

## Early specialist orthotic interventions for the lower limb in adult stroke patients: a systematic literature review

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**Background** Stroke is a leading cause of long-term disability worldwide, estimated to affect up to 50% of stroke survivors. Many stroke survivors use orthotic splints and braces to help address difficulties with mobility and gait dysfunction both early after the stroke event and longer-term.

**Objectives** The aim of this systematic review was to identify, synthesise and appraise the evidence on early orthotic involvement for the lower limb following stroke.

**Study design** Systematic literature review

**Methods** We conducted a systematic search of electronic databases including: AMED (1985 to present); CINAHL (1982 to present); EMBASE (1980 to present); MEDLINE (1949 to present); PsycINFO (1967 to present). The search took place on 18/10/2019. Included studies evaluated an early orthotic intervention designed to either promote mobility or reduce secondary complications after stroke. Articles were screened for inclusion by two independent reviewers.

**Results** This review included six articles from one research group in the Netherlands. Methodological quality was considered good in each of the included studies. Limitations include small sample size, restricted descriptions of the intervention and short-term follow-ups.

**Conclusion** This systematic review suggests that earlier lower limb orthotic interventions can result in improved walking speed and balance, and enhanced ability to perform activities of daily living in the early weeks post-stroke. Future research would benefit from considering wider orthotic and orthotist intervention with larger sample sizes and longer-term outcomes.

**Keywords:** orthotics, stroke, early intervention, mobility, rehabilitation, lower limb, contracture

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Stroke is a leading cause of adult disability worldwide [1], with the global burden of stroke related illness and disability predicted to double by 2035 [4]. Reduced mobility and gait dysfunction are among the most commonly experienced impairments post stroke [5], and many stroke survivors use orthotic splints and braces to help address these difficulties in the immediate and longer-term [2,3].

Orthotic interventions can help to promote normal body movement and function, and delays in their provision can contribute to the development of complications, making treatment much more difficult, costly, and less effective [6,7]. It has been suggested that earlier involvement of the orthotist and subsequent orthotic intervention can complement and enhance other therapy effects specifically in the lower limb [8], optimising alignment and ensuring

consistent repeatable movements essential for motor learning [6].

The aim of this systematic review is to build on work started through a national report by the National Health Service (NHS) Quality Improvement Scheme (QIS), and systematic review conducted by Tyson et al [9], with the purpose of identifying studies which have evaluated orthotic interventions following stroke for the lower limb that were delivered 'early'. Evidence has shown that effective rehabilitation starting early after stroke is essential to gaining optimal physical recovery for stroke survivors [10]. Therefore we are seeking to explore whether earlier lower limb orthotic intervention, delivered within the acute (1-7 days) and early sub-acute (7 days- 3 month) time period, as described by Bernhardt et al [11], lead to enhanced rehabilitation through facilitation of earlier and more efficient mobilising.

## Methods

The review was registered in the PROSPERO database (CRD42020204134)[12] and conforms to the PRISMA statement [13]. Studies that compared an orthotic intervention designed to influence lower limb mobility/reduce complication with routine input or usual care were eligible for inclusion in the form of randomised controlled trials (RCTs), non-randomised controlled trials, and controlled before and after studies. Participants included individuals aged 18 years or older with confirmed diagnosis of stroke. Studies that focused on the use of Functional Electrical Stimulation (FES) or robotic orthotic devices were excluded as these are not yet commonly available within orthotic practice.

The main outcome of interest was performance in mobility scores for the lower limb. This could include spatial and temporal parameters of walking including speed, velocity, cadence, stride time, stride length, step length and balance. Other outcomes included: Reduced complications; Health related quality of life; Functional mobility: Timed Up and Go Test; Activity limitations: using measures such as Barthel Index and the Functional Independence Measure; Number of falls.

The following bibliographic databases were searched for studies prior to October 2019: AMED (1985 to present); CINAHL (1982 to present); EMBASE (1980 to present); MEDLINE (1949 to present); PsycINFO (1967 to present). The search was conducted in English and the strategy consisted of a combination of subject headings and free text terms. The search strategy for Medline is shown in Table 1, this was adapted for use in the other databases.

