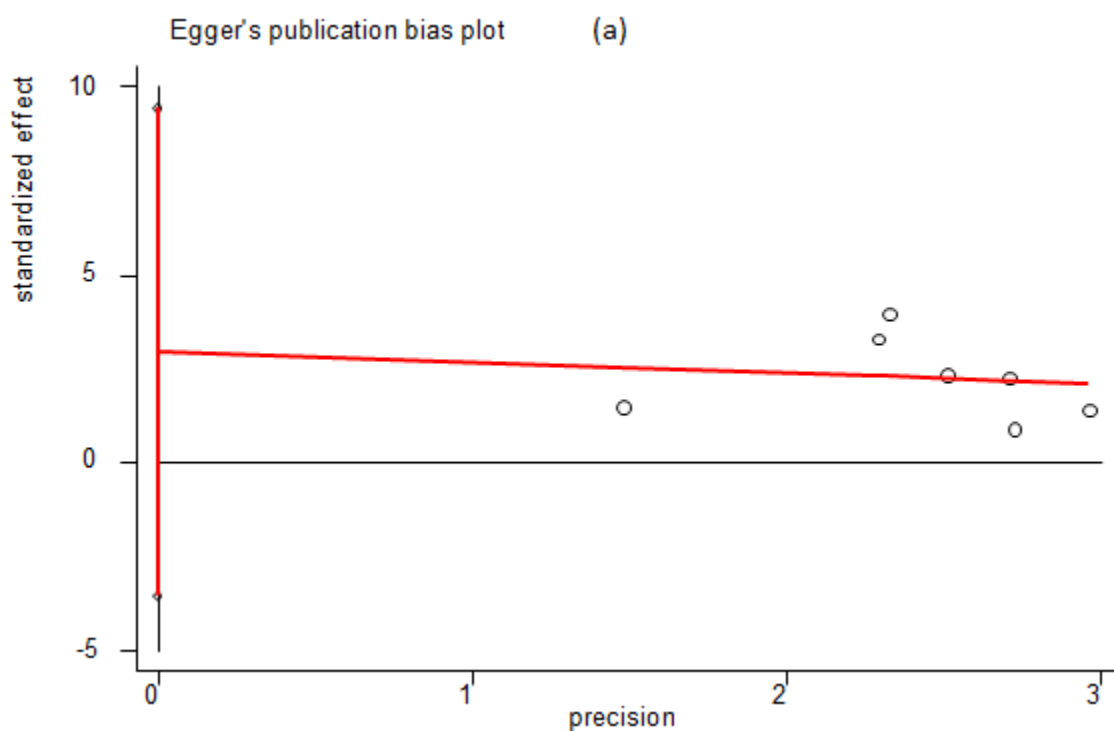


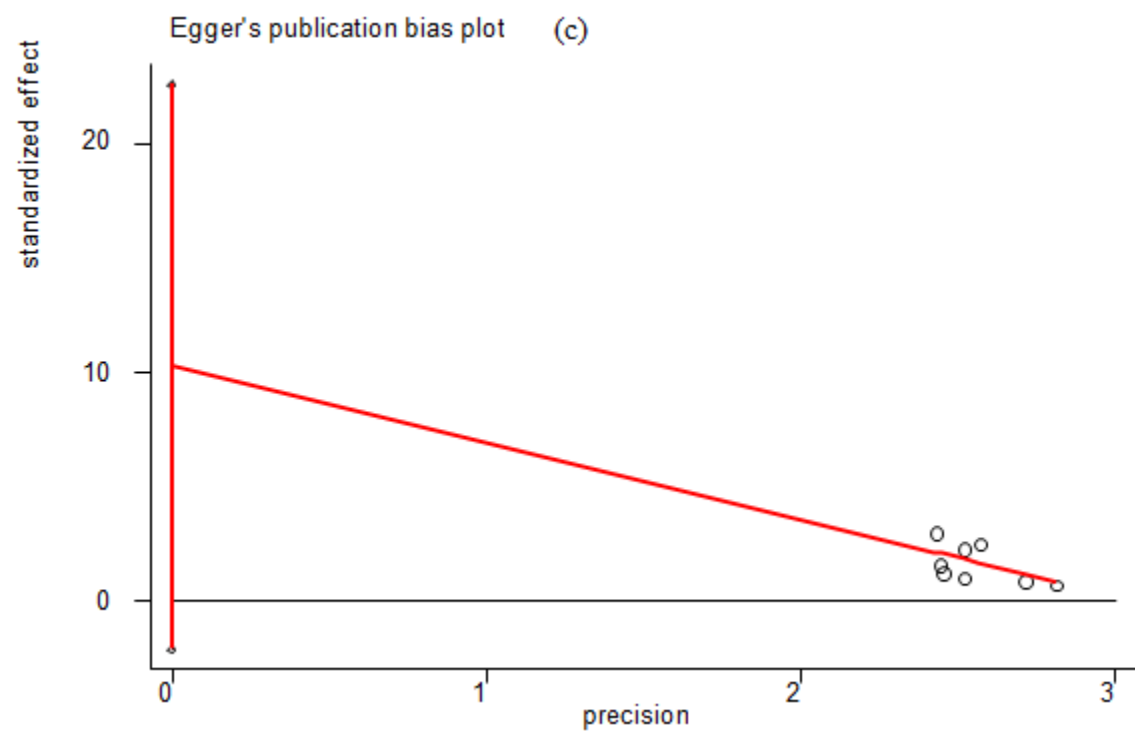
Supplemental Figure 7. Funnel plot. Solid circles indicate the included studies. a) Berg Balance Scale, b) Timed Up and Go test, c) Functional Ambulation Categories. SMD: standardized mean difference.





Supplemental Figure 8. Egger's graphs show no potential publication bias for the outcomes (confidence interval crosses zero). Solid and open circles indicate the included studies. a) 6-Minute Walking Test, b) Timed Up-Stairs, c) Motricity Index.





Supplemental table 1. Sub-group analysis between potential factors for Berg Balance Scale

Subgroup variables	Categorized into	No. of trials	SMD	CI 95%	% Weight	Heterogeneity Chi ²	I ²	P-value
Stroke phase	<6 months	7	0.765	0.251, 1.278	60.94	27.15	77.9%	0.000
	> 6 months	4	0.211	-0.126, 0.547	39.06	4.64	35.3%	0.200
	mixed	-	-	-	-	-	-	-
Adaptation time	immediate	2	0.059	-0.214, 0.332	22.68	0.12	0.0%	0.724
	<3 months	6	0.479	0.069, 0.888	53.67	10.28	59.7%	0.029
	> 3 months	3	1.190	0.170, 2.211	23.66	12.42	80.5%	0.006
Quality	poor	2	0.115	-0.447, 0.677	17.43	1.36	26.5%	0.243
	fair	5	0.253	-0.092, 0.597	52.13	10.78	62.9%	0.029
	good	4	1.274	0.754, 1.794	30.44	4.92	39.1%	0.178
Walking speed	household	5	1.104	0.646, 1.561	41.71	8.52	53.0%	0.005
	Limited-community	4	0.076	-0.161, 0.313	40.10	1.55	0.0%	0.634
	community	1	-0.287	-0.989, 0.415	8.55	0.00	-	-

SMD, Standardized Mean Difference

Supplemental table 2. Sub-group analysis between potential factors for Timed Up and Go test

