2013•2014

FACULTEIT GENEESKUNDE EN LEVENSWETENSCHAPPEN

master in de revalidatiewetenschappen en de kinesitherapie: revalidatiewetenschappen en kinesitherapie bij musculoskeletale aandoeningen

Masterproef deel 1

What is the effect of an ankle-foot orthosis (AFO) on the dynamic balance and walking capacity in stroke patients?

Promotor :
Prof. dr. Peter FEYS

Copromotor :
Mevrouw ELS HOUBEN
Mevrouw VENDULA DOLE ZALOV

Lotte Schaekers , Leni Meuws

Eerste deel van het proefschrift ingediend tot het behalen van de graad van master in de revalidatiewetenschappen en de kinesitherapie revalidatiewetenschappen en kinesitherapie bij musculoskeletale aandoeningen

universiteit hasselt
KNOWLEDGE IN ACTION

Universiteit Hasselt | Campus Hasselt | Martelarenlaan 42 | BE-3500 Hasselt
Universiteit Hasselt | Campus Diepenbeek | Agoralaan Gebouw D | BE-3590 Diepenbeek

universiteit hasselt
KNOWLEDGE IN ACTION

2013•2014

FACULTEIT GENEESKUNDE EN LEVENSWETENSCHAPPEN

master in de revalidatiewetenschappen en de kinesitherapie: revalidatiewetenschappen en kinesitherapie bij musculoskeletale aandoeningen

Masterproef deel 1

What is the effect of an ankle-foot orthosis (AFO) on the dynamic balance and walking capacity in stroke patients?

Promotor :
Prof. dr. Peter FEYS

Copromotor :
Mevrouw ELS HOUBEN
Mevrouw VENDULA DOLE ZALOV

Lotte Schaekers , Leni Meuws

Eerste deel van het proefschrift ingediend tot het behalen van de graad van master in de revalidatiewetenschappen en de kinesitherapie revalidatiewetenschappen en kinesitherapie bij musculoskeletale aandoeningen

universiteit hasselt
KNOWLEDGE IN ACTION

FRAMEWORK

Problems in gait and balance are two of the most important impairments of people after stroke. An ankle-foot orthosis (AFO) is often prescribed to alter the gait pattern in a positive way and to improve walking and balance. The specific effects of an AFO on walking and balance are not well known. Although, there is a widely spread use of AFO's in the population with stroke. Therefore, the research on the effects of an AFO in stroke patients is a very important aspect.

This duo master thesis is situated in the faculty 'Medicine and Health Sciences' of the University of Hasselt and it concerns the field of neurological rehabilitation. It is a part of an ongoing research targeting the use of AFO's in people with stroke. The research group was set up by a collaboration between the Rehabilitation Department of ZOL (Ziekenhuis Oost-Limburg) in Lanaken and the University of Hasselt. In the Rehabilitation Department of ZOL (Ziekenhuis Oost-Limburg) in Lanaken, the use of an AFO is greatly encouraged. Lic. E. Houben is a physiotherapist in this hospital and co-promotor of this study. There, over the last eight years, she has been participating in a multi-disciplinary, (physician, physical therapist and orthotic technician) weekly ankle-foot orthosis consult. From her clinical experience, she noted major effects of the AFO and wanted to see them reflected in actual scientific research. In conjunction with prof. dr. P. Feys, the promotor of this study, the collaboration has been set up in the academic year (AY) 2012-13. Prof. dr. P. Feys, is the head of the neurological rehabilitation division of the University of Hasselt and is also a researcher of the REVAL (study center for rehabilitation research) team. Together, they determined the research question: 'What is the effect of an ankle-foot orthosis (AFO) on the dynamic balance and walking capacity in stroke patients?'.

Last AY, 2012-13, master student Dorine Tancsik performed a literature search on the effects of an AFO on the spatio-temporal parameters in stroke patients as a first important aspect of the pilot study. Further, she prepared a protocol for this pilot study that has been carried out this AY (2013-14) in the context of the collaboration. Therefore, the protocol described in this article, is an updated version of the protocol made by Dorine Tancsik.

As a second important aspect of this pilot study, our literature search will be focussing on the effects of an AFO on the dynamic balance and walking capacity of people after stroke.

At the same time (AY 2013-14), the pilot study was carried out where the spatio-temporal parameters (Dorine Tancsik), dynamic balance and functional walking were investigated in stroke patients when wearing no AFO, a standard pre-fabricated AFO (Maramed) and an individualised AFO (Y-Tech). We have used the GAITRite® system, four functional balance tests and one functional walking test as the outcome measures. This pilot study was guided by E. Houben and Vendula Doležalová (intern REVAL) and performed in the Rehabilitation Department of ZOL (Ziekenhuis Oost-Limburg) in Lanaken.

In this literature search, the central format was applied and we carried out the literature search together.

The protocol of the pilot study was approved in June 2013 by the committee of Medical Ethics of ZOL (Ziekenhuis Oost-Limburg) and by the University of Hasselt.

CONTENT PART 1: LITERATURE STUDY

CONTENT PART 2: RESEARCH PROTOCOL

PART 1: LITERATURE STUDY

1. Abstract

Background Drawing conclusions out of articles is difficult because the results of studies with regard to the effects of an ankle-foot orthosis (AFO) on dynamic balance and walking capacity in patients with stroke are inconsistent. It is not known which are the specific effects on these parameters and when an AFO should be prescribed. Therefore it seemed useful to carry out a review of the literature.

Method A systematic literature search has been performed in Pubmed and Web of Knowledge databases concerning articles which investigated the dynamic balance and walking capacity in stroke patients, comparing no AFO with an AFO.

Results The search resulted in 132 articles. 21 Articles were found double and a total of 101 articles were excluded based on inclusion and exclusion criteria. Ten articles were included and additional seven were added from reference lists and related articles on Pubmed. When comparing no AFO with AFO, significant effects on TUG, BBS, mEFAP and FAC scores were found, although there were inconsistent results found in some articles. Further, significant effects on walking capacity were found for the 6MWT, 25ftW and 10mWT, in favour of the AFO.

Discussion and conclusion Little is known about the effects of an AFO based on the severity of patients. Further, a variety of different types of AFO are used so therefore the specific effects on balance and walking are inconclusive. A clear classification of different types of AFO is lacking. Further research on these concerns is necessary.

Goal To determine the effects of wearing an AFO on dynamic balance and walking capacity in patients with stroke.

Important keywords Stroke, orthotic devices, balance, walking

2. Introduction

Dynamic balance and walking capacity are important aspects in daily life functioning. They both are key elements of walking or ambulation. Walking is defined as serving an individual's basic need to move from place to place. In the healthy population walking is one of the most common activities in daily life (Neumann, 2002). To minimize fatigue, prevent falls and associated injuries, walking has to be efficient and safe (Neumann, 2002). Ambulation is the sensory-motor skill that underlies basic activities of daily living (BADL), such as feeding, dressing, hygiene and instrumental activities of daily living (IADL) such as shopping and cooking (Susan B. O'Sullivan, 2006). For people with stroke, ambulation is not obvious. In these individuals, impairments of mobility are caused by muscle weakness, spasticity and impaired sensory motor control (Abe, Michimata, Sugawara, Sugaya, & Izumi, 2009).

Stroke is a neurological dysfunction with an acute onset, which can be caused by sudden haemorrhages or ischemia in the brain (Wang et al., 2005). According to Feigin et al., 2003, stroke was the second leading cause of death worldwide in 1990 and it is one of the main reasons for long-term disability (Abe et al., 2009; Feigin, Lawes, Bennett, & Anderson, 2003). Approximately 30-40% of stroke patients have significant disability (Wang et al., 2005). Consequences of stroke are impairments of sensory, motor, cognitive, perceptual and language functions ((Tyson & Rogerson, 2009) and O'Sullivan S., 2007). Motor deficits are characterized by paralysis or weakness. Although there are many disabling symptoms, recovery of mobility has been identified as a major goal for rehabilitation in stroke patients (Abe et al., 2009; Hung, Chen, Yu, & Hsieh, 2011; Tyson & Rogerson, 2009). As a part of this restoration of function, there are a lot of factors that play a role in the limitation of walking and have a significant restrictive role in the activities of daily living of stroke patients (Cakar, Durmus, Tekin, Dincer, & Kiralp, 2010). As mentioned earlier, two of them are dynamic balance and walking capacity.

