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SYSTEMATIC REVIEW

Is functional electrical stimulation effective in improving walking in adults with lower limb impairment due to an upper motor neuron lesion? An umbrella review

Georgia Andreopoulou[1] | Giulia Busselli[2,3] | Tamsyn Street[4] | Cathy Bulley[1] | Reza Safari[5] | Marietta L. van der Linden[1] | Jane Burridge[6]

[1]Centre for Health, Activity and Rehabilitation Research, Queen Margaret University, Edinburgh, UK

[2]Department of Neurosciences, Biomedicine and Movement Sciences, University of Verona, Verona, Italy

[3]UOC Neurorehabilitation, AOUI Verona, Verona, Italy

[4]Clinical Sciences and Engineering, Salisbury NHS Foundation Trust and Bournemouth University, Salisbury, UK

[5]College of Health, Psychology and Social Care, University of Derby, Derby, UK

[6]School of Health Sciences, Faculty of Environmental and Life Sciences, University of Southampton, Southampton, UK

Correspondence
Marietta L. van der Linden, Centre for Health, Activity and Rehabilitation Research, Queen Margaret University, Edinburgh, UK.
Email: mvanderlinden@qmu.ac.uk

Present address
Georgia Andreopoulou, Anne Rowling Regenerative Neurology Clinic, Centre for Clinical Brain Sciences, University of Edinburgh, Edinburgh, UK

Abstract

Purpose: To conduct an umbrella review of systematic reviews on functional electrical stimulation (FES) to improve walking in adults with an upper motor neuron lesion.

Methods: Five electronic databases were searched, focusing on the effect of FES on walking. The methodological quality of reviews was evaluated using AMSTAR2 and certainty of evidence was established through the GRADE approach.

Results: The methodological quality of the 24 eligible reviews (stroke, $n=16$; spinal cord injury (SCI), $n=5$; multiple sclerosis (MS); $n=2$; mixed population, $n=1$) ranged from critically low to high.

Stroke reviews concluded that FES improved walking speed through an orthotic (immediate) effect and had a therapeutic benefit (i.e., over time) compared to usual care (low certainty evidence). There was low-to-moderate certainty evidence that FES was no better or worse than an Ankle Foot Orthosis regarding walking speed post 6 months. MS reviews concluded that FES had an orthotic but no therapeutic effect on walking. SCI reviews concluded that FES with or without treadmill training improved speed but combined with an orthosis was no better than orthosis alone. FES may improve quality of life and reduce falls in MS and stroke populations.

Conclusion: FES has orthotic and therapeutic benefits. Certainty of evidence was low-to-moderate, mostly due to high risk of bias, low sample sizes, and wide variation in outcome measures. Future trials must be of higher quality, use agreed outcome measures, including measures other than walking speed, and examine the effects of FES for adults with cerebral palsy, traumatic and acquired brain injury, and Parkinson's disease.

Georgia Andreopoulou and Giulia Busselli are the joint first authors.

Marietta L. van der Linden and Jane Burridge joint last co-authors.

KEYWORDS
functional electrical stimulation, lower limb impairment, overview of systematic review, systematic review, upper motor neuron lesions, walking

1 | INTRODUCTION

Upper motor neuron (UMN) lesions are commonly associated with impaired motor coordination, lack of selective voluntary motor control, spasticity, muscle weakness, and secondary decreased range of motion. Walking impairments such as foot drop or drop-foot, due to insufficient ankle dorsiflexion during the swing phase of walking which can lead to trips and falls, are common.

Functional electrical stimulation (FES) has the potential to aid walking performance or motor function in general by stimulating the peripheral nerve of the muscle through electrodes that are placed on the skin or implanted in the muscle. Over the last two decades, FES has translated from a research tool to become a widely used treatment in 70 countries.[1] There are no published data on the number of FES-trained therapists nor the number of patients treated worldwide. However, at the time of the publication of this article over 3000 clinicians had attended the FES training courses provided by Odstock Medical Ltd (OML), a major commercial provider of FES devices in the UK and worldwide. It is estimated that in excess of 27 000 people in the UK alone were provided with OML devices.[2]

The most commonly used FES application for the lower limbs is the drop-foot stimulator in which stimulation of the common peroneal nerve causes a contraction in the anterior tibial and peronei muscles to lift the foot, with slight ankle eversion, during the swing phase of walking.[3] In some cases, stimulation of the peroneal nerve elicits a withdrawal reflex, that is, dorsiflexion at the ankle and knee and hip flexion. The combined effect increases ground clearance during the swing phase, sometimes more effectively than dorsiflexion of the ankle alone, but in people with hyper-reflex responses, the effect can also result in an abnormal gait pattern.[4]

Multiple channels can activate other movements associated with walking, such as: calf stimulation to improve "push-off"; hamstring stimulation to increase knee flexion or prevent knee hyperextension in stance phase; quadriceps stimulation to improve knee stability; gluteal stimulation to improve hip extension and hip stability.[5] Bilateral FES is often used for people with bilateral problems such as spinal cord injury (SCI) and sometimes in people with MS.

FES can result in an orthotic effect or a therapeutic effect or both (Table 1). The term "orthotic effect" is commonly used in the literature to describe an immediate difference in walking outcomes when FES is turned on compared to walking without FES at the same assessment point. Therapeutic effect (or treatment or training effect) is the change in walking parameters, measured without stimulation, following a period of use of the stimulator and the total orthotic (or combined) effect is the change in walking parameters with stimulation following a period of use compared to without stimulation prior to the intervention.

Over the last decade, a number of systematic reviews synthesizing the evidence for the impact of FES on outcomes such as walking speed have been published, mostly focussing on one particular health condition such as stroke or SCI. These systematic reviews differ from each other with respect to characteristics such as aims and inclusion criteria, but the high number of reviews currently available may make it difficult to interpret their findings. Umbrella reviews have been developed to address this issue. They are reviews of previously published systematic reviews or meta-analyses and represent one of the highest levels of evidence synthesis currently available.[6]

The aim of this umbrella review was to systematically locate, appraise and synthesize the results of systematic

TABLE 1 Comparisons used to measure changes in walking performance from FES.

	Day 1		Follow-up	
Effect	**No stimulation**	**Stimulation**	**No stimulation**	**Stimulation**
Initial orthotic	✓	✓		
Continuing orthotic			✓	✓
Total orthotic	✓			✓
Therapeutic (Training)	✓		✓	

reviews with and without meta-analysis, offering a comprehensive and up-to-date evaluation of the evidence for the orthotic and therapeutic effect of FES to improve walking for adults with UMN lesions. We included reviews on the following UMN lesions: stroke, Parkinson's Disease (PD), multiple sclerosis (MS), incomplete spinal cord injury (SCI), traumatic brain injury (TBI), and cerebral palsy (CP). In this umbrella review, we have used the term Functional Electrical Stimulation (FES) to mean electrical stimulation to achieve a functional movement or purpose, which in this review is walking. We used the term neuromuscular electrical stimulation (NMES) where the primary objective is muscle conditioning, rather than directly assisting a functional movement.

2 | METHODS

The protocol was developed using the Preferred Reporting Items for Overviews of Reviews (PRIOR)[7] and has been published on PROSPERO.[8] A systematic literature search for relevant published reviews was conducted using the following databases: MEDLINE (EBSCO interface), CINAHL (EBSCO interface), EMBASE (Ovid interface), and Web of Science Core collection. Grey literature was searched using Open Grey, MedNar, NICE (National Institute for Health for Health and Care Excellence), and Epistemonikos. Registers such as PEDro, Cochrane Database of Systematic Reviews, and PROSPERO were also searched for potentially eligible systematic reviews. Only completed reviews with published results were included. If a published version could not be located, we contacted the authors listed on PROSPERO. Reference lists of the reviews were hand-searched for additional potentially relevant articles. Reviews published up to the date of the last literature search in August 2021 were eligible for inclusion.

Literature search strategies used medical subject headings (MeSH) and text words, used individually or in combination, including functional electrical simulation (FES), walking, lower limb weakness, stroke, Parkinson's disease (PD), multiple sclerosis (MS), spinal cord injury (SCI), traumatic brain injury (TBI) and cerebral palsy (CP). An example of the search strategy for Medline (EBSCO) is included in the Supplementary Material S1.