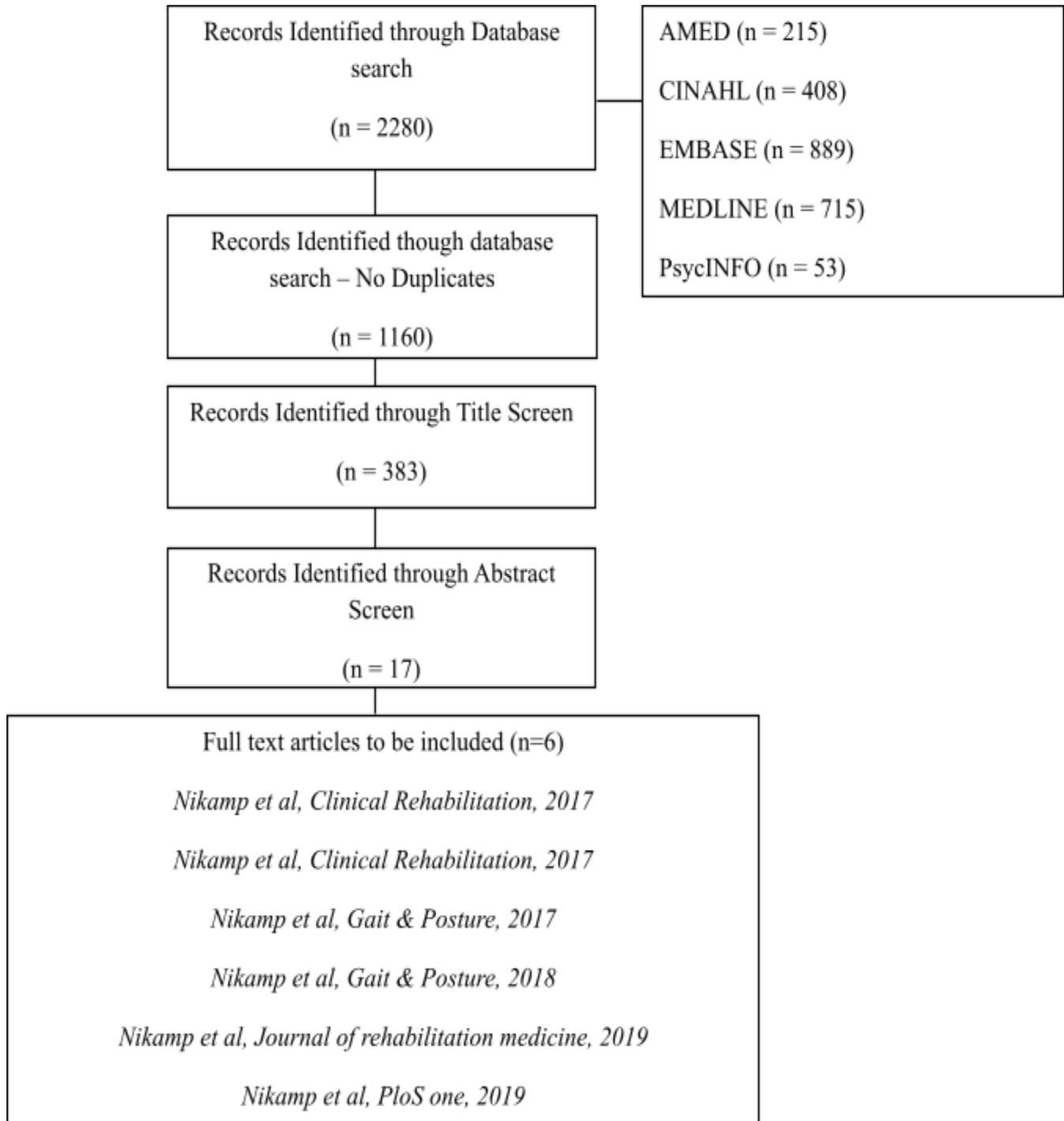
Studies extracted from the different databases were compiled and duplicates removed. Two reviewers then followed a three-stage screening process where titles, then abstracts, then full papers were screened, with all studies not found to be pertinent excluded. Agreement was then reached between the two reviewers as to the final included studies before data was extracted using pre-prepared and piloted data-extraction forms. The results of this data extraction were then discussed by all review authors.