Balance has been reported as a frequently disturbed factor and results in impairments in steadiness, symmetry and dynamic stability (Wang et al., 2005). Because falls occur frequently in this population, the assessment and rehabilitation of balance (static and dynamic) is very important. Falling in stroke patients leads to a less independent lifestyle and has a negative impact on their activity and participation levels (Cho & Lee, 2013). Balance can be measured with functional tests, like the Berg Balance Scale or with non-functional or instrumental tests like the Balance Master System. There is no golden standard for measuring balance in stroke patients.
Walking can be defined as 'An activity in which the body advances at a slow to moderate pace by moving the feet in a coordinated fashion. This included recreational walking, walking for fitness and competitive race-walking (MeSH).'. Because of their disturbed gait pattern, patients with stroke have an increased muscular effort and therefore a higher energy expenditure (Erel, Uygur, Engin Simsek, & Yakut, 2011). It is important to measure the energy cost of patients after stroke while walking to estimate their limitations in daily life. Walking capacity can be measured with the Six-Minute Walk Test (6MWT), 25-Foot Walk (25ftW), 10-Meter Walk Test (10mWT) and 5-Meter Walk Test (5mWT) in combination with the Physiological Cost Index (PCI, $[HR_{walking}-HR_{Rest}]$/ Walking speed). With a combination of the 6MWT and the PCI, an estimation can be made of the patients' capacity and fatigue.

By using an ankle-foot orthosis (AFO) in the rehabilitation of stroke patients, walking and balance can be improved. An AFO is an apparatus used to support, to align, to prevent or to improve the function of the ankle joint (MeSH). An AFO provides medio-lateral stability in the stance phase, facilitates toe clearance in swing phase, promotes heel strike, supports dorsiflexion, stops excessive plantar flexion and corrects the ankle joint (Abe et al., 2009; de Wit, Buurke, Nijlant, Ijzerman, & Hermens, 2004; Erel et al., 2011; Park, Chun, Ahn, Yu, & Kang, 2009; Simons, van Asseldonk, van der Kooij, Geurts, & Buurke, 2009; Tyson & Thornton, 2001).There are many different types of AFO, which can be divided into static versus dynamic or anterior versus posterior or custom-made versus prefabricated AFO's.

Previous studies showed that the use of an AFO could reduce the energy expenditure and could increase the walking speed (Danielsson & Sunnerhagen, 2004; Lehmann, 1979; Lehmann, Condon, Price, & deLateur, 1987). Whether an AFO has an effect on walking capacity or not, depends on the composition of the orthosis (Gok, Kucukdeveci, Altinkaynak, Yavuzer, & Ergin, 2003). Out of previous studies, it can be concluded that an AFO has a positive effect on spatio-temporal parameters but it is not known how meaningful these changes are for daily life balance and walking capacity. Therefore, the purpose of our literature review was to summarize the effects of an AFO on dynamic balance and walking capacity in stroke patients.

3. Method

3.1 Research question

What is the effect of an ankle-foot orthosis (AFO) on the dynamic balance and walking capacity in stroke patients?

3.2 Literature search

From October till December 2013, two databases were screened for appropriate articles. In April 2014, a last update of the search has been performed. Pubmed was screened with a combination of MeSH-terms and key terms. The final used MeSH-terms were “Stroke” and “Orthotic devices” and the final used key terms were “Balance” and “Walking”. Web of Knowledge was searched with the same combination of key terms, “Stroke”, “Orthotic devices”, “Balance” and “Walking. No limits were set.

3.3 Selection criteria

The inclusion criteria were: 1) Population: stroke patients, 2) Comparison AFO – no AFO 3) Measurements: functional balance or functional walking tests.
The exclusion criteria were: 1) Language (not in English), 2) If study exclusively applied instrumental balance and walking tests, 3) No AFO (all electric devices, robots, taping, splinting, etc.) 4) Systematic review/ review.

3.4 Quality assessment

To carry out the quality assessment of the two included randomised controlled trials (RCT), the Cochrane checklist for randomised controlled trials (RCT’s) was used *(Appendix 4).* The other fifteen included articles were quasi-experimental designs. For these articles a new checklist has been made in which the important criteria of the Cochrane checklist for RCT’s were extracted and merged with self-selected criteria. The blinding criteria of the Cochrane checklist for RCT’s were left out because it is not possible to mask if someone is wearing an AFO or not. Also, loss-to-follow-up*,* intention-to-treat analysis and comparability of interventions were left out because they are not applicable to quasi-experimental research. As self-selected criteria, ‘sample size’, ‘homogeneity of patients’, ‘homogeneity between groups’ and ‘use of different AFO types in condition AFO’ were included.
Overall, the assessment of biases (selection, performance, exclusion, detection) was performed.

3.5 Data-extraction

Sample size, patient characteristics (age, gender, diagnosis, time since stroke, severity level, affected side), inclusion and exclusion criteria, AFO type, time with AFO before study onset (AFO time), drop-outs and outcome measurements (dynamic balance and walking capacity) and relevant results were extracted from the included articles.

4. Results

4.1 Results study selection

Search number 9:"Stroke" [Mesh] AND "Orthotic Devices" [Mesh] AND (balance OR walking), was the final combination that was used *(see table 1).* With this search combination we found 132 hits. 97 Hits were found in Pubmed and 35 hits in WoK. Of these articles, 21 were double articles and after excluding these, 111 articles remained. These remaining articles were screened, based on title and abstract. Later, the full texts were screened according to the inclusion- and exclusion criteria that were set up in advance (*see 3.3 selection criteria)*. A total of 101 articles were excluded for several reasons that are listed in *Table 2.* Ten articles were included and additionally related articles in Pubmed and the reference lists of the included articles were screened. This resulted in seven additional articles. All seventeen included articles were found in Pubmed and four articles were also hits in WoK. A detailed description of the results of the study selection is given in *Figure 1.*

Table 1: Overview of used search terms and number of hits in Pubmed and Web of Knowledge (WoK)

Search	Query	# Hits Pubmed	# Hits WoK
#1	"Stroke" [Mesh]	81347	192947
#2	"Stroke" [Mesh]) AND "Orthotic Devices" [Mesh]	199	64
#3	"Stroke" [Mesh] AND "Orthotic Devices" [Mesh] AND "Walking" [Mesh]	58	35
#4	"Stroke" [Mesh] AND "Orthotic Devices" [Mesh] AND "Walking" [Mesh] AND physical endurance	0	1
#5	"Stroke" [Mesh] AND "Orthotic Devices" [Mesh] AND "Walking" [Mesh] AND exercise tolerance	0	0
#6	"Stroke" [Mesh] AND "Orthotic Devices" [Mesh] AND "Postural Balance" [Mesh]	14	4
#7	"Stroke" [Mesh] AND "Orthotic Devices" [Mesh] AND balance	22	9
#8	"Stroke" [Mesh] AND "Orthotic Devices" [Mesh] AND "Walking" [Mesh] OR Balance	70	35
#9	**"Stroke" [Mesh] AND "Orthotic Devices"[Mesh] AND (balance OR walking)**	**97**	**35**
#10	"Stroke" [Mesh] AND "Orthotic Devices" [Mesh] AND functional tests	8	11
#11	"Stroke" [Mesh] AND "Orthotic Devices" [Mesh] AND "Rehabilitation"[Mesh]) AND "Gait"[Mesh]	10	32
#12	"Stroke" [Mesh]) AND "Foot Orthoses" [Mesh]) AND "Rehabilitation" [Mesh]) AND "Gait" [Mesh]	0	32