2.1 | Eligibility criteria

Systematic reviews (SRs) with either or both narrative synthesis and meta-analysis were eligible for inclusion. Reviews including studies investigating the effect of FES with or without another intervention in adults with UMN lesions, as listed above, were included.

Reviews were also included if they focussed on a wider range of treatments (e.g., 'physiotherapy') rather than just FES as long as they reported the results and conclusions for the studies reporting on just FES.

We considered reviews that addressed FES for the treatment of walking impairments due to an UMN lesion. Reviews including studies on single and multi-channel electrical stimulation, with all types of external triggering and both surface and implanted systems that aimed to activate one or more muscle groups during walking were eligible for inclusion. We did not limit our selection of reviews to those that compared FES with a specific alternative treatment, such as orthoses, or no treatment. Reviews including all comparators were therefore eligible for inclusion.

2.2 | Exclusion criteria

We excluded reviews of studies where electrical stimulation was used solely for muscle conditioning and not to assist walking. We did not apply any language filters to the search strategy but for pragmatic reasons (languages spoken by the authors) only reviews in languages other than English, German, French, Spanish, Italian, Greek, and Dutch were excluded.

2.3 | Outcomes

Primary outcomes were walking speed and distance, functional walking tests (e.g., Timed Up and Go: TUG), observational and instrumented gait analysis parameters (e.g., joint kinematics), and effort of walking (e.g., perceived exertion, Physiological Cost Index (PCI) and oxygen consumption) either for orthotic or therapeutic effect.

Secondary outcomes were: falls or near falls, self-reported Quality of Life (QoL: e.g., Short Form 36; Short Form 12, EQ-5D), activities of daily living related outcomes (e.g., Stroke Impact Scale, Multiple Sclerosis Impact Scale; Canadian Occupational Performance Measure) and spasticity or tone (e.g., clinical measurements such as the Modified Ashworth Scale) and stiffness (e.g., reflex stiffness and range of motion). Reviews focussing on secondary outcomes were included as long as at least one study in the review reported a primary outcome. We also aimed to extract data on device-related adverse events (type and frequency).

2.4 | Screening process

Literature search results were uploaded to EndNote (Version X9.2) and duplicates removed. Two reviewers (JB, GB) independently and separately screened the titles and abstracts and classified them as "probably relevant" and "definitely irrelevant." If consensus was not reached, a third reviewer (TS) was available. Full texts of articles that were considered 'probably relevant' were independently screened against the inclusion and exclusion criteria by two pairs of authors (JB and GB; MvdL and GA) and classified as 'relevant' and 'definitely irrelevant' and 'unsure'. We emailed the main author of articles classed as unsure i.e., lacking sufficient information to evaluate the final eligibility, or for ongoing systematic reviews (maximum of 3 emails in a 3-week period) for clarification. The reviewers were not blinded to the study authors or their institutions. Any disagreements were discussed by all four reviewers until consensus was achieved. Reasons for the exclusion of "definitely irrelevant" full-text articles were noted and included in a PRISMA flow diagram.

2.5 | Data extraction and management

A standard data extraction form was used. Initially, review team members, working in pairs (JB and GB; MvdL and GA), extracted data from three reviews. Extracted data forms were then compared to check for agreement. Once agreement was confirmed, the included systematic reviews were assigned randomly 50/50 to each pair who extracted data independently. Any disagreements were resolved as described above.

For those reviews that included studies on interventions other than FES we only extracted the results and conclusions for the studies that reported on the effects of FES. Both the number of studies reporting on FES and the total number of studies included in the review were extracted and reported in the data extraction table.

2.6 | Assessment of overlap

To assess the overlap between reviews with respect to the studies included, the corrected covered area (CCA) was calculated both for the umbrella review as a whole and each individual pathology (e.g., stroke, MS, SCI) separately. $CCA = \frac{(N-r)}{rc-r}$ where N is the total number of publications included in the reviews (including double counting), r is the number of index publications, and c is the number of reviews. Interpretation of the overlap was as follows: slight (0–5), moderate (6–10), high (11–15), or very high (greater than 15).[9]

2.7 | Appraisal of methodological quality of the included reviews

Four team authors worked in pairs to independently assess the methodological quality of included systematic reviews using A Measurement Tool to Assess Systematic Reviews version 2 (AMSTAR 2).[10] The authors of AMSTAR2 recommend reporting items most relevant to a particular umbrella review, rather than the total score, for rating methodological quality.[10] For the purpose of this umbrella review, the following four items were regarded as critical: '4' (comprehensive literature search strategy), "9" [satisfactory technique for assessing the Risk of Bias (RoB)], 11 (meta-analysis if performed), and 13 (account for RoB in when discussing the results of the review). Disagreements were resolved as described above. Reviews were not excluded on the basis of these ratings.

2.8 | Summary of findings

The certainty of evidence presented in the reviews that included a meta-analysis of more than one controlled trial was assessed using the Grading of Recommendation Assessment, Development and Evaluation (GRADE) approach.[11] The certainty of the overall evidence was assessed based on the rating of four main domains: limitations in design (e.g., risk of bias), imprecision in results (e.g., low sample size), indirectness (population, intervention, or comparator irrelevant to the review) and inconsistency (statistically significant heterogeneity) of results. For the rating of the RoB, we extracted information from the conclusions on RoB in each review. Based on an alpha of 0.05, beta of 0.2, and an effect size of 0.2, we regarded a total sample size of less than 200 per arm for each comparison as a low sample size.[12] We used GRADEpro to prepare the 'Summary of findings' table for the main comparisons of each eligible review and to report the certainty of the evidence.

2.9 | Measures of treatment effect

In this umbrella review, it was not possible to summarize the evidence using a formal statistical analysis (e.g., a meta meta-analysis) due to the variation in the aims of the reviews and thus the studies included. This variation was mostly in terms of interventions (e.g., muscles undergoing stimulation, interventions in addition to FES) and comparators (e.g., usual care, AFO, exercise) and effect of FES (orthotic, therapeutic, total orthotic). Therefore, in addition to the GRADE summary of findings table for the meta-analyses, a narrative summary of the findings and data was used to describe, discuss and synthesize key

findings and conclusions of reviews for each neurological condition separately.

3 | RESULTS

The results of the literature search are presented in the PRISMA flow diagram (Figure 1).

3.1 | Deviations from protocol

Although our protocol excluded systematic reviews of FES with children, we included a review in which 14 of the 450 participants were children with CP as they included a separate analysis enabling data for adults with stroke to be extracted.[29] We also included one SCI review in which there was one study with one participant aged 12.[30] Despite being unable to exclude this study, we included this review.

Reasons for the exclusion of reviews are included in the PRISMA flow diagram (Figure 1).

3.2 | Included reviews

The literature search, after the removal of duplicates, identified 1352 reviews of which 24 met the inclusion criteria (see PRISMA Flow diagram Figure 1). Table 2 shows the