- exp Stroke/
- exp Patients/
- exp Stroke Rehabilitation/
- hemip\*.mp
- 1 or 2 or 3 or 4
- exp Orthotic Devices/
- exp Foot Orthoses/
- afo.mp.
- ankle foot ortho\*.mp.
- ankle-foot o\*.mp.
- exp Splints/
- orthotist.mp.
- 6 or 7 or 8 or 9 or 10 or 11 or 12
- exp Mobility Limitation/
- mobility.mp.
- exp Walking/
- exp Postural Balance/
- exp Early Ambulation/
- exp Locomotion/
- exp Gait Disorders, Neurologic/
- exp Gait/
- exp Contracture/
- exp Lower Extremity/
- adult hemiplegia.mp.
- muscle activity.mp.
- functional recovery.mp.
- exp Muscle Spasticity/
- 14 or 15 or 16 or 17 or 18 or 19 or 20 or 21 or 22 or 23 or 24 or 25 or 26 or 27
- 5 and 13 and 28

**Table 1** MEDLINE systematic review search strategy.

## Results

The search process is summarised in Figure 1. The reviewers identified 2280 records through electronic database searches, with 1160 original works once duplicates were removed. Three hundred and eighty-three were included following a title screen, with 16 remaining once abstracts were assessed for suitability. Finally, six manuscripts were included following review of the full articles. A summary of study characteristics is given in Table 2.



**Figure 1** Flow diagram of search process.

Country of study & Reference	Study type	Participants	Primary outcome	Follow-up (in weeks)
The Netherlands, Nikamp et al. [14]	RCT	Unilateral hemiparetic stroke patients (up to 6 weeks post stroke) with indication for use of an ankle-foot orthosis.	Comfortable walking speed, assessed with the 10-metre walk test.	1,3,9,11
The Netherlands, Nikamp et al.[15]	RCT	Unilateral hemiparetic stroke patients (up to 6 weeks post stroke) with indication for use of an ankle-foot orthosis.	Comfortable walking speed, assessed with the 10-metre walk test.	1,3,5,7,9,11, 13,15,17, 26
The Netherlands, Nikamp et al.[16]	RCT	Unilateral hemiparetic stroke patients (up to 6 weeks post stroke) with indication for use of an ankle-foot orthosis.	Sagittal ankle movement (dorsiflexion), measured at initial contact and foot-off and values in stance (max) and swing (min and max).	1,9
The Netherlands, Nikamp et al.[17]	RCT	Unilateral hemiparetic stroke patients (up to 6 weeks post stroke) with indication for use of an ankle-foot orthosis.	Pelvic obliquity, hip ab/adduction and hip and knee flexion/extension at week 26	1,9,17,26
The Netherlands, Nikamp et al.[18]	RCT	Unilateral hemiparetic stroke patients (up to 6 weeks post stroke) with indication for use of an ankle-foot orthosis.	Tibialis Anterior activity during swing during normal walking to evoke foot clearance	1,9,17,26
The Netherlands, Nikamp et al.[19]	RCT	Unilateral hemiparetic stroke patients (up to 6 weeks post stroke) with indication for use of an ankle-foot orthosis.	Effects of Ankle-foot orthoses provision on occurrence and circumstances of falls/near falls.	9,52

**Table 2** Characteristics of included studies.

All six of the included studies were authored by the same research group in the Netherlands and constitute the results of different aspects of the same trial conducted on the early provision of Ankle Foot Orthoses (AFO) specifically for stroke patients. The same cohort of participants are reported upon in each of the studies, which collectively showed improved walking speed (10-metre walk test +0.14m/s,  $p=0.093$ ), cadence (+2.1 steps/min,  $p = 0.026$ ), and balance (Berg Balance Scale  $p=0.011$ ). Significant positive effects of AFO provision for ankle dorsiflexion at initial contact, foot-off and during swing were found, ( $3.6^\circ$  degrees (7.3) vs  $3.0^\circ$  degrees (3.9);  $0.0^\circ$  degrees (7.4) vs  $5.2^\circ$  degrees (3.7); and  $6.1^\circ$  degrees (7.8) vs  $2.6^\circ$  degrees (3.5),

respectively), and no long term negative effect on tibialis anterior muscle activity ( $p = 0.207$ ) with AFO use. Independence in activities of daily life were found to improve (Barthel Index +1.9 points,  $p=0.002$ ), following the early (on average 32 days after stroke) and delayed (eight weeks after stroke) provision of AFOs to stroke patients. Effects were shown to be more pronounced when the orthosis was provided early [14].