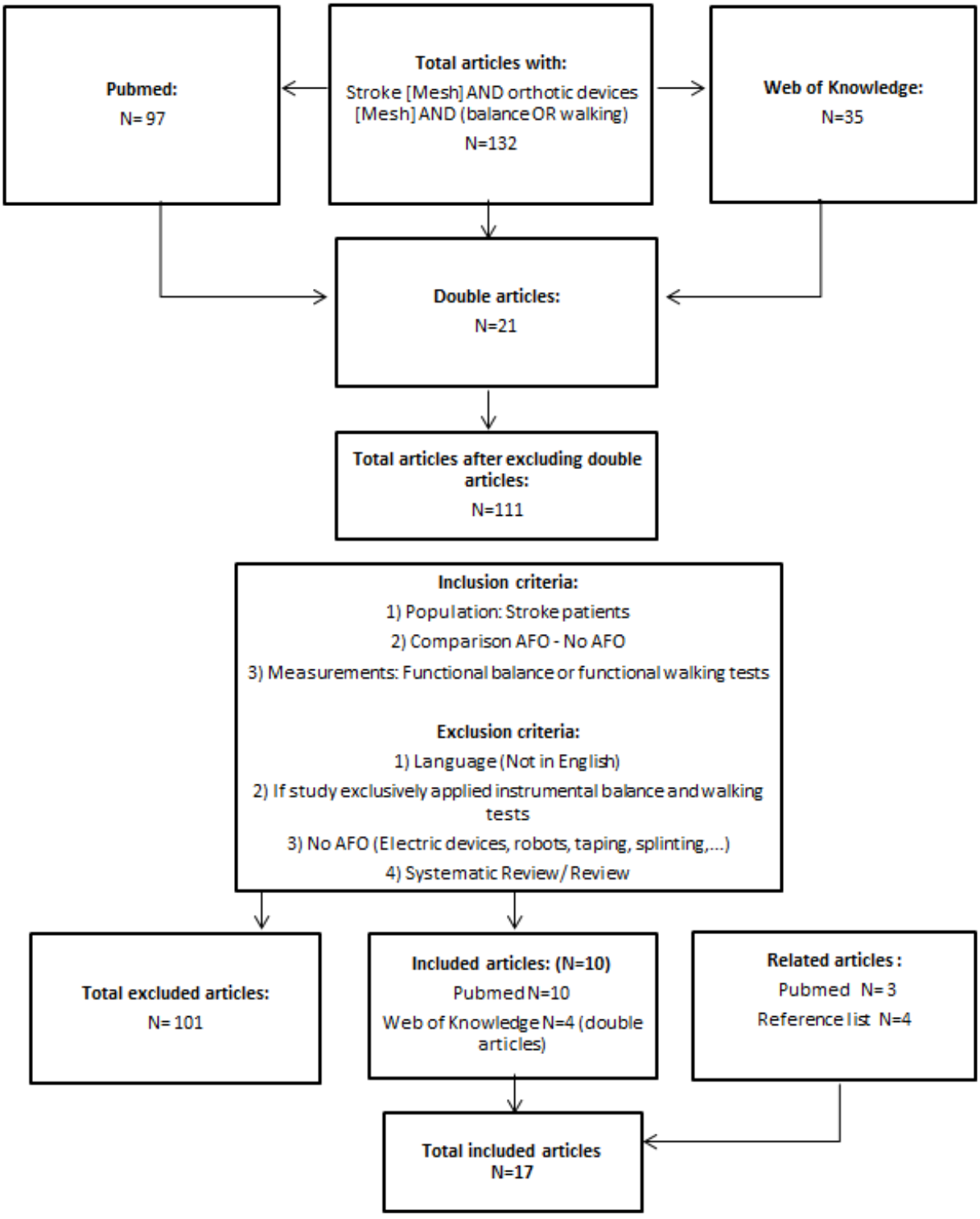


Figure 1: Flow-chart of article selection

Table 2: Overview of excluded articles and reason for exclusion (N=101)

Reason for exclusion	Number of studies	References
Exclusion based on study design (n=2)		
Systematic review	1	Tyson et al. (2013)
Review	1	Bosch et al. (2014)
Exclusion based on population (n=5)		
Patients with neuromuscular disorders	5	Chisholm et al. (2012); Guillebastre et al. (2013); Harlaar et al. (2010); Scivoletto et al. (2008); Sutliff et al. (2008)
Exclusion based on intervention (n=60)		
No comparison AFO/ no AFO	13	Knarr et al. (2013); de Sèze et al. (2011); Teasell et al. (2001); Tilson et al. (2008); Høyer et al. (2012); Langhammer et al.(2010); Krishnamoorthy et al. (2008); Hesse et al. (2008); Mehrholz et al. (2007); Chen et al. (2006); Moseley et al. (2005); Moseley et al. (2003); Kosak et al. (2000)
No AFO:	47	
• Robot	10	Hesse et al. (2012); Sale et al. (2012); Coenen et al. (2012); Mehrholz et al. (2012); Hornby et al. (2008); Mankala et al. (2009); Herr et al. (2004); Magagnin et al. (2010); Schwartz et al. (2009); Husemann et al. (2007)
• Walk-Mate	1	Muto et al. (2012)
• Electrical stimulation	16	Harvard Medical School (2012); Sheffler et al. (2013); Salisbury et al. (2013); van Swigchem et al. (2012); Bulley et al. (2011); van Swigchem et al. (2010); Ring et al. (2009); Kottink et al. (2008); Bayram et al. (2006); Kottink et al. (2004); Taylor et al. (1999); Everaert et al. (2013); Stein et al. (2010); Burridge et al. (2007); Shimada et al. (2006); Malezic et al. (1992)
• Elastic Walking Band	1	Hwang et al. (2013)
• TheraTogs	2	Maguire et al. (2012); Maguire et al. (2010)
• Hip Flexion Orthosis	1	Carda et al. (2012)
• Robotic knee orthosis	1	Wong et al. (2012)
• Effect of custom made shoes	1	Eckhardt et al. (2011)
• Effect of insole shoe wedge	2	Sungkarat et al. (2011); Chen et al. (2010)
• Effect of an arm sling	2	Han et al. (2011); Yavuzer et al. (2002)
• Knee Nook	1	Black et al. (2008)
• Locomat gait orthosis	1	Mayr et al. (2007)
• Gait rehabilitation machines	1	Schmidt et al. (2007)
• Effect of a Functional Electric Orthesis (FEO)	1	Fernandes et al. (2006)
• Effect of a Long Leg Brace	1	Yamanaka et al. (2004)
• Effect of a Short Leg Brace	1	Yamanaka et al. (2004)
• Effect of footwear on AFO	1	Churchill et al. (2003)
• Lower limb orthoses	1	Fish et al. (2001)
• Plantar pressure control device	1	Femery et al. (2004)
• Prosthesis	1	Hase et al. (2011)
Exclusion based on measurements (n=24)		
Kinematics/ kinetics/ biomechanics/electromyography/ Energy expenditure	14	Kobayashi et al. (2011); Kobayashi et al. (2013); Carse et al. (2011); Yamamoto et al. (2011); Lairamore et al. (2011); Bregman et al. (2011); Chen et al. (2010); Bregman et al. (2010); Mulroy et

		al. (2010); Fatone et al. (2007); Fatone et al. (2009); Danielsson et al. (2004); Cheng et al. (2003); Waters et al. (1999)
Spatio-temporal parameters	8	Hwang et al. (2012); Nolan et al. (2011); Nolan et al. (2010); Thijssen et al. (2007); Pohl et al. (2006); Zancan et al. (2004); Iwata et al. (2003); Do et al. (2014)
Postural stability measured with SMART balance master	1	Chen et al. (2008)
Postural stability measured with Computer Dyno Graphy system	1	Chen et al. (1999)
Exclusion based on withdrawns (n=2)		
Withdrawn	2	Tyson et al. (2009); Tyson et al. (2009)
Exclusion based on language (n=3)		
Article not in English	3	Sereda et al. (2012); Xu et al. (2011); Caillet et al. (2003)
Other reasons for exclusion (n=5)		
Gait control after stroke	1	Verma et al. (2012)
Restoring mobility	1	Sivan et al. (2008)
Validity/ reliability of functional tests	1	Hiengkaew et al. (2012)
Impact of functional therapy after stroke	1	Van Peppen et al. (2004)
(fMRI) activation paradigm	1	Dobkin et al. (2004)

4.2 Results quality assessment

Table 3a summarizes the quality assessment of the included randomised controlled trials (RCT's). For every grey coloured area, a half or one point was given based on the represented symbols. Low scores appear because blinding of patients and practitioners is not possible with an AFO, however we included these criteria because they are a part of the Cochrane checklist for RCT's. Therefore a performance bias is always present. De Wit et al., 2004 showed a very low score because the article did not report any possible presence of concealment of allocation, blinding of the outcome assessor, intention-to-treat-analysis, selection- and detection bias. When drop-outs were absent or present but reported, a score of '-' was given for exclusion bias. See *appendix 2* for a detailed description of the given scores on the checklists. *Table 4* describes the strengths and weaknesses of the included RCT's.