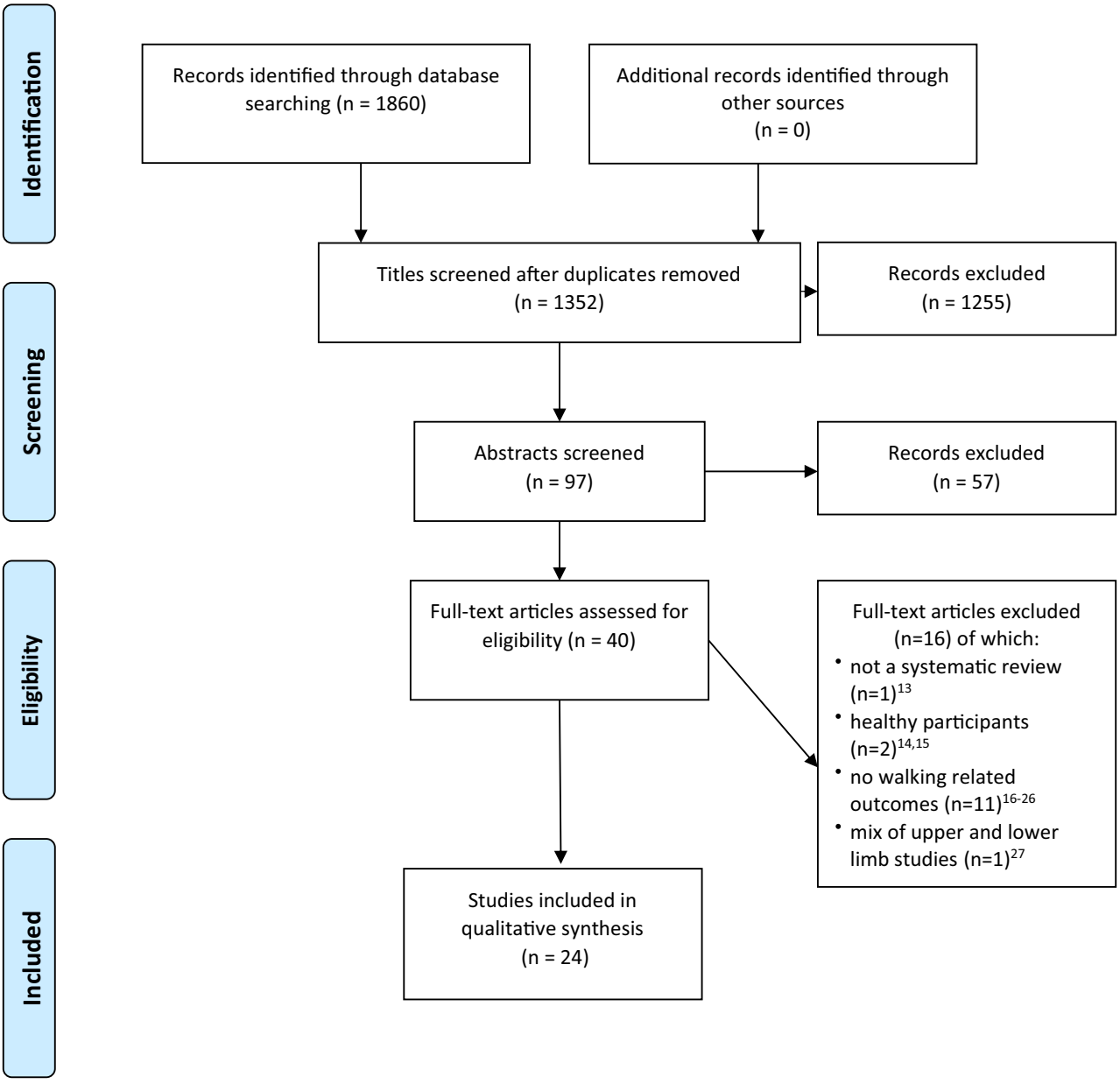

FIGURE 1 PRISMA flow diagram.

TABLE 2 Characteristics of the included reviews by patient population.

Study	Diagnosis; disease characteristics; age	Number of FES studies (total number of studies); study design	Surface versus implanted; single or multiple channels; type of signal switch	Details of interventions; location; duration; days per week (h/day)
Stroke				
Busk et al. 2020 [31]	Stroke; acute/subacute (range 16–166 days); mean 60.9 years (range 51–67 years)	$n=8$ (8); RCTs	Surface FES; NR; NR	FES + active rehabilitation (cycling, ergometry, balance exercises, treadmill supported walking, functional kinesiotherapy) versus active rehabilitation-only; NR; 2–12 weeks; 1–5 per week (20–60 min per session)
da Cunha et al. 2020 [32]	Stroke; acute/subacute/chronic; (<1 to 108 months); mean range 45–72 years	$n=14$ (14); RCTs ($n=13$), crossover RCT ($n=1$)	Surface and implanted FES; single channel; NR	FES + unsupervised home exercises, FES + physiotherapy, FES + regular activities at home versus to AFO/other type of stimulation/or sham; home/outpatients; 2–30 weeks (1 day for $n=1$); 3–7 per week (20–60 min to all day stimulation)
Dunning et al. 2015 [33]	Stroke; subacute/chronic; 53–64 years	$n=6$ (6); RCT ($n=4$); RCT crossover ($n=2$)	Surface FES; single channel; NR	FES only, FES + PT; NR; 6–30 weeks; daily (NR)
Hollands et al. 2011 [34]	Stroke; chronic; 54–58 years	$n=3$ (33); non-RCTs with multi-factorial experimental designs	FES (NR); NR; NR	FES only, FES + gravity balanced AFO + feedback, FES + BWSTT; NR; 15 days-9 weeks; 3–7 per week (45 min–unrestricted)
Hong et al. 2018 [35]	Stroke; chronic (ischemic+hemorrhagic); 49.1–63.8 years	$n=21$ (21); RCT ($n=21$)	Surface and implanted FES; single and multiple channels; NR	FES only, FES + PT, FES + BWSTT, FES + TT + RPT, FES + CPT, ES + MT, ES + LCE, FES + RPT, FES + TT, NMES+CRP, FES + GT; NR; 3–52 weeks; NR
Howlett et al. 2015 [36]	Stroke; acute/subacute/chronic (<1–46 months post-stroke); 18–85 years	$n=8$ (18); RCT ($n=6$), cross over ($n=1$), controlled clinical trial ($n=1$)	Surface FES; single and multiple channels; foot switch (frequency 25 to 50 HZ; pulse width 200 to 400 μs; both UL and LL, not specified for LL only)	FES only, FES + standard rehabilitation, FES + walking training; NR; 3–12 weeks; 2–5 per week (20–60 min)
Jakubowitz et al. 2017 [37]	Stroke; NR; NR	$n=20$ (20); RCT ($n=18$), cohort ($n=2$)	Surface and implanted FES; single and multiple channels; NR	NR; NR; NR; NR

TABLE 2 (Continued)

Study	Diagnosis; disease characteristics; age	Number of FES studies (total number of studies); study design	Surface versus implanted; single or multiple channels; type of signal switch	Details of interventions; location; duration; days per week (h/day)
Kafri et al. 2015 [38]	Stroke; acute/subacute/ chronic; 49.1–68.2 years	$n=16$ (16); RCT, RCT crossover, alternate assignment	Surface and implanted FES; single and multiple channels; NR	FES only, FES + PT + OT, FES + PT, FES + education; clinic/home; 3–30 weeks; 4 days to daily use (20 min–8 h)
Kottink et al. 2004 [39]	Stroke; acute/subacute/ chronic; 31–58 years	$n=8$ (8); RCT ($n=1$), crossover studies ($n=2$), within-subject comparison ($n=5$)	Surface and implanted FES; single and multiple channels; NR	FES only, FES + AFO; home/inpatients; 1 week-6 months; 5–7 days (30 min–14 h)
Mahmoudi et al. 2021 [40]	Stroke; subacute/chronic; 42.5–58.7 years	$n=5$ (9); RCTs	Surface FES; single and multiple channels; NR	FES only, FES + CPT; NR; 4–12 weeks; 2–7 days (30 min–2 h)
Mendes et al. 2020 [41]	Stroke; chronic (>3 months); mean range 53–64 years	$n=4$ (4); RCTs	Surface and implanted FES; single and two channels; tilt sensor and heel switch	FES versus AFO; home; 12 weeks-12 months; 2 days–daily (15 min to all day)
Nascimento et al. 2020 [42]	Stroke; acute/chronic; 45–65 years	$n=9$ (11); RCTs	Surface FES; single and multiple channels; tilt sensors and foot switch	FES only, FES versus AFO; NR; 6–30 weeks; continuously used throughout the day
Pereira et al. 2012 [43]	Stroke; chronic (ischemic+hemorrhagic); 51.2–63.6 years	$n=7$ (7); RCTs	Surface and implanted FES; single and multiple channels; NR	FES only, FES + PT versus PT alone, FES + GT versus GT alone; FES versus conventional walking device; FES versus walking program; ES-assisted cycling versus cycling with sham stimulation; NR; NR; NR
Prenton et al. 2016 [44]	Stroke; chronic; 52.6–64.3 years	$n=7$ (7); RCTs	Surface and implanted FES; NR; NR	FES versus AFO; home/outpatients; 3–26 weeks; 2 days–daily (15 min–all day)
Prenton et al. 2018 [29]	CP/stroke; unilateral foot drop, stroke: acute/subacute/chronic; 8–61.58 years	$n=7$ (8 in total); RCT crossover ($n=1$), parallel group RCT ($n=7$)	Surface and implanted FES; single and dual channel; NR	FES versus AFO; home/outpatients; 3–36 weeks; 5 days–daily (15 min–all day)
Romera de Francisco et al. 2016 [45]	Stroke; acute/chronic; 48–67 years	$n=11$ (11); RCTs	Surface and implanted FES; single and multiple channels; NR	FES only, FES versus exercise program; home; 2 weeks–6 months; daily (NR)
Spinal cord injury				
Hamzaid and Davis, 2009 [46]	Spinal cord injury; C4–T8, ASIA C/D; NR	$n=1$ (33); experimental designs	FES (NR); NR; NR	FES + BWSTT + overground gait training; NR; 4 weeks; 5 per week (1 h per day)
Harvey et al. 2016 [47]	Spinal cord injury; acute (C4–T9); NR	$n=1$ (38); RCTs and crossover design	ES (NR); NR; NR	ES + BWSTT + overground gait training; NR; 4 weeks; 5 per week (1 h per day)