Subgroup variables	Categorized into	No. of trials	SMD	CI 95%	% Weight	Heterogeneity Chi ²	I ²	P-value
Stroke phase	<6 months	5	-0.348	-0.645, -0.050	34.72	1.60	0.0%	0.809
	> 6 months	10	-0.501	-0.821, -0.182	65.28	15.70	42.7%	0.073
	mixed	-	-	-	-	-	-	-
AFO type	non-articulated	8	-0.259	0.599, 0.081	44.06	9.09	23.0%	0.246
	articulated	3	-0.736	-1.348, -0.124	27.74	5.33	62.5%	0.070
	mixed	4	-0.592	-0.942, -0.243	28.20	0.58	0.0%	0.900
Adaptation time	immediate	3	-0.860	-1.359, -0.360	15.39	0.41	0.0%	0.813
	<3 months	6	-0.305	-0.740, -	48.98	12.69	60.6%	0.026

				0.064				
	> 3 months	6	-0.466	-0.787, -0.145	35.63	1.12	0.0%	0.953
Quality	poor	5	-0.766	-1.089, -0.443	36.01	2.76	0.0%	0.737
	fair	6	-0.233	-0.490, 0.023	45.01	8.02	50.1%	0.091
	good	4	-0.437	-0.896, 0.022	18.98	1.35	0.0%	0.717
Walking speed	household	5	-0.433	-0.731, -0.134	34.09	2.03	0.0%	0.729
	Limited-community	9	-0.573	-0.821, -0.326	58.81	5.71	0.0%	0.679
	community	1	0.661	-0.058, 1.379	7.10	0.00	-	-

SMD: Standardized Mean Difference, AFO: Ankle-Foot Orthosis

Supplemental table 3. Sub-group analysis between potential factors for Functional Ambulation Categories

Subgroup variables	Categorized into	No. of trials	SMD	CI 95%	% Weight	Heterogeneity Chi ²	I ²	P-value
Stroke phase	<6 months	10	1.849	1.209, 2.490	69.27	46.54	80.7%	0.000
	> 6 months	2	1.581	0.878, 2.283	14.93	1.67	40.3%	0.196
	mixed	2	1.324	-0.053, 2.701	15.81	8.84	88.7%	0.003
AFO type	non-articulated	9	1.870	1.128, 2.612	62.94	53.72	85.1%	0.000
	articulated	3	1.491	0.878, 2.103	22.13	3.63	44.9%	0.163
	mixed	2	1.548	0.878, 2.283	14.93	1.67	40.3%	0.196
Adaptation time	immediate	1	4.345	3.188, 5.501	5.97	0.00	-	-
	<3 months	8	1.328	0.857, 1.799	59.40	20.97	66.6%	0.004
	> 3 months	5	1.896	1.256, 2.536	34.64	10.27	61.0%	0.036
Quality	poor	3	1.198	0.334, 2.062	22.47	7.76	74.2%	0.021
	fair	7	1.812	1.047, 2.577	49.92	36.14	83.4%	0.000
	good	4	1.999	1.170, 2.829	27.60	10.06	70.2%	0.018

SMD: Standardized Mean Difference, AFO: Ankle-Foot Orthosis

Supplemental table 4. Sub-group analysis between potential factors for 6-Minute Walking Test

Subgroup variables	Categorized into	No. of trials	SMD	CI 95%	% Weight	Heterogeneity Chi ²	I ²	P-value
Stroke phase	<6 months	5	1.014	0.543, 1.486	74.92	7.28	45.0%	0.122
	> 6 months	2	0.564	-0.029, 1.157	25.66	0.43	0.0%	0.513
	mixed	-	-	-	-	-	-	-
Adaptation time	immediate	2	0.473	-0.160, 1.106	23.36	0.67	0.0%	0.412
	<3 months	2	0.880	0.350, 1.411	31.51	0.04	0.0%	0.845
	> 3 months	3	1.167	0.375, 1.958	45.13	6.11	67.3%	0.047
Quality	poor	3	0.469	0.011, 0.927	41.66	0.67	0.0%	0.714
	fair	-	-	-	-	-	-	-
	good	4	1.187	0.782, 1.593	58.34	3.11	3.7%	0.374
Walking speed	household	5	0.995	0.654, 1.336	77.52		38.0%	0.168
	Limited-community	2	0.473	-0.160, 1.106	22.48		0.0%	0.412
	community	-	-	-	-		-	-