Table 3a: Quality assessment of the included RCT's (N=2)

	Sample size (N)	Randomisation	Concealment of allocation	Blinding of pts	Blinding of practitioner	Blinding of outcome assessor	Homogeneity of groups	Loss-to-follow-up	Intention-to-treat analyse	Comparability intervention	Selection bias	Performance bias	Exclusion bias	Detection bias	Score (/ 14)	**General conclusion**
Erel et al. (2011)	28	+	+	-	-	-	+	+	+	+	-	+	-	+	7	**+**
de Wit et al. (2004)	20	+/-	/	-	-	/	+	-	/	+	/	+	-	/	4,5	**+/-**

+: Present; -: Absent; +/-: Not consequent; /: Not enough information reported

In *table 3b* the results of the quality assessment of the quasi-experimental studies are shown. All these articles show a relative low score. This can be explained by the fact that there is always a selection bias present. This is because in these included articles there is always only one group of patients investigated, except for Wang et al., 2005. This article compared two different groups which were classified based on patient characteristics, so also no randomisation with concealment of allocation was performed here. Further, a performance bias is present in all articles. This is again because blinding of patients and practitioner is not possible, you can't mask if a patient wears an AFO or not. Detection bias were not reported in any article. When drop-outs were absent or present but reported, a score of '-' was given for exclusion bias. See *appendix 3* for a detailed description of the given scores on the checklists. *Table 4* describes the strengths and weaknesses of the included quasi-experimental studies.

Table 3b: Quality assessment of the included quasi-experimental studies (N=15)

	Sample size (N)	Randomisation (for condition)	Homogeneity of pts	Homgeneity between groups	Use of different AFO types in condition 'AFO'	Selection bias	Performance bias	Exclusion bias	Detection bias	Score (/8)
Abe et al. (2009)	16	+	+/-	N/A	+	+	+	-	/	3,5
Cakar et al. (2010)	25	-	+	N/A	-	+	+	-	/	4
Dogan et al. (2010)	51	-	+/-	N/A	-	+	+	-	/	3,5
Franceschini et al. (2003)	9	/	+/-	N/A	/	+	+	-	/	1,5
Hesse et al. (1996)	19	/	-	N/A	-	+	+	-	/	3
Hesse et al. (1999)	21	/	-	N/A	-	+	+	-	/	3
Hung et al. (2010)	52	-	+	N/A	+/-	+	+	-	/	3,5

Mojica et al. (1998)	8	+	-	N/A	-	+	+	-	/	3
Nolan et al. (2009)	18	+	+/-	N/A	+	+	+	-	/	3,5
Park et al. (2009)	17	-	+	N/A	-	+	+	-	/	4
Sheffler et al. (2006)	14	+	/	N/A	+	+	+	-	/	2
Simons et al. (2009)	20	+	+/-	N/A	+	+	+	-	/	3,5
Tyson & Rogerson (2009)	20	+	+/-	N/A	-	+	+	-	/	4,5
Tyson & Thornton (2001)	25	+	+/-	N/A	-	+	+	-	/	4,5
Wang et al. (2005)	42	+	N/A	+	-	+	+	-	/	5

+, Present; -, Absent; +/-, Not consequent; /, Not enough information reported; N/A, Not applicable

Table 4: Strengths and weaknesses analysis of included articles (N=17)

	Reference	Strengths	Weaknesses
RCT's	**S. Erel et al. 2011** *Clin. Rehabil.*	* Randomisation of groups * Homogeneity of groups * Intention-to-treat analysis * No selection bias * No detection bias * RCT	* The outcome assessor knew in which group the pts were (detection bias) * Only a small effect size for Timed Up Stairs * Sample size (N=28) * Performance bias * Exclusion bias possible, not well reported * Use of different AFO's in condition AFO when comparing no AFO vs. AFO
	DCM. de Wit et al. 2004 *Clin. Rehabil.*	***** Homogeneity between groups * No exclusion bias * RCT	* No exclusion criteria * Sample size (N=20) * The a priori defined clinically relevant differences were perhaps too high and arbitrary. * Randomisation and concealment of allocation not well described * Blinding of outcome assessor not well described * Performance bias * No description of potential selection bias and detection bias
Quasi- experimental design	**H. Abe et al. 2009** *Tohuku J. Exp.Med.*	* Sample size (N=16) * Randomisation of condition * No exclusion bias	* Not included pts who were unable to walk without a plastic AFO * All pts improved over the 2 weeks following prescription of the plastic AFO (results could be influenced by individual adaptations) * Use of different AFO's in condition AFO when comparing no AFO vs. AFO * No description of potential detection bias * No exclusion criteria
	E. Cakar et al. 2010 *Eur J. Phys. Rehabil. Med.*	* Sample size (N=25) * Homogeneity of pts * No exclusion bias * Used the same AFO in AFO condition	* The assessments of this study were made in clinical settings and it is difficult to generalize these results to daily life * No randomisation for conditions * No description of potential detection bias
	A. Dogan et al. 2010 *Disability and Rehabil.*	* Does not require expensive equipment or technical specialisation * The first study to evaluate the effect of an AFO by means of the STREAM * Sample size (N=51) * No exclusion bias * Used the same AFO in AFO condition	* They did not evaluate the validity and reliability of the TUG, BBS and STREAM * Pts were evaluated by only one physician * The evaluations were not repeated in the study (results of test already done in rehabilitation program were sometimes used as baseline measurement) * No randomisation for conditions * No description of potential detection bias
	M. Franceschini et al. 2003 *Clin. Rehabil*	* No exclusion bias	* Randomisation for condition not reported * Not reported which kind of AFO used * No description of potential detection bias * Sample size (N=9)

Quasi- experimental design	**S. Hesse et al. 1996** *Int. J. Rehab Science*	* Sample size (N=19) * No exclusion bias * Used the same AFO in AFO condition * Habituation time of AFO varied only from 0-1week	* No description of randomisation * No description of potential detection bias * No exclusion criteria
	S. Hesse et al. 1999 *American Heart Association*	* Sample size (N= 21) * No exclusion bias * Used the same AFO in AFO condition * Habituation time of AFO varied only from 0-1week	* No description of randomisation * No description of potential detection bias * No exclusion criteria
	J-W. Hung et al. 2010 *Am. J. Phys Med. Rehabil.*	* Does not require expensive equipment or technical specialisation * Sample size (N=52) * Homogeneity of pts * Used the same AFO in AFO condition * No exclusion bias	* No standardized resting time between the testing * No exclusion criteria * Generalisation: limited only for pts. who can walk 10 m with/ without assistive device * All pts wore their own A-AFO. It was not mentioned if there were differences between the AFO's (no standardisation) * No randomisation for conditions * No description of potential detection bias
	J.A.P. Mojica et al. 1988 *Tohuku J. Exp.Med.*	* No exclusion bias * Randomisation of conditions and tests * Used the same AFO in AFO condition	* Sample size (N=8) * No description of potential detection bias * Heterogeneity of pts * No exclusion criteria
	K. J. Nolan et al. 2009 *Am. Academy of PM&R*	* Sample size (N=18) * Randomisation of conditions * No exclusion bias	* No standardisation for AFO type (pts used their own AFO's) * Time between execution of 6MWT with/without AFO was not standardized for each patient * Not mentioned: how long pts were wearing AFO * Not mentioned: range of time since stroke * No description of potential detection bias
	J.H. Park et al. 2009 *Am. J. Phys Med. Rehabil.*	* Sample size (N=17) * Homogeneity of pts * Used the same AFO in AFO condition * No exclusion bias	* No exclusion criteria * No examination of the effects of AFO in pts with haemorrhagic stroke * Measuring of pts only without shoes for evaluating indoor life, so maybe there is a limited value for outdoor life * No description of potential detection bias * No randomisation of condition
	L.R. Sheffler et al. 2006 *Neurorehabil. Neural Repair*	* Standardized resting time between the 3 conditions * Randomisation of conditions	* Sample size (N=14) * Possible carry-over effect, when ODFS condition was first * Not mentioned how long pts were wearing the AFO * No description of potential detection bias * Use of different AFO's in condition AFO when comparing no AFO vs. AFO * Not enough information about patients' characteristics * No description of potential exclusion bias