(Continues)

TABLE 2 (Continued)

Study	Diagnosis; disease characteristics; age	Number of FES studies (total number of studies); study design	Surface versus implanted; single or multiple channels; type of signal switch	Details of interventions; location; duration; days per week (h/day)
Karimi, 2013 [48]	Spinal cord injury; NR; 22–55 years	$n=16$ (16); case studies and clinical trials	FES (NR); NR; NR	FES only, mechanical orthoses, hybrid (FES + mechanical orthoses); NR; NR (NR)
Lam et al. 2007 [30]	Spinal cord injury; chronic complete/incomplete; 18–64 years (except for one individual aged 12)	$n=17$ (41); RCT ($n=1$); pre/post-test ($n=16$)	Surface and implanted FES; single and multiple channels; NR	FES only, FES + gait training, FES + bracing; home/inpatients/outpatients; 5 weeks to 3 years; FES only: 3–5 days (20 min-3 h), FES + gait training: 3–5 days (20–<90 min), FES + bracing: various (NR)
Nightingale et al. 2007 [49]	Spinal cord injury; complete/incomplete; NR	$n=36$ (36); case studies	Surface and implanted FES; NR; NR	FES versus orthotics, FES with/without; Home (partially reported); 4 weeks–18 months; 5 per week–daily (NR)
Multiple sclerosis				
Miller et al. 2017 [50]	Multiple sclerosis; EDSS 3.5–5.9; 46.5–56 years	$n=19$ (19); non-RCT ($n=8$), RCT ($n=1$), RCT crossover ($n=1$), observational ($n=8$), case-control ($n=1$)	Surface and implanted FES; single and dual channel; NR	FES versus AFOs, FES versus exercise program; hospital/home; NR; daily (unrestricted)
Springer et al. 2017 [51]	Multiple sclerosis; 8.6–17.7 years since diagnosis; 47.8–57 years	$n=12$ (12); RCT ($n=2$), RCT crossover ($n=1$), case series ($n=4$), comparative studies ($n=3$), cross-sectional ($n=2$)	Surface FES; single and dual channel; NR	FES versus exercise program, FES versus no intervention; home; 2 weeks–6 months; daily (NR)
Mixed patient populations				
Roche et al. 2009 [52]	Stroke/MS/SCI/TBI; acute/subacute/chronic CVA, SCI, chronic TBI; NR	$n=30$ (30); RCTs, case studies	Surface and implanted FES, NMES; single and multiple channels; footswitch	FES only, FES versus PT/HEP/OT/electroacupuncture/AFO), FES combined conventional rehab/PT/BTX/gait trainer; home/inpatient; 2 days–3 years; one-off-daily (10 min–all day)

Abbreviations: AFO, ankle foot orthosis; BTX, botulinum toxin; BWSTT, body weight supported treadmill training; CP, cerebral palsy; CPT, conventional physical therapy; CRP, conventional rehabilitation program; CVA, cerebrovascular accident; EDSS, Expanded Disability Status Scale; ES, electrical stimulation; FDS, foot drop stimulator; FES, functional electrical stimulation; GT, gait trainer exercise; HEP, home exercise program; LCE, leg cycling exercise; LL, lower limb; MS, multiple sclerosis; MT, mirror therapy; NMES, neuromuscular electrical stimulation; NR, not reported; OT, occupational therapy; PNS, peroneal nerve stimulation; PT, physical therapy; RCT, randomized controlled trial; RPT, regular physical therapy; SCI, spinal cord injury; TBI, traumatic brain injury; TT, treadmill training; UL, upper limb.

characteristics of the included reviews, grouped by patient population. The majority of the reviews focused on stroke populations ($n=16$),[29,31–45] followed by SCI ($n=5$),[30,46–49] MS ($n=2$)[50,51] and one with mixed populations.[52] No reviews of PD, adult CP or TBI were found. Reviews were published between 2004 and 2021. The total number of relevant studies included in this review was 285 and the number of relevant studies in each review ranged from 1 to 41.

To take into account the overlap of the included studies in the reviews, we calculated the corrected covered area (CCA) which was 2.5% for the whole umbrella review which is defined as "slight overlap." However, when the CCA was calculated for each pathology separately this was 45% for the reviews on MS ("very high"), 8.0% for stroke ("moderate") and 7.5% for SCI ("moderate").

Reviews reported either the average age range of participants or the actual age range. Where reported, the average age for the studies in the stroke reviews ranged from 49 to 72 years and for the MS reviews from 47 to 57 years. The average age was not reported for the studies included in the SCI reviews, but the age ranged between 12 and 64. Five reviews did not report the age of the participants in the included studies.[37,46,47,49,52]

Twenty reviews used the term FES and four used either Electrical Stimulation (ES) or NMES but we only extracted the information regarding interventions in which the nerves were stimulated during gait (i.e., functional). However, for two reviews it was not clear whether the interventions in the included studies investigated FES or NMES as defined in this umbrella review.[35,43]

The majority ($n=15$) of the reviews included studies reporting on both single and multi-channel stimulation,[29,30,35–43,45,50–52] with two reviews including only studies which investigated the effect of single-channel stimulation.[32,33] The remaining reviews did not report this information.[31,34,44,46–49] Fourteen reviews stated that studies of both surface and implanted FES were included,[29–31,35,37–39,41,49,50,52] with six reviews only including studies using surface stimulation[31,33,36,40,42,51]; in four reviews the inclusion criteria for this were not reported.[34,46–48] Information on the type of signal switch was only provided in four reviews.[36,41,42,52] Four reviews were known to have included studies reporting the use of both bilateral and single-leg stimulation.[30,38,39,50]

The most common comparators in the interventions were ankle foot orthoses (AFOs) ($n=12$),[29,32,34,39,41,42,44,45,48–50,52] physiotherapy ($n=9$),[32,33,35,36,38,40,43,45,52] gait training ($n=7$),[30,31,35,36,43,46,47] bodyweight-supported treadmill training (BWSTT),[35,45–47] and exercise programmes ($n=4$).[31,32,50,51]

3.3 | Methodological quality of the reviews

Based on four items of the AMSTAR2 which we regarded as critical, the overall methodological quality of nine reviews was rated as "critically low" (more than one critical flaw), or "low" (one critical flaw), in five this was "moderate" (one or more than one non-critical weakness) and in one (Cochrane) review this was "high" (no weakness) (see Supplementary Material S2). Considering each health condition separately, the methodological quality of reviews on stroke was "critically low" ($n=6$), "low" ($n=7$), "moderate" ($n=2$), and "high" ($n=1$), for the two MS reviews this was "low" and "moderate," respectively, and for the five SCI reviews this was "low" ($n=1$) or "critically low" ($n=3$) except the review by Harvey et al.[47] ("moderate" quality). The methodological quality of the mixed population review was also rated as "moderate." The reason for downgrading the methodological quality was mostly due to not explaining why the search was restricted to articles in the English language (criteria 4, comprehensive literature search strategy). Further, nearly half of the systematic reviews did not account for the risk of bias when discussing the results in the reviews, hence were given a "no" for item 13.