Short-term effects were found on ankle kinematics initially after stroke, however the timing of AFO provision did not influence the results [16] and another of the papers found that whilst earlier provision improved distal issues such as ‘foot-drop’,

there was no evidence of influencing compensatory patterns in more proximal joints with similar pelvic obliquity and abduction in the frontal plane, and hip and knee flexion seen in the sagittal plane in both groups [17].

The impact on falls was investigated with one of the studies finding that during the first eight weeks, falls occurred significantly more often in the 'early' group of patients who had been provided with AFOs, compared with the control patients who had not yet been provided with AFOs. However, it is important to note that 63.6% of the falls in patients who had been provided with an AFO, occurred when the AFO was not in use, the majority taking place during the time period where patients had no independent walking ability.

None of the included studies conducted longer-term follow ups (longer than 1 year) though medium-term findings from the Netherlands group showed no difference at six-months in functional outcomes of providing ankle foot orthoses at different moments in the early rehabilitation after stroke [15]. The authors did acknowledge that the study from which all the papers were reporting was underpowered and further research with larger numbers of subjects is warranted across all the outcomes and findings.

## **Discussion**

There were numerous other studies, which analysed the effects of predominantly AFO use after stroke, that were not included within this review as they focused on a later time period covering late subacute (3-6 months) and chronic stroke (>6 months). These have been previously evaluated in systematic review not focused on early intervention [20–24].

Papers of note which are relevant to this field Carse et al. [25], Wang & Huang [26] and Tyson et al. [27]. The first study by Carse et al. considered the effects of AFO and their tuning in early stroke rehabilitation and found immediate significant improvements in walking speed, step length and cadence, when compared to walking with shoes only. As a pre–post-test experimental study it was not included within the review but offers supportive evidence. The second paper also explored early AFOs use in a randomized control trial style study and which found some improvements in the participants gait cycle at 3 months post-stroke follow up but we were unable to obtain the full paper so were not able to include it

within the review. Finally Tyson et al have produced several papers in this field, this one is an RCT comparison of bespoke vs off-the-shelf devices. When considered overall the team found that AFO use was conducive to improved mobility outcomes but no significant difference between the two options.

The search, though systematic and comprehensive, only returned studies from a single research group which were all produced from one small, underpowered trial with a single group of participants. This is an indication of the paucity of research in this area. Moreover, the included studies all focused on a single orthotic intervention, the provision of an ankle foot orthoses, which limits the generalisability of this review to include the wider spectrum of orthotic interventions following stroke. AFO fitting for trial subjects was reported to have been performed by a licensed orthotist though there is limited indication of their assessment or prescription decisions with all six of the papers stating “AFO type was chosen according to a custom developed protocol”. It is a limitation of the included studies that they do not report on the role of the prescribing clinician and focus solely on the devices themselves as the intervention which were all 1 of 3 types of off-the-shelf orthotic device. This again does not reflect usual clinical practice where numerous styles of orthotic device could be used and decided upon to best suit the needs of the patient at any given time.

Whilst the overall findings of the six included papers evidenced a positive impact of earlier AFO provision, the increased risk of falls evidenced in one of the papers [19], raises an interesting question. It is widely accepted earlier mobilisation after stroke is of benefit to the stroke survivor [10], however when independent walking is not possible without assistive aids, is it appropriate given the increased risk of falling? It is reasonable therefore to suggest that orthoses provision should not be carried out in isolation and efforts made to mitigate any potential increase in falls risk through additional therapy input and giving careful instructions on the use of the orthoses and assistive devices warranted.

## **Conclusion**

The potential for earlier orthotic intervention to promote quicker and more efficient mobilising is important to consider within the landscape of stroke rehabilitation. Much of the current research on this topic focuses on ankle foot orthoses provision

specifically, and the impact that has on functional outcomes. The findings from this review advance the body of knowledge in suggesting how earlier orthotic intervention can result in improved walking speed and balance, and ability to perform activities of daily living in the early weeks post-stroke. It also highlights how aspects such as increases in the number of falls and use of longer-term outcomes need further consideration and investigation.

**Authors' contributions:** MG-D developed the search strategy, carried out the database search, extracted the outcomes of the included study and was the first reviewer for data analysis. NP was the second reviewer for data extraction and analysis. MW, ST and JH acted as third reviewers and assisted in the interpretation of the results, also overseeing the review and preparation of the manuscript. LT oversaw the review and preparation of the manuscript. All authors read and approved the final manuscript.

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**Conflicts of Interest declaration:** The authors declare no known conflicts of interest.

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