Quasi- experimental design	**C.D.M. Simons et al. 2009** *Clin. Biomech.*	* Sample size (N=20) * Randomisation of conditions	* Range of months after stroke was very wide (5-127mo) * Use of different types of AFO (no overall effect of an AFO, because of many differences in design) * Not enough information about patients' characteristics * No description of potential exclusion bias * No description of potential detection bias
	SF Tyson & L Rogerson 2009 *Archives of Physical Medicine and Rehabil.*	* Sample size (N=20) * Randomisation of condition * Used the same AFO in AFO condition * No exclusion bias	* No exclusion criteria * Not mentioned: the exact FAC scores with/without AFO * Short time to familiarize with the AFO (possible explanation for the lack of effect on gait parameters) * No description of potential detection bias
	SF Tyson & HA Thornton 2001 *Clin. Rehabil.*	* Several measures were taken to minimize possible bias * Sample size (N=25) * Randomisation of conditions * Used the same AFO in AFO condition * No exclusion bias	* No exclusion criteria * Costs of study (each AFO £250) * Not mentioned: habituation time, AFO time before study * No description of potential detection bias
	R-Y. Wang et al. 2005 *Clin. Rehabil.*	* Study makes difference between pts (<6months / >12 mo post stroke) * Sample size (N=42) * Randomisation of conditions * Homogeneity between 2 different groups * Used the same AFO in AFO conditions	* No exclusion criteria Not mentioned: habituation time, AFO time before study * No description of potential detection bias

Pts, Patients; N, number; TUG, Timed Up and Go; BBS, Berg Balance Scale; STREAM, Stroke Rehabilitation Assessment of Movement Measure; A-AFO, Anterior Ankle-foot Orthosis; 6MWT, Six-Minute Walking Test; ODFS, Odstock Dropped-Foot-Stimulator; FAC, Functional Ambulation Categories.

4.3 Results data-extraction

Patients' characteristics

For categorising the patients according to time since stroke, the KNGF guidelines for stroke were used (http://www.kngfrichtlijnen.nl). Tyson & Rogerson, 2009 included only acute patients and Park et al., 2009 included acute and sub-acute patients. Four articles included post-acute and chronic patients (Abe et al., 2009; Franceschini, Massucci, Ferrari, Agosti, & Paroli, 2003; Mojica et al., 1988; Simons et al., 2009). Seven articles included only chronic patients (Cakar et al., 2010; de Wit et al., 2004; Erel et al., 2011; Hung et al., 2011; Nolan, Savalia, Lequerica, & Elovic, 2009; Sheffler, Hennessey, Naples, & Chae, 2006; Tyson & Thornton, 2001). Wang et al., 2005 included acute and chronic patients. Dogan et al., 2010, Hesse et al., 1996 and Hesse et al., 1999 included sub-acute, post-acute and chronic patients. *See table 5 (pp. 18-23)* for an overview of the patients' characteristics of the seventeen included articles.

AFO type

Four articles use different types of AFO's in one AFO condition so they did not consider the different aspects of each AFO type. They just compared 'AFO condition' with 'no AFO condition' (Abe et al., 2009; de Wit et al., 2004; Nolan et al., 2009; Sheffler et al., 2006). Thirteen articles used the same AFO in one AFO condition (Cakar et al., 2010; Dogan, Mengulluoglu, & Ozgirgin, 2011; Erel et al., 2011; Franceschini et al., 2003; Hesse, Luecke, Jahnke, & Mauritz, 1996; Hesse, Werner, Matthias, Stephen, & Berteanu, 1999; Hung et al., 2011; Mojica et al., 1988; Park et al., 2009; Simons et al., 2009; Tyson & Rogerson, 2009; Tyson & Thornton, 2001; Wang et al., 2005). See *table 6 (pp. 24-30)* for the AFO characteristics of the included articles.

Most of the included articles used a posterior leaf spring AFO (PAFO, *see figure 2*). Erel et al., 2011 and Nolan et al., 2009 were the only two articles that used a dynamic posterior AFO (Erel et al., 2011; Nolan et al., 2009). Its features are that it is a supra-malleolar orthosis, it allows limited quantities of all ankle movements and it has tone-inhibiting characteristics. This in contrast to a normal posterior AFO (PAFO) used in most of the included studies. This normal PAFO can be made of plastic (Abe et al., 2009; Cakar et al., 2010; de Wit et al., 2004; Nolan et al., 2009; Park et al., 2009; Sheffler et al., 2006; Simons et al., 2009; Tyson & Rogerson, 2009; Wang et al., 2005) or either metal (Hesse et al., 1996; Hesse et al., 1999; Simons et al., 2009). Mojica et al., 1988 also used a normal PAFO but did not report the material of which the AFO was manufactured. Another type of PAFO is the hinged or articulated orthosis, it contains two lateral hinges at the ankle joint to allow greater dorsiflexion range of motion (ROM) and thereby it improves weight transfers in stance phase. This AFO also could be made of plastic or metal *(see figure 3)* (Abe et al., 2009; Dogan et al., 2011; Nolan et al., 2009; Sheffler et al., 2006; Tyson & Thornton, 2001). Hung et al., 2011 and Park et al., 2009 were the only two articles which used an anterior AFO (A-AFO, *see figure 2).* The most important difference is that an A-AFO has an anterior leaf spring and therefore it is more appropriate for walking barefoot. A clear classification of AFO's does not exist, because of the wide variety of the different types of AFO's.

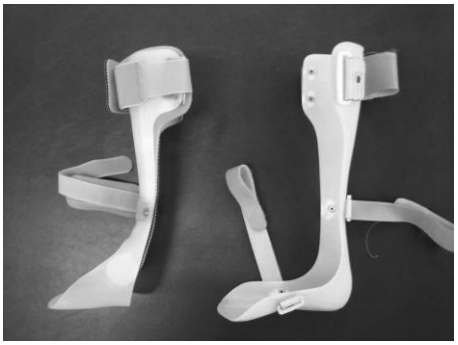


Figure 2: Polypropylene, non- articulated A-AFO and PAFO (Park et al., 2009)

Figure 3: Articulated, metal AFO (Simons et al., 2009)

Dynamic balance and mobility

*Table 6 (see pp. 24-30) r*epresents the different interventions and results of the included articles. *Table 7 (see p. 31)* shows a brief summary of the results.

Six out of seventeen included articles used the Timed Up & Go (TUG) as an outcome measurement. Five out of these six showed significant results revealing a reduction of the time needed to complete the test when wearing an AFO. Only Erel et al., 2010 showed no significant improvements. Both Hung et al., 2010 and Sheffler et al., 2006 investigated the TUG as a part of the Modified Emory Functional Ambulation Profile (mEFAP). Sheffler et al., 2006 reported '5m walk on hard floor' and '5m walk on carpeted surface' as other significant components of the mEFAP in advantage of the AFO. Borderline significance has been found for 'standardized obstacle course' (p=0.092) and 'ascending/descending five stairs' (p=0.067). Hung et al., 2010 found significant differences in all the items of the mEFAP in favour of the AFO.

The Berg Balance Scale (BBS) was investigated in five out of seventeen included articles. Three of them showed significant increases in BBS total score in favour of the AFO. Dogan et al., 2010 reported only significant differences in items 6 till 14 (standing with eyes closed, standing with feet together, reaching forward with an outstretched arm, retrieving object from floor, turning to look behind, turning 360°, placing alternate foot on stool, standing with one foot in front of the other foot and standing on one foot), this is logical because items 1-5 require more static balance.

Abe et al., 2009, Simons et al., 2009, Tyson & Thornton, 2001 and Tyson & Rogerson, 2009 were the only four articles that investigated the Functional Ambulation Categories (FAC). They all found significant positive changes in the FAC score when wearing an AFO compared to no AFO. Only Dogan et al., 2010 reported the Ashburn walking and stairs test. This test showed a significant reduction in walking time needed to complete the 15m with an AFO compared to walking without an AFO, but showed no significant effects on the Ashburn stairs test.

Dogan et al., 2010 used the basic mobility subscale of the Stroke Rehabilitation Assessment of Movement Measure (STREAM). They reported significant changes in 5 out of 10 items of the basic mobility subscale. These items are: 'placing affected foot onto first step', 'three steps backward', 'three steps to affected side', 'walking 10m' and 'walking down three stairs'.