Another common weakness, which was regarded as non-critical in our umbrella review was the failure to publish the review protocol prior to performing the review (Item 2, $n=17$)[30,31,33–35,37–40,43,44,46–49,51,52] and not providing the references for potentially relevant studies which did not fit the inclusion criteria (Item 7, $n=19$).[29,30,32,34–38,40,43–52]

3.4 | Pathology-specific effects of FES on walking-related outcomes

3.4.1 | Stroke

Ten reviews investigated the effects in the chronic phase[29,31,33–35,39–41,43,44] and one review did not report this information.[37] Five reviews included studies with stroke survivors in the acute, subacute, and chronic phase.[32,36,38,42,45] Of the 16 reviews with stroke survivors, one summarized the evidence on the orthotic effect of FES,[39] 13 the therapeutic effect or total orthotic effect,[29,31–36,38,40–44] one reported on both[37] and in one it was not clear whether the focus was an orthotic or therapeutic effect.[45]

3.4.2 | Orthotic effect in stroke reviews

Only the review by Kottink et al.[39] included a meta-analysis of the orthotic effect and it was found that the

pooled effect of FES on versus off was an increase in walking speed of 0.13 m/s. Other reviews also concluded that FES has a positive total orthotic effect on outcomes such as walking speed and the Timed Up and Go test (Table 3).[33,37,44,45]

3.4.3 | Therapeutic effect and total orthotic effect in stroke reviews

Table 4 reports the certainty of evidence provided in nine reviews (meta-analyses of 14 comparisons) on the therapeutic effect or total orthotic effect of FES in stroke survivors.[29,31,32,35,36,41–44] These nine reviews could be divided into two categories; (1) reviews including studies investigating the effect of any type of FES on the lower limbs with or without other interventions and compared with any other intervention or treatment as usual (TAU), (2) reviews which only included studies on the effect of FES to treat foot drop and compared this to AFOs or TAU. For the first category, a significant therapeutic effect on walking speed favoring FES was found by Busk et al.[31] (FES to any lower limb muscle plus active rehabilitation versus active rehabilitation only, mean difference (MD) 0.15 m/s, low certainty evidence), Hong et al.[35] (FES to any lower limb muscle vs. intervention without FES; standardized mean difference (SMD) 0.41 m/s, moderate certainty evidence) and da Cunha[32] (FES plus physiotherapy vs. physiotherapy only, MD 0.15 m/s, low certainty evidence). The remaining comparisons in the reviews by da Cunha et al.[32] and Pereira et al.[43] did not favor the intervention involving FES nor the control intervention (low certainty evidence).

For those reviews that only included studies aiming to investigate the therapeutic effect of FES to treat foot drop in particular, only the review by Nascimento et al.[42] showed a significant effect favoring FES (FES vs. TAU, MD 0.09 m/s, low certainty evidence). However, there is low-to-moderate certainty evidence that there is no difference in the therapeutic effect on walking speed between FES and AFO.[29,42] Two reviews including studies investigating the total orthotic effect (i.e., meta-analysis of walking speed when assisted by FES or AFO at follow-up) reported a significant effect favoring AFOs at short-term follow-up (Mendes et al.,[41] FES vs. AFO follow-up up to 6 months, MD 0.05 m/s, moderate certainty evidence and Prenton et al.,[44] FES vs. AFO, follow-up at 12 weeks, MD 0.04 m/s, moderate certainty evidence). However, there is moderate certainty evidence that there is no difference in the total orthotic effect between AFO and FES at a follow-up at more than 6 months.[41,44]

Two reviews comparing FES with AFOs but not included in the GRADE table also concluded that although FES had a therapeutic or total orthotic effect, it was not superior nor inferior to that of an orthosis (Table 3).[37,38] A further review, also not included in the GRADE table, concluded that FES combined with physiotherapy was more effective in improving walking speed compared to physiotherapy only,[45] which agrees with the results of the meta-analyses by Busk et al.[31] and da Cunha et al.[32] described above.

3.4.4 | Orthotic and therapeutic effects in people with SCI

Of the five reviews of studies with SCI participants, two reported the exact level of spinal injury of the participants in the studies,[46,47] while two only stated "complete" or "incomplete,"[30,49] with one review not reporting either.[48] Two reviews summarized the evidence on a therapeutic effect of FES,[46,47] two on the orthotic effect,[48,49] one on both (Table 3).[30]

One review reported the effect of FES in combination with BWSTT and found therapeutic improvement in gait speed and endurance.[46] Another compared hybrid orthoses (FES + Orthosis) with orthoses alone and found no difference in the outcome.[48] Harvey et al.[47] reviewed the effect of a range of physiotherapy strategies, including FES with inconclusive results on FES (only one study). The remaining two reviews both concluded that evidence that FES can improve gait,[30,49] with Lam et al.[30] finding that the therapeutic effect was greater in the subacute phase. In addition, Nightingale et al.[49] suggested increased cardiorespiratory fitness and muscle strength through improved walking performance.

3.4.5 | Orthotic and therapeutic effects in people with MS

Both reviews with MS reported on both orthotic and therapeutic effects[50,51] and so did the one review with a mixed population including people with MS.[52] Only one review reported the range of Expanded Disability Status Scale (EDSS) of those taking part in the studies,[50] which was 3.5 to 6. Both concluded that FES resulted in an orthotic effect on walking speed over short distances which was maintained over time, but neither found evidence for a therapeutic effect (Table 3).[50,51]

3.5 | Effect of FES on secondary outcome measures (all health conditions)

Sixteen of the 24 reviews evaluated the effect of FES on secondary outcomes as defined in this review. Stroke

TABLE 3 Aims, outcomes, and conclusions of the included reviews.

Study	Aims	Primary outcome measures (orthotic/therapeutic effects)	Secondary outcome measures	Conclusion
Stroke				
Busk et al. 2020 [31]	Explore the evidence of functional outcomes and gait in stroke provided with FES during physical activity up to 6 months after stroke	Walking speed (T)	Activities of daily living (Barthel Index)	Small significant positive effect on gait speed of FES during activity compared to the control group (physical activity only). Results should be interpreted with caution as low-quality studies were included.
da Cunha et al. 2020 [32]	Evaluate the effectiveness of FES applied to the paretic peroneal nerve on gait speed, active ankle DF mobility, balance, and functional mobility	Walking speed (T); gait analysis (T)		Low quality of evidence revealed positive effects of FES on gait speed when combined with physiotherapy compared to physiotherapy alone. FES combined with unsupervised home exercise or regular activities did not improve gait speed compared to other therapies. Low-quality evidence for positive effects on active ankle mobility and TUG
Dunning et al. 2015 [33]	To investigate the effect of daily use of single-channel surface FDS in people with stroke on change in gait speed and other relevant outcomes.	Walking speed (total O + T); walking distance (total O + T); PCI (total O + T)	Falls/near falls; QoL (SIS, SSQOL, SF-36); Activities of daily living; adverse effects	Significant and clinically meaningful increases in gait speed. Significant increases also for endurance, PCI, and improvement in TUG.
Hollands et al. 2011 [34]	To determine the current best evidence of therapeutic interventions for stroke to improve coordination of axial segments & stepping patterns while turning.	Walking speed (T)	NR	Orthoses (FES & AFOs) produced a change of 0.05 m/s
Hong et al. 2018 [35]	To determine the effectiveness of lower limb NMES compared with a control group in improving motor function outcomes after chronic stroke.	Walking speed (T); walking distance (T); gait analysis (T)	Spasticity/muscle or joint stiffness	Pooled analysis showed a statistically significant improvement in lower extremity motor function compared with the control group. NMES with other interventions: 0.47, but NMES alone not: 0.25. Significant reduction in TUG with NMES compared to control.
Howlett et al. 2015 [36]	To examine the latest evidence for the use of FES after stroke. Is FES effective in improving activity after stroke? Is FES more effective than activity training alone?	Walking speed (T)	NR	FES improved lower limb activity (walking speed) compared to the control group (mean difference 0.08 m/s, CI 0.02–0.15, $p < 0.01$)

(Continues)

TABLE 3 (Continued)