SMD: Standardized Mean Difference,

Supplemental table 5. Sub-group analysis between potential factors for Timed Up-Stairs

Subgroup variables	Categorized into	No. of trials	SMD	CI 95%	% Weight	Heterogeneity Chi ²	I ²	P-value
Stroke phase	<6 months	5	-0.383	-0.898, 0.132	57.59	6.56	39.1%	0.161
	> 6 months	3	-0.410	-0.816, -0.003	42.41	1.40	0.0%	0.497
	mixed	-	-	-	-	-	-	-
Adaptation time	immediate	1	-0.796	-1.568, -0.024	12.22	0.00	-	-
	<3 months	3	-0.099	-0.447, 0.249	45.30	1.09	0.0%	0.580
	> 3 months	4	-0.470	-0.969, 0.028	42.48	4.08	26.4%	0.253
Quality	poor	-	-	-	-	-	-	-
	fair	4	-0.220	-0.507, 0.068	74.81	3.09	2.9%	0.378
	good	4	-0.621	-1.245, -0.003	25.19	3.68	8.5%	0.298

				0.003				
Walking speed	household	6	-0.458	-0.912, -0.005	69.81	8.34	40.0%	0.139
	Limited-community	2	-0.262	-0.739, 0.216	30.19	0.07	0.0%	0.794
	community	-	-	-	-	-	-	-

SMD: Standardized Mean Difference,

Supplemental table 6. Sub-group analysis between potential factors for Motricity Index

Subgroup variables	Categorized into	No. of trials	SMD	CI 95%	% Weight	Heterogeneity Chi ²	I ²	P-value
Adaptation time	immediate	-	-	-	-	-	-	-
	<3 months	4	0.479	0.109, 0.850	53.28	1.59	0.0%	0.661
	> 3 months	4	0.847	0.451, 1.243	1.243	1.76	0.0%	0.623
Quality	poor	-	-	-	-	-	-	-
	fair	4	0.489	0.103	0.876	0.34	0.0%	0.953
	good	4	0.812	0.405, 1.219	51.02	3.47	13.4%	0.325
Walking speed	household	-	-	-	-	-	-	-
	Limited-community	-	-	-	-	-	-	-
	community	-	-	-	-	-	-	-

SMD: Standardized Mean Difference,

Supplemental table 7. Assessment of publication bias

Analysis	No. of trials	Publication bias	
		Begg's test: z-test P-value	Egger's test: Intercept t-test P-value
Berg Balance Scale	11	1.95 0.052	1.67 0.130
Timed Up and Go test	15	-0.84 0.400	-0.64 0.536
Functional Ambulation Categories	14	3.12 0.002	4.29 0.001
6-Minute Walking Test	7	1.65 0.099	1.15 0.302
Timed Up-Stairs	8	-0.99 0.322	-1.84 0.116
Motricity Index	8	1.73 0.083	2.05 0.087

Supplemental table 8. The list of the studies identified for quantitative analysis by a meta-analysis with reference numbers

Author/ Year
Abe(2009) ³⁷
Assawapalangchai(2017) ³⁸
Cakar(2010) ²⁸
De Sèze(2011) ⁵⁰
de Wit (2004) ⁵¹
Doğan (2011) ²⁵
Erel (2011) ⁴⁶
Hale(2013) ³²
Hyun(2015) ³³
Maeda(2009) ²³
Nevisipour(2019) ⁵²
Nikamp(2017) ⁴⁷
Nikamp(2017) ⁴⁸
Pardo (2015) ⁴⁰
Pavlik (2008) ³⁹
Simons (2009) ³⁴
Sheffler(2006) ²⁹
Tomioka(2017) ³¹
Tyson(2009) ³⁶
Tyson(2001) ³⁵
Wang(2005) ⁴³
Yue (2013) ⁵⁵