Erel et al., 2010 was the only study that used the Functional Reach (FR), Timed Up Stairs (TUS) and Timed Down Stairs (TDS) as an outcome measurement. Significant results in favour of the AFO were only seen in the TUS. For the FR and TDS, no significant effects were reported. The stairs test was reported once by de Wit et al., 2004. There was a significant effect found on time to complete the test in advantage of the AFO. The Timed Balance Test (TBT) was investigated by Simons et al., 2009, they found a borderline significant (p=0,051) effect in favour of the AFO.

Walking capacity

Six out of the seventeen included articles investigated the 10- Meter Walk Test (10mWT) (de Wit et al., 2004; Hesse et al., 1996; Hesse et al., 1999; Mojica et al., 1988; Simons et al., 2009; Wang et al., 2005). Three out of these six used comfortable walking speed as an instruction (de Wit et al., 2004; Simons et al., 2009; Wang et al., 2005). The other three articles used the maximum walking speed (Hesse et al., 1996; Hesse et al., 1999; Mojica et al., 1988).

For the comfortable walking speed instruction, all three articles showed significant improvements in walking speed in the 10mWT, except for the chronic patient group of Wang et al., 2005.

In the maximum walking speed articles, two out of three articles reported significant effects in favour of the AFO (Hesse et al., 1996; Mojica et al., 1988). Only Hesse et al., 1999 found no significant results.

Tyson & Rogerson, 2009 was the only article that used the 5-Meter Walk Test (5mWT) and they found no significant differences when comparing an AFO with no AFO.

Three out of seventeen included articles reported the Six-Minute Walk Test (6MWT) (Franceschini et al., 2003; Hung et al., 2011; Nolan et al., 2009). Significant differences were found in total distance covered in two studies in benefit of the AFO (Hung et al., 2011; Nolan et al., 2009). Further, Nolan et al., 2009 divided the population in three groups based on the Ambulation Index (AI). In group one, (the fast patients, walked 25ft. in ≤ 10sec) there were no differences between not wearing an AFO and wearing an AFO. In group 2 (the moderate patients, walked 25ft. in ≤ 20sec) borderline significance (p=0,069) was found in benefit of the AFO. Only in group 3 (the slow patients: walked 25ft. in > 20sec) they found significant increases in covered distance in favour of wearing an AFO. Franceschini et al., 2003 did not report the total distance covered, but found significant improvements in self-selected speed and energy cost of walking when patients were wearing an AFO. Nolan et al., 2009 also reported a significant increase in the mean velocity when wearing an AFO compared to not wearing an AFO. In the study of Erel et al., 2010, patients walked 100m with a heart rate monitor to measure the Physical Cost Index (PCI). The PCI is the walking heart rate minus resting heart rate divided by the walking speed ($[HR_{walking}-HR_{Rest}]$/ Walking speed). Significant decreases in the PCI were seen when patients walked with an AFO compared to not wearing an AFO.

Table 5: Overview of the patients' characteristics of the included articles (N=17)

Reference	Population	Severity	Inclusion criteria/ Exlusion criteria
H. Abe et al. 2009 *Tohuku J. Exp.Med.*	N: 16 Age: 55,9 ± 11,8 Gender M | F: 11 | 5 Diagnosis: Haemorrhage 11, Infarction 5 Aff side R | L: 10 | 6 Time since stroke (months): 31,11 (2-113,8) → post-acute and chronic pts Drop-outs: No *Mean ± SD; Mean (min-max); Aff, affected side*	Brunnstrom's Recovery Stage (LE): - 5/16 pts.: stage 3 - 11/16: stage 4 SIAS sensory scale: - 3/16 pts.: score 0 - 1/16: score 2 - 12/16: score 3 /p/ DF ankle: - 6/16: 20°; 4/16: 15°; 2/16: 10°; 1/16: 5°; 3/16: 0°	Inclusion: 1) Had been prescribed plastic AFO 2) Unilateral hemi paresis caused by CVD 3) Ability to walk ≥ 8m, 4 times bare feet without external support, except cane 4) FIM score of ≥3 5) No neglect (SIAS score=3) 6) No history of orthopaedic problems of the LE Exclusion: /
E. Cakar et al. 2010 *Eur J. Phys. Rehabil. Med.*	N: 25 Age: 60 ± 11,43 Gender M | F: 17 | 8 Time since stroke (months): 20,32 ± 7,46 (8-36) → chronic pts Drop-outs: No *Mean ± SD (min-max)*	MAS: Grade 1-2 at affected calf muscles LE Brunnstrom: Stage 2-3 → Spastic pts	Inclusion: 1) MAS: Grade 1-2 2) LE Brunnstrom motor recovery: stage 2-3 3) Walk independently without assistive device Exclusion: 1) Cognitive impairment (MMSE < 24) 2) Visual defects of clinical importance 3) Hemi neglect 4) Severe heart failure 5) Co-morbidities that possibly affect mobility
A. Dogan et al. 2010 *Disability and Rehabil.*	N: 51 Age: 60,7 ± 12,5 Gender M | F: 24 | 27 Diagnosis: Haemorrhage 18, Infarction 33 Aff side R | L: 29 | 22 Time since stroke (days): 69 (21-218) → sub-acute, post-acute and chronic pts Drop-outs: No *Mean ± SD; Mean (min-max)*	MAS: - 12/51 → Score 1 - 8/51 → Score 2-3 - 31/51 → Score 0 (normal tone) Barthel Index: -Mean score = 66,1 (46-84) -Rehab program: Mean time = 35 days (21-85)	Inclusion: 1) Pts who underwent whole rehab. program 2) Pts with hemiplegia as a result of intracranial cerebral haemorrhage or ischemia Exclusion: 1) Pts who were unable to ambulate 2) Co-morbidity with effect on ambulation 3) Deficits in vision, proprioception or sensory 4) Contractures in LE 5) Morbid obesity 6) Uncooperative pts 7) Additional orthopaedic or neurologic deficits

<table>
<tr>
<td>S. Erel et al. 2011
Clin. Rehabil.</td>
<td>
<table>
<tr><th></th><th>SG</th><th>CG</th></tr>
<tr><td>N</td><td>14</td><td>14</td></tr>
<tr><td>Age</td><td>42,50 ± 14,89</td><td>50,64 ± 9,22</td></tr>
<tr><td>Gender M | F</td><td>11 | 3</td><td>7 | 7</td></tr>
<tr><td>Diagnosis:
Haemorrhage
Ischemic</td><td>
11
3</td><td>
13
1</td></tr>
<tr><td>Aff side R | L</td><td>5 | 9</td><td>4 | 10</td></tr>
<tr><td>Time since stroke (mo)</td><td>30,21 ± 13,84
→ chronic pts</td><td>25,36 ± 13,44
→ chronic pts</td></tr>
<tr><td>Drop-outs</td><td>1 (died)</td><td>1(moved away)</td></tr>
</table>
Mean ± SD; SG, Study group; CG, control group
</td>
<td>FAC: Level 3-5
MAS: max level 3
/p/ DF ankle: ≥ 90°</td>
<td>Inclusion:
1) Cognitive level to understand aim of study, to give informed consent, understand and follow instructions
2) FAC: Level 3-5
3) Not wearing an AFO
4) Post stroke ≥ 6mo
5) MAS: Max level 3
6) /p/ DF ankle: ≥ 90°
7) > 18y
Exclusion:
1) Co morbidities, orthopaedic or postural problems that could affect the outcomes.
2) Had used a dynamic AFO before</td>
</tr>
<tr>
<td>M. Franceschini et al. 2003
Clin. Rehabil</td>
<td>
<table>
<tr><td>N</td><td>9</td></tr>
<tr><td>Age</td><td>66,5 ± 16,4</td></tr>
<tr><td>Gender M | F</td><td>6 | 3</td></tr>
<tr><td>Aff side R | L</td><td>3 | 6</td></tr>
<tr><td>Time since stroke (mo)</td><td>39 (2-244)
→ post-acute and chronic pts</td></tr>
<tr><td>Drop-outs</td><td>No</td></tr>
</table>
Mean ± SD; Median (min-max)
</td>
<td>Walking speed:
Mean= 0.26 m/sec</td>
<td>Inclusion:
1) Completed intense rehabilitation program
2) Able to walk independently ≥6 min with/without walking aids
3) Used AFO before study
Exclusion:
1) Cardio-pulmonary disorders</td>
</tr>
<tr>
<td>S. Hesse et al. 1996
Int. J. Rehab Science</td>
<td>
<table>
<tr><td>N</td><td>19</td></tr>
<tr><td>Age</td><td>55,2 (30-79)</td></tr>
<tr><td>Gender M | F</td><td>12 | 7</td></tr>
<tr><td>Diagnosis:
Haemorrhage
Infarction
Other (tumour)</td><td>
5
10
4</td></tr>
<tr><td>Time since stroke (mo)</td><td>5,1 (1,5-16)
→ sub-acute, post-acute and chronic pts</td></tr>
<tr><td>Drop-outs</td><td>No</td></tr>
</table>
Mean (Min-max)
</td>
<td>- MAS ankle DF lying score: mean 3,7 (range: 3-5)
- All pts marked plantar flexor spasticity
- 9/19 pts: sensory impairment
- 3/19 pts: signs of sensori-motor neglect syndrome
- 8/19 pts: achilles tendon cloni occurred in walking barefoot</td>
<td>Inclusion:
1) Ability to walk 20m barefoot without physical help
2) Newly prescribed AFO (Patient should have practiced with the AFO no longer than 1week)
3) Marked ankle extensor spasticity with a min. grade 3 (ankle DF while lying) with MAS
4) No obvious ankle contracture (plantigrade posture after at least 10min standing in the standing bar)
5) No additional orthopaedic or neurological deficits impairing ambulation
Exclusion:
/</td>
</tr>
</table>