Study	Aims	Primary outcome measures (orthotic/therapeutic effects)	Secondary outcome measures	Conclusion
Jakubowitz et al. 2017 [37]	To investigate the medical evidence of FES to treat foot drop in people after a stroke.	Walking speed (O + T)	NR	The majority ($n = 12$) of the RCTs showed a significant advantage of FES compared to control or pre-treatment, while the other studies ($n = 4$) showed non-inferiority. Two studies showed a therapeutic effect. FES is a valuable treatment option for some patients.
Kafri et al. 2015 [38]	To present the therapeutic effects of FES on motor performance in people post-stroke.	Walking speed (T); walking distance (T); gait analysis (T); PCI (T)	QoL (SIS, SSQOL); activities of daily living (step count); spasticity/muscle or joint stiffness	Overall, there were clinically important increases in gait speed, positive therapeutic effect also for walking distance, PCI, walking independence; no significant effect in TUG. When FES was used as an alternative to an orthotic device, it had no superior therapeutic effects at the activity level, yet patients still seem to prefer it
Kottink et al. 2004 [39]	To present available evidence on the improvement of walking in stroke patients with a dropped foot when using peroneus stimulation.	Walking speed (O); gait analysis (O); PCI (O)	Spasticity/muscle or joint stiffness	Positive orthotic effect of FES on walking speed (pooled orthotic effect of 0.13 m/s) and PCI. Walking speed seems also to increase when FES is compared with an AFO.
Mahmoudi et al. 2021 [40]	To investigate the effect of FES on balance post-stroke.	Walking speed (T)	NR	The TUG (within groups) was improved in all four studies and 3 of the four for between groups; One study showed significant improvement in 10 mWT within groups.
Mendes et al. 2020 [41]	Assess the effects of motor neuroprosthesis for improving independence in ADL, activities involving limbs, participation scales of HRQoL, exercise capacity balance, adverse effects after stroke	Walking speed (T); walking endurance (T)	Falls; QoL; activities of daily living (mEFAP); adverse effects	Use of FES does not appear to be more beneficial than other assistive devices (AFO) for improving walking speed and exercise capacity or TUG after 6 months or more.
Nascimento et al. 2020 [42]	To examine the efficacy of interventions aimed at reducing foot drop, that is, AFOs and FES, on walking speed and balance after stroke.	Walking speed (T)	NR	Moderate quality evidence that FES improves walking speed (0.09 m/s; CI 0.03–0.14). Moderate quality evidence of no difference in efficacy between FES and AFO. (0.00 m/s; CI-0.06–0.05).
Pereira et al. 2012 [43]	To conduct a systematic review on the effectiveness of FES in improving lower extremity function in chronic stroke.	Walking speed (T); walking distance (T); gait analysis (T)	NR	FES may be an effective intervention in the chronic phase post-stroke. However, its therapeutic value in improving lower extremity function and superiority over other gait training approaches remains unclear.

TABLE 3 (Continued)

Study	Aims	Primary outcome measures (orthotic/therapeutic effects)	Secondary outcome measures	Conclusion
Prenton et al. 2016 [44]	To compare the effects on walking of FES) and AFOs for foot drop of central neurological origin, assessed in terms of unassisted walking behaviors compared with assisted walking following a period of use.	Walking speed (total O); walking speed (total O); gait analysis (total O); PCI (total O)	QoL (SIS)	In contrast to assumptions that predict FES superiority, ankle foot orthoses have equally positive combined-orthotic effects as FES on key walking measures for foot drop caused by stroke. An improvement in TUG was also reported.
Prenton et al. 2018 [29]	To compare the randomized controlled trial evidence for therapeutic effects on walking of FES and AFOs for foot drop caused by central nervous system conditions.	Walking speed (T); walking speed (T); gait analysis (T); PCI (T)	NR	FES and AFOs have an equally positive therapeutic effect on walking speed in non-progressive central nervous system diagnoses. One study reported an improvement on TUG.
Romera de Francisco et al. 2016 [45]	To determine the effectiveness of the FES in general skills, gait, general capacities, and quality of stroke patients through. Also, a secondary objective was to know the best method of application of this technique.	Walking speed (NR); walking distance (NR); gait analysis (NR); effort of walking (NR)	QoL; adverse effects; spasticity/muscle or joint stiffness	FES showed an improvement in gait, QoL, and motor abilities. It is more effective when combined with other physiotherapy techniques. FES alone does not provide better results than other physiotherapy techniques.
Spinal cord injury				
Hamzaid and Davis, 2009 [46]	Does FES-evoked exercise of lower limbs promote health & fitness benefits for the SCI population and to what extent?	Walking speed (T)	NR	FES + BWSTT increases walking endurance and speed
Harvey et al. 2016 [47]	To provide an unbiased summary of evidence underpinning physiotherapy practice	Walking speed (T)	NR	Inconclusive results of whether or not there is or not a therapeutic effect of ES + BWSTT
Karimi, 2013 [48]	To compare & evaluate the performance of SCI people standing and walking with FES and hybrid orthoses	Walking speed (O); gait analysis (O); PCI (O)	NR	FES (i.e., hybrid orthosis) did not add any benefit compared to mechanical orthosis only
Lam et al. 2007 [30]	To systematically review the evidence for the efficacy of different rehabilitation strategies on functional ambulation following SCI.	Walking speed (O + T); Walking distance (O + T); gait analysis (O)	NR	FES can improve functional ambulation in SCI. Some evidence for neuroplastic effect—long-term without FES. Sub-acute best response. Low level of evidence (level 4) that FES + bracing is better than either intervention alone
Nightingale et al. 2007 [49]	This review article investigated the objective evidence of benefits derived from FES-assisted gait for people with SCI.	Walking speed (O); walking distance (O); gait analysis (O); effort of walking (O)	Activities of daily living; spasticity, muscle or joint stiffness	FES can enhance gait, muscle strength, and cardiorespiratory fitness and reduce muscle spasms for people with incomplete SCI

(Continues)

TABLE 3 (Continued)

Study	Aims	Primary outcome measures (orthotic/therapeutic effects)	Secondary outcome measures	Conclusion
Multiple sclerosis				
Miller et al. 2017 [50]	To review the efficacy of FES used for foot drop in people with multiple sclerosis on gait speed in short and long walking performance tests.	Walking speed (O + T)	Quality of life (SF36), Impact of MS on daily living MSIS29	FES used for foot drop has a positive initial and ongoing orthotic effect on gait speed in short walking but not during longer (>2 min) tests. No therapeutic effect
Springer et al. 2017 [51]	To critically evaluate the literature describing the orthotic and therapeutic effects of FES on gait in people with MS.	Walking speed (O + T); Walking distance/endurance (O + T); gait analysis (O); PCI and O2 uptake (O)	Falls/near falls; adverse effects (difficulty to use, skin irritation)	FES has a positive orthotic effect on walking in people with MS. Therapeutic efficacy of FES was not demonstrated.
Mixed patient populations				
Roche et al. 2009 [52]	To source and evaluate the current available evidence for both the orthotic and the therapeutic effect of surface-FES for the correction of drop-foot after stroke.	Walking speed (O + T); walking speed (O + T); gait analysis (O + T); effort of walking (O + T)	QoL; spasticity & muscle or joint stiffness	Evidence exists to support an orthotic rather than therapeutic effect of FES. No effect on TUG.

Abbreviations: ADL, activities of daily living; AFOs, ankle foot orthoses; BWSTT, body weight support treadmill training; CI, confidence intervals; DF, dorsiflexion; ES: electrical stimulation; FDS, foot drop stimulator; FES, functional electrical stimulation; HRQoL, health-related quality of life; mEFAP, modified Emory Functional Ambulation Profile; MS, multiple sclerosis; MSIS29, Multiple Sclerosis Impact Scale; NMES, neuromuscular electrical stimulation; O, orthotic effect; PCI, physiological cost index; QoL, quality of life; RCT, randomized controlled trial; SCI, spinal cord injury; SF36, 36-item short form survey; SIS, Stroke Impact Scale; SSQOL, stroke-specific quality of life scale; T, therapeutic effect; TUG, timed up and go.

TABLE 4 Summary of results for walking speed-related outcomes for each review for which the assessment of the certainty of the evidence was possible using the GRADE criteria.