S. Hesse et al. 1999 *American Heart Association*	N: 21 Age: 58.20 (30-79) Gender M | F: 11 | 10 Diagnosis: Haemorrhage 3, Ischemic 17, Tumor surgery 1 Aff side R | L: 12 | 9 Time since stroke (mo): 4.9 (1.5-16) → sub-acute, post-acute and chronic pts Drop-outs: No *Mean (min-max)*	- <u>MAS</u> ankle DF lying score: mean 3.6 (range: 3-5) - All pts marked plantar flexor spasticity - 7/21 pts: sensory impairment - 3/21 pts : signs of sensori-motor neglect syndrome - 7/21 pts: achilles tendon cloni occurred in walking barefoot	<u>Inclusion:</u> 1) Ability to walk 20m barefoot without physical help by a therapist 2) Use of a Valens AFO for <1 week 3) Minimum MAS score of 3 4) No obvious ankle contracture 5) No additional orthopaedic or neurological deficits impairing ambulation <u>Exclusion:</u> /
J-W. Hung et al. 2010 *Am. J. Phys Med. Rehabil.*	N: 52 Age: 54,50 (43,65) Gender M | F: 35 | 17 Diagnosis: Haemorrhage 28, Infarction 22 Aff side R | L: 29 | 23 Time since stroke (mo): 33,5 (15,75) → chronic pts Drop-outs: No *Mean (25,75 percentiles)*	<u>Pre-test assessment no AFO:</u> - Muscle strength Aff.ankle: • DF, impossible/ with movement: 32/20 pts • PF, impossible/ with movement: 30/22pts - <u>MAS:</u> • 31/52 pts: Score <2 • 21/52 pts: Score≥2 - <u>Sensation:</u> Impaired/ normal: 26/26 pts - <u>10mWT</u>: median: 0.29m/sec - <u>BBS:</u> mean score: 46 (40,51)	<u>Inclusion:</u> 1) Unilat. Hemi paresis secondary to stroke > 6mo 2) Gait instability (DF/eversion weakness or mild-moderate PF/inversion spasticity or both) 3) Wearing AFO ≥5 mo before the study 4) Ability to walk for 10m with/without an assistive device 5) Ability to follow simple verbal commands 6) No history of orthopaedic problems, concomitant neurological diagnoses or medical instability that interferes with performing tests <u>Exclusion:</u> /
J.A.P. Mojica et al. 1988 *Tohuku J. Exp.Med.*	N: 8 Age: (46-66) Gender M | F: 5 | 3 Aff side R | L: 5 | 3 Time since stroke (weeks): 20.7 (7-32) → post-acute and chronic pts Drop-outs: No *Mean (min-max)*	- Aff. LE: mild to moderate hypertonia - /p/ ROM LE: normal limits - <u>LE Brunnstrom:</u> Stage 2-3	<u>Inclusion:</u> 1) All pts could stand alone 2) Have used a plastic AFO for everyday ambulation <u>Exclusion:</u> /

K. J. Nolan et al. 2009 *Am. Academy of PM&R*	N: 18 Age: 53,44 ± 11,5 Time since stroke (mo): 54,89 ± 36,98 → chronic pts Drop-outs: 2 Not able to fully complete the study *Mean ± SD*	Ambulation index (AI): - Group 1: 5/18 pts (AI score=1 &2) (= Fast pts: Walk 25ft. in ≤ 10sec) - Group 2: 8/18 pts (AI score=3 &4) (= Moderate pts: Walk 25ft. in ≤ 20sec) - Group 3: 5/18 pts (AI score= 5) (= Slow pts: Walk 25ft. in > 20sec)	Inclusion: 1) Uninvolved LE no history of injury/ history/ pathology 2) Walk indep./ supervision 25ft with/ without AFO 3) Wear AFO at least 50% of time when walking 4) >6mo post-stroke 5) Had been prescribed AFO Exclusion: 1) Significant orthopaedic, neuromuscular, neurological pathology or history that interferes with walking or limits ROM of legs
J.H. Park et al. 2009 *Am. J. Phys Med. Rehabil.*	N: 17 Age: 57,7 ± 7,5 Gender M | F: 10 | 7 Aff side R | L: 11 | 6 Time since stroke (days): 36,8 ± 11,9 → acute and sub-acute pts Drop-outs: No *Mean ± SD*	Able to walk independently with cane	Inclusion: 1) Unilat. hemi paresis caused by CVA 2) Muscle strength hip/ knee: fair and over. Ankle:< fair 3) Sensory function of paretic limb is reduced 4) Able to walk without/with AFO 5) Able to follow simple commands or instructions 6) No history of orthopaedic problems 7) <6 Months post stroke 8) No history of having worn AFO before study 9) No severe spasticity: MAS <2 Exclusion: /
L.R. Sheffler et al. 2006 *Neurorehabil. Neural Repair*	N: 14 Age: 56,7 Gender M | F: 9 | 5 Aff side R | L: 6 | 8 Time since stroke (mo): 30,8 → chronic pts Drop-outs: 3 (medical issues), 1 (↑ DF strength) *Average scores*	- Median quadriceps strength: 4 - Median DF strength: 2 - Median PF strength: 2 - Sensory deficit of LE in 50% of pts	Inclusion: 1) >90 Days post stroke 2) Sufficient endurance and motor ability to ambulate ≥ 30ft. (minimal assistance/ without AFO) 3) Pts. met the ankle functional clinical indications for a custom-molded AFO: *ankle DF strength ≤ 4/5 when standing.*foot drop 4) BBS: ≥ 30/56 5) Intact skin/ absence of oedema of the affected leg 6) Passive ankle ROM to neutral Exclusion: 1) Fixed PF contracture 2) AFO required to prevent knee flexion collapse 3) Medical instability 4) History of implanted electronic devices 5) Concomitant neurological diagnoses 6)MMSE: score < 4th quartile

C.D.M. Simons et al. 2009 *Clin. Biomech.*	N: 20 Age: 57,2 (36-78) Gender M | F: 14 | 6 Diagnosis: Haemorrhage / Ischemic: 3 / 17 Aff side R | L: 10 | 10 Time since stroke (months): 39,3 (5-127) → post-acute and chronic pts Drop-outs: 2 (epileptic insult) and 1 (not able to perform tests) *Mean (min-max)*	- RMI mean score: 12.6 - MI mean score: • 81.7(total) • 48.2 (leg)	Inclusion: 1) First unilat. stroke leading to hemi paresis 2) >18y + 3mo post stroke 3) Use of AFO 2 months before study 4) Able to stand with/without AFO for 90s independent/ unsupported 5) Walk for 10m with/ without assistive device 6) Able to follow verbal instructions Exclusion: 1) Severe aphasia/ neglect 2) Medication 3) Non-stroke related disorders that affect balance
SF Tyson & L Rogerson 2009 *Archives of Physical Medicine and Rehabil.*	N: 20 Age: 65,6 ± 10,4 Aff side R | L: 7 | 13 Time since stroke (weeks): 6,5 ± 5,7 → acute pts Drop-outs: No *Mean ± SD*	- MI mean score: 48/100 - RASP mean score: 6.7/18 - BBA mean score: 6.4/12 → Severely impaired pts *RASP: Rivermead Assessment of Somatosensory Perception*	Inclusion: 1) Unable to walk ≥2 weeks after their stroke 2) Undergoing inpatient rehab to restore walking 3) Unable to mobilize indep. without aid in ADL on ward 4) Able to step and practice walking during physiotherapy sessions with/without support 5) Able to walk 5m without physical support 6) Able to give informed consent Exclusion: /
SF Tyson & HA Thornton 2001 *Clin. Rehabil.*	N: 25 Age: 49,9 ± 1 Gender M | F: 16 | 9 Aff side R | L: 16 | 9 Time since stroke (mo): 8,3 ± 5,5 → chronic pts Drop-outs: No *Mean ± SD*	Pts with severe hemiplegic who were undergoing rehabilitation in a regional rehab. unit	Inclusion: 1) ≥ 18 Years 2) Hemiplegia following stroke 3) Able to weight bear/ step with the weak leg 4) Sufficient range to obtain plantar grade in both heels Exclusion: /
R-Y. Wang et al. 2005 *Clin. Rehabil.*	SD / LD N: 42 / 61 Age: 59,9 ± 13 / 62,3 ± 11,8 Gender M | F: 23 | 19 / 51 | 10 Aff. Side R | L: 27 | 15 / 35 | 26 Time since stroke(days): 101 ± 51,3 →acute pts / 1043,6 ± 1104,9 → chronic pts Drop-outs: No / No *Mean ± SD; SD, Short duration (<6mo post stroke); LD, Long duration (>12mo post stroke)*	Not reported	Inclusion: 1) Unilat. hemi paresis after stroke (<6mo or >12mo) 2) Stand without support for at least 1min. 3) Ability to walk 10m (with/without aid) 4) Able to follow simple verbal instructions 5) No history of orthopaedic problems Exclusion: /

<table>
<tr>
<td>DCM. de Wit et al. 2004
Clin. Rehabil.</td>
<td>
<table>
<tr><th></th><th>G1</th><th>G2</th></tr>
<tr><td>N</td><td>10</td><td>10</td></tr>
<tr><td>Age</td><td>61,1 (51-73)</td><td>61,2 (41-70)</td></tr>
<tr><td>Gender M | F</td><td colspan="2">12 | 8</td></tr>
<tr><td>Aff side R | L</td><td>3 | 7</td><td>6 | 4</td></tr>
<tr><td>Diagnosis:
Haemorrhage
Ischemic</td><td>
1
9</td><td>
1
9</td></tr>
<tr><td>Time since stroke (days)</td><td>26,9 (8-42)
→ chronic pts</td><td>24,2 (8-48)
→ chronic pts</td></tr>
<tr><td>Drop-outs</td><td>No</td><td>No</td></tr>
</table>
Median (IQR); G1, AFO first; G2, without AFO first
</td>
<td><u>MI</u> median score (aff LE):58
<u>FAC</u> median score: 4.5
<u>UCO</u> measuring communicative abilities: median score: 6.0
<u>MMSE</u> measuring cognitive abilities: median score: 26.0</td>
<td><u>Inclusion:</u>
1) ≥ 6 Mo post stroke
2) Wearing a plastic, non-articulated AFO daily and for at least 6 months
3) Walk independently with shoes with and without orthosis
4) Sufficient communication, cognitive abilities and a satisfactory condition were required to participate
<u>Exclusion:</u>
/</td>
</tr>
</table>

N, patients who completed the study; Time since stroke categories, According to KNGF guidelines for stroke(2004); AFO, Ankle-foot orthosis; LE, Lower extremity; ROM, range of motion; mo, months; SIAS, Stroke Impairment Assessment Set; /p/, passive; DF, dorsiflexion ankle; PF, plantairfexion ankle; pts, patients; MAS, Modified Ashworth Scale; MMSE, Mini Mental State Examination; FAC, Functional Ambulation Categories; BBS, Berg Balance Scale; RMI, Rivermead Motricity Index; 10mWT, 10-Meter Walk Test; MI, Motricity Index; BBA, Brunel Balance Assessment; UCO, Utrechts Communication Examination.

Table 6 : Overview of the different interventions and results of the included articles (N=17)

<table>
<tr><th>Reference</th><th>AFO Type + Comparison</th><th>AFO Time</th><th>Outcome measurements</th><th>Relevant results</th></tr>
<tr>
<td>H. Abe et al. 2009
Tohuku J. Exp.Med.</td>
<td>- 9/16: Shoehorn-type plastic AFO (posterior leaf/no PF or DF possible)
- 6/16: Gillette double-flexure joint AFO (hinged AFO)
- 1/16: Tamarack flexure joint AFO (hinged AFO)

With AFO -
Without AFO(Barefoot)</td>
<td>AFO prescribed. Time not reported</td>
<td>- Spatio-temporal parameters (paper walkways with ink patches)

- Mobility (FAC)</td>
<td>1) Sign. ↑ with plastic AFO
<table>
<tr><th>Parameter</th><th>No AFO ⇔ plastic AFO</th><th>p-value</th></tr>
<tr><td>Velocity</td><td>126,5%</td><td>p=0,0032*</td></tr>
<tr><td>Cadence</td><td>109,7 %</td><td>p=0,015*</td></tr>
<tr><td>Stride length</td><td>115,5%</td><td>p=0,0041*</td></tr>
<tr><td>Step width</td><td>3%</td><td>p=0,034*</td></tr>
<tr><td>Step length unaff</td><td>119,8%</td><td>p=0,0011*</td></tr>
<tr><td>Step length aff</td><td>111,8%</td><td>p=0,044*</td></tr>
<tr><td>Variance step-length symmetry</td><td>↓ 69,4%</td><td>Ns</td></tr>
</table>
*, significant at p<0.05 ; ns, not significant; aff, affected side; unaff, unaffected side
2) Sign. ↑ FAC with plastic AFO
<table>
<tr><th rowspan="2">FAC</th><th colspan="2">Subject number (%)</th></tr>
<tr><th>No AFO</th><th>Plastic AFO</th></tr>
<tr><td>0</td><td>0 (0)</td><td>0 (0)</td></tr>
<tr><td>1</td><td>0 (0)</td><td>0 (0)</td></tr>
<tr><td>2</td><td>0 (0)</td><td>0 (0)</td></tr>
<tr><td>3</td><td>9 (56,3)</td><td>1 (6,3)</td></tr>
<tr><td>4</td><td>7 (43,8)</td><td>5 (31,3)</td></tr>
<tr><td>5</td><td>0 (0)</td><td>10 (62,5)</td></tr>
</table>
</td>
</tr>
<tr>
<td>E. Cakar et al. 2010
Eur J. Phys. Rehabil. Med.</td>
<td>Thermoplastic prefabricated, leaf spring AFO (PLS-AFO)

With AFO -
Without AFO</td>
<td>-1 training session with a PT (walking)
-Pts had to use the AFO during all walking activities at home for 1 week</td>
<td>- Balance: BBS,
Biodex Balance System:
• Postural stability test (PST)
• Fall Risk Test (FRT): Overall stability index (OSI)</td>
<td>1) Sign. ↑ with PLS-AFO
<table>
<tr><th>Parameter</th><th>No AFO</th><th>AFO</th><th>p-value</th></tr>
<tr><td>BBS</td><td>42,12 ± 9,09</td><td>47,52 ± 7,77</td><td>p=0,001*</td></tr>
<tr><td>FRT: OSI</td><td>3,35 ± 1,97</td><td>2,69 ± 1,65</td><td>p=0,001*</td></tr>
</table>
Values are mean ± SD ; *, significant at p<0.05

2) PST: ns</td>
</tr>
</table>

<table>
<tr>
<td>A. Dogan et al. 2010
Disability and Rehabil.</td>
<td>Articulated AFO with 90° PF stop

With AFO - Without AFO</td>
<td>- Mean time AFO education: 4 days
- Range 1-9 days</td>
<td>- Balance: TUG, BBS, Ashburn battery test
- Mobility: TUG, Ashburn, STREAM

STREAM: Stroke Rehabilitation Assessment of Movement Measure</