	Certainty assessment								№ of patients		Absolute effect FES compared to comparator (95% CI)	Certainty
	№ of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Experimental/ control (outcome measure)	Experimental	Control		
Busk et al 2020 [31]	5	4 randomized trials and 1 controlled trial	Serious[a]	Not serious	Not serious	Serious[b]	None	Any FES to LL + active rehabilitation /active rehabilitation (walking speed—therapeutic effect)	60	60	**MD 0.15 m/s higher (0.08 higher to 0.21 higher)**	⨁⨁◯◯ Low
Da Cunha et al 2020 [32]	12	Randomized trials	Serious[a]	Serious[c]	Not serious	Not serious	None	Any FES to LL plus other (including robot-assisted)/conventional treatment (walking speed—therapeutic effect)	537	540	MD 0.092 m/s higher (0.35 lower to 0.53 higher)	⨁⨁◯◯ Low
	4	Randomized trials	Serious[a]	Not serious	Not serious	Serious[b]	None	Any FES to LL + unsupervised home exercises/AFO + training OR PT (walking speed—therapeutic effect)	178	177	MD 0.02 m/s lower (0.23 lower to 0.19 higher)	⨁⨁◯◯ Low
	5	Randomized trials	Serious[a]	Not serious	Not serious	Serious[b]	None	Any FES to LL + PT/PT alone (walking speed—therapeutic effect)	66	67	**MD 0.51 m/s higher (0.16 higher to 0.86 higher)**	⨁⨁◯◯ Low
	3	Randomized trials	Serious[a]	Serious[c]	Not serious	Not serious	None	Any FES to LL + regular activities at home/AFO or conventional device (walking speed—therapeutic effect)	293	296	MD 0.28 lower (1.53 lower to 0.96 higher)	⨁⨁◯◯ Low
Hong et al 2018 [35]	15	Randomized trials	Serious[a]	Not serious	Not serious	Not serious	None	FES + NMES to LL alone or with other interventions/ treatments without ES (walking speed—therapeutic effect)	493	528	**SMD 0.41 SD higher (0.22 higher to 0.61 higher)**	⨁⨁⨁◯ Moderate

(Continues)

TABLE 4 (Continued)

	Certainty assessment								№ of patients		Absolute effect FES compared to comparator (95% CI)	Certainty
	№ of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Experimental/ control (outcome measure)	Experimental	Control		
Howlett et al 2015 [36]	8	Randomized trials	Serious[a]	Not serious	Not serious	Serious[b]	None	Any FES to LL/activity training, Placebo, or TAU (walking speed—therapeutic effect)	100	103	**MD 0.08 m/s higher (0.02 higher to 0.15 higher)**	⨁⨁◯◯ Low
Mendes et al 2020 [41]	2	Randomized trials	Serious[a]	Not serious	Not serious	Not serious	None	FES to peroneal muscles / AFOs (walking speed—therapeutic and total orthotic effect up to 6 months use)	296	309	**MD 0.05 m/s lower (0.1 lower to − 0 lower)**	⨁⨁⨁◯ Moderate
	3	Randomized trials	Serious[a]	Not serious	Not serious	Not serious	None	FES to peroneal muscles / AFOs (walking speed—therapeutic & ongoing effect 6–12 months use)	350	363	MD 0 m/s (0.05 lower to 0.05 higher)	⨁⨁⨁◯ Moderate
	2	Randomized trials	Serious[a]	Not serious	Not serious	Not serious	None	FES to peroneal muscles / AFOs (TUG—any FU time point)	341	351	MD 0.51 s higher (4.41 lower to 5.43 higher)	⨁⨁⨁◯ Moderate
Nascimento et al 2020 [42]	4	Randomized trials	Serious[a]	Not serious	Not serious	Serious[b]	None	FES to improve DF/TAU (walking speed—therapeutic effect)	62	63	**MD 0.09 m/s higher (0.03 higher to 0.14 higher)**	⨁⨁◯◯ Low
	4	Randomized trials	Serious[a]	Serious[c]	Not serious	Not serious	None	FES to improve DF/AFO (walking speed—therapeutic effect)	433	462	MD 0.00001 m/s lower (0.06 lower to 0.05 higher)	⨁⨁◯◯ Low
Pereira et al 2012 [43]	6	Randomized trials	Serious[a]	Not serious	Not serious	Serious[b]	None	Any NMES or FES to LL + PT or gait training/sham or PT alone or gait training (walking speed—therapeutic effect)	NR (but total sample size is 175)	NR (but total sample size is 175)	SMD 0.269 SD higher (0.051 lower to 0.59 higher)	⨁⨁◯◯ Low

TABLE 4 (Continued)

	Certainty assessment								№ of patients		Absolute effect FES compared to comparator (95% CI)	Certainty
	№ of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Experimental/ control (outcome measure)	Experimental	Control		
Prenton et al 2016 [44]	5	Randomized trials	Serious[a]	Not serious	Not serious	Not serious	None	FES to treat foot drop /AFOs (walking speed—total orthotic effect) (any FU time point)	391	398	MD 0.01 m/s higher (0.04 lower to 0.05 higher)	⊕⊕⊕◯ Moderate
	4	Randomized trials	Serious[a]	Serious[c]	Not serious	Not serious	None	FES to treat foot drop /AFOs (walking speed—short-term total orthotic effect)	384	387	MD 0.02 m/s higher (0.05 lower to 0.1 higher)	⊕⊕◯◯ Low
	3	Randomized trials	Serious[a]	Not serious	Not serious	Not serious	None	FES to treat foot drop /AFOs (walking speed—medium-term total orthotic effect)	344	355	**MD 0.04 m/s lower (0.09 lower to- 0)**	⊕⊕⊕◯ Moderate
	3	Randomized trials	Serious[a]	Not serious	Not serious	Not serious	None	FES to treat foot drop /AFOs (walking speed—long-term total orthotic effect)	350	363	MD 0.02 m/s lower (0.06 lower to 0.03 higher)	⊕⊕⊕◯ Moderate
Prenton et al 2018 [29]	6	Randomized trials	Serious[a]	Not serious	Not serious	Not serious	None	FES to treat foot drop /AFOs (walking speed—therapeutic effect) (any FU time point)	215	208	MD 0.02 m/s higher (0.03 lower to 0.07 higher)	⊕⊕⊕◯ Moderate
	5	Randomized trials	Serious[a]	Not serious	Not serious	Serious[b]	None	FES to treat foot drop /AFOs (walking speed—therapeutic effect 4–6 weeks)	62	54	MD 0.03 m/s higher (0.06 lower to 0.12 higher)	⊕⊕◯◯ Low

Note: All reviews in this table focused on the effect of FES in stroke survivors and mean differences are derived from mean values post-intervention. Significant absolute effects are in bold.

Abbreviations: AFO, ankle foot orthosis; CI, confidence interval; DF, dorsiflexion; FES, functional electrical stimulation; FU, follow-up; LL, lower limb; MD, mean difference; NMES, neuromuscular electrical stimulation; PT, physiotherapy; SMD, standardized mean difference; TAU, treatment as usual; TUG, time up and go.

[a]Lack of blinding of participants and personnel.

[b]Small sample size; less than 200 per arm.

[c]Significant heterogeneity.

reviews concluded that there is evidence that FES positively affects QoL[33,38,45]; walking-related activities of daily living[33,38]; falls[33]; spasticity[35]; active range of motion.[32] However, in their review of FES for people with MS, Springer et al.[51] concluded that there was no therapeutic effect on the modified Emory Functional Ambulation Profile (mEFAP).

Reviews comparing the effects of FES with AFOs concluded that both were equally beneficial with regard to QoL[41,44] or number of falls.[33,41] Dunning et al.[33] reported that the percentage of participants reporting skin irritation ranged from 8% to 35% in FES users compared to 2%–2.3% in AFO users. Mendes et al.[41] concluded there was low-to-moderate certainty evidence that the use of FES did not increase the number of serious adverse events such as falls compared to an AFO, but that there was low certainty evidence that FES may result in a higher number of dropouts (e.g., due non-compliance with the protocol and discontinuation of the interventions). However, interestingly, a user preference for FES over an AFO was also reported by three reviews.[33,45,49]

4 | DISCUSSION

The aim of this umbrella review was to evaluate the effectiveness of FES applied to the lower limb to improve walking outcomes for adults with UMN lesions. All reviews in stroke concluded that there was a positive orthotic and/or therapeutic effect of FES on walking. There is currently no evidence for the superiority of the therapeutic effect of FES compared to other treatments such as AFOs. However, three stroke reviews concluded that FES combined with physiotherapy is more effective in improving walking compared to physiotherapy alone. Both reviews for people with MS concluded that FES has a positive orthotic effect but no therapeutic effect. The reviews on SCI concluded that FES with or without BWSTT improved gait speed and endurance but outcomes with FES combined with a mechanical orthosis did not improve walking speed compared to a mechanical orthosis only. The only review including both studies on MS and stroke survivors concluded that FES has an orthotic but not a therapeutic effect during walking.

Synthesizing findings has generated support for the use of FES, especially in terms of its orthotic benefit with regard to walking speed regardless of health condition. Reviews that included studies with acute and sub-acute stroke patients, who may have experienced natural recovery, may partly have accounted for the therapeutic benefits reported and concluded in those reviews.[32] The two reviews on MS concluded that the majority of the studies did not report any therapeutic benefits. The authors in both reviews suggested that the presence of a therapeutic effect may depend on a range of factors such as the duration of FES use, walking ability of the participants at baseline, and the type of MS (progressive vs. relapse remitting).[50,51] The progressive nature of MS may also play a role when exploring the therapeutic effect of FES over a period of several years. However, using FES may allow people with MS to retain their functional walking category and mobility for longer.[53]

Although the majority of the reviews focus on walking speed as their primary outcome measure, it is important to highlight that FES was also found to improve quality of life, reduce falls, increase active range of motion, decrease spasticity, and improve walking-related activities of daily living. Further, three reviews concluded that most patients preferred FES over an AFO. This is interesting as most meta-analyses showed that in terms of improved walking speed, both are equally effective. It is possible that FES users also value outcomes other than walking speed such as the ability to perform walking-related activities of daily living or a reduction in the number of falls. Unfortunately, relatively few reviews synthesized the findings of these secondary measures. Authors may have omitted secondary outcomes in their reviews simply because of the wide range of outcome measures used by individual studies, which would have made pooling evidence impractical. These findings support the call for internationally agreed core outcome measures[54] and for FES studies to always include a range of outcomes taken from each category of the International Classification of Function (ICF) Framework.[55] In combination, these weaknesses in the included reviews highlight the need for more comprehensive evidence for the benefit of FES on secondary outcomes.

A recent narrative review of the use of FES, by Smith et al.[56] also concluded that future studies should investigate the impact of FES on a wider range of Patient Reported Outcomes (PROMS) but also use qualitative approaches to capture users' opinions and observed changes in addition to changes in quantitative outcomes. A qualitative study by Wilkinson et al.[57] of 20 people less than 6 months post-stroke explored 'valued personal' benefits of FES not measured by walking speed and identified factors such as spontaneity, freedom, automaticity (ability to walk without thinking about it), and self-determination as important benefits. Other qualitative studies by Bulley et al.[58] and Miller Renfrew et al.[59] including people with MS reported similar findings. These self-reported benefits but also possible adverse events of FES such as skin irritation and how to deal with these are rarely included in systematic reviews, which highlights the need to incorporate expert consensus and the views of all stakeholders for the development of clinical practice guidelines on FES.

The AMSTAR2 appraisal tool showed that the methodological quality of 18 out of 24 of the reviews was rated low or critically low. The methodological quality of many of the reviews was downgraded due to not explaining why the search was restricted to articles in the English language only and not taking into account the Risk of Bias when discussing the results. The majority ($n = 18$ out of 24) of these reviews were published before the AMSTAR2 tool was published, so it may be expected that the methodological quality in future reviews will be higher.

Of the 24 systematic reviews, only 11 included a meta-analysis of which nine had sufficient data to be included in the GRADE summary of findings table. Certainty of the evidence presented in the systematic review was often downgraded because of the high risk of bias due to lack of blinding of the outcome assessor, participants, or both. Blinding of the participants is impossible in FES research but blinding of the outcome assessor in studies investigating the therapeutic effect is possible and should be considered in future studies. Another reason for downgrading the certainty of evidence was that the majority of the studies included in the reviews had small sample sizes (<50 per arm) with wide confidence intervals.

Synthesizing the conclusions and conducting meta-analysis was also complicated by the fact that many reviews included a broad variety of FES interventions, that is, variety of muscles targeted by FES, applied with or without other interventions, or setting (hospital or daily use at home).

Reviews included very few trials with a follow-up of 1 year or more. While clearly, long-term benefits are critical to adoption, extended follow-up assessments are frequently omitted from RCTs for practical reasons. Evidence for long-term effects does however exist from audit data, for example, Taylor et al.[60] reported the mean time for use of a drop-foot stimulator was 3.6 years and people with stroke experienced a total orthotic effect increase of 45% in walking speed over the course of their treatment.

There was no evidence for differences in the number of falls between FES and AFO, but the effect of assistive technology to aid walking on falls is hard to gauge; if FES (or an AFO) enables people to walk further and out-of-doors then the "opportunity" for, and, therefore, number of falls, may increase. Future studies might include outcomes such as a step counter or activity monitor, to not only measure change in the amount of walking, but also to verify whether more walking is associated with an increased number of falls. Measuring the walking activity such as step count in trials investigating the therapeutic effect of FES may also provide insight into the reasons for the presence or absence of such an effect.

4.1 | Limitations of the reviews included in the umbrella review

Limitations include the low methodological quality of the included systematic reviews and the wide variety of methodologies used made the interpretation of results complex. Six of the 24 reviews included did not distinguish between, or directly report, orthotic and therapeutic effects. Only through careful examination of their data were we able to extract this information from five of the six reviews. In our view, future reviews should clearly define and separately report orthotic, therapeutic, and total orthotic effects of FES. Ten reviews did not report on any secondary outcomes and adverse events were only reported in four reviews, despite the primary importance of safety for the transfer of technologies to clinical practice.[61] Falls and near falls were also only reported in three reviews. We did not identify any systematic reviews of FES with people with PD, adults with CP, or acquired brain injury possibly due to the novelty of its application in these populations, despite there being RCT evidence to support its use.[62]

4.2 | Strengths of the umbrella review

This is the first umbrella review on the effect of FES on walking outcomes and secondary outcome measures across the ICF domains in adults with a UMN lesion. In our comprehensive synthesis of the available evidence, we highlighted consensus among the reviews with regard to the orthotic effect of FES, the equally beneficial effect of FES and AFO on walking speed, and the additional benefit of FES when combined with physiotherapy compared to physiotherapy alone. We also identified several gaps in the evidence, such as the lack of evidence on outcomes other than walking speed and recommended directions for future research.

5 | CONCLUSIONS

This comprehensive umbrella review found evidence for both orthotic and therapeutic benefits of FES in improving walking in stroke. There is low-to-moderate certainty evidence that FES is neither superior nor inferior to an orthosis in improving walking speed. FES for people with MS has orthotic effects, but a therapeutic effect may depend on factors such as type of MS (progressive vs. relapse-remitting), amount of FES use, and baseline walking ability. The reviews on SCI concluded that FES with or without Body Weight Supported Treadmill Training improved gait speed and endurance but outcomes with FES combined with a mechanical orthosis

did not improve walking speed compared to a mechanical orthosis alone.

As FES becomes more widely recommended and used clinically, recording of clinical data becomes imperative. For such data to be useful, core outcome measures need to be agreed upon and best practice protocols adhered to. As the database of clinical evidence grows, we can learn more about how FES can be used to benefit patients in the most effective way.

AUTHOR CONTRIBUTIONS

GA was responsible for the conduction of the repeat database searches and screening for additional eligible reviews. GA was also involved in the data extraction, review quality appraisal, and evidence synthesis using the GRADE and produced first drafts of some sections of the manuscript. GA reviewed further drafts of the manuscript and approved the final version for submission. GB designed the review methodology, constructed the search strategy, and ran the initial database searches. GB conducted the screening for eligible reviews and was involved in the data extraction and review quality appraisal. GB reviewed drafts of the manuscript and approved the final version for submission. TS proposed the idea of completing an umbrella review and contributed to developing the aims and search strategy. TS reviewed drafts of the manuscript and approved the final manuscript for submission. CB contributed to the concept of the umbrella review and review protocol. CB reviewed drafts of the manuscript and approved the final version for submission. RS advised on the evidence synthesis using the GRADE, reviewed drafts of the manuscript, and approved the final version for submission. MvdL was involved in the data extraction, review quality appraisal, and evidence synthesis using the GRADE. MvdL produced first drafts of some sections of the first draft, reviewed further drafts of the manuscript, and approved the final version for submission. JB led the project from the start, developed the umbrella review concept, and contributed to the search strategy, screening for eligible reviews, data extraction, and review quality appraisal. JB wrote sections of the first draft, reviewed further versions of the manuscript, and approved the final manuscript for submission.

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CONFLICT OF INTEREST

The authors report there are no competing interests to declare.

ORCID

Georgia Andreopoulou https://orcid.org/0000-0003-1616-1354
Tamsyn Street https://orcid.org/0000-0002-9859-6732
Cathy Bulley https://orcid.org/0000-0001-8338-5388
Reza Safari https://orcid.org/0000-0001-5434-8844
Marietta L. van der Linden https://orcid.org/0000-0003-2256-6673
Jane Burridge https://orcid.org/0000-0003-3497-6725

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SUPPORTING INFORMATION

Additional supporting information can be found online in the Supporting Information section at the end of this article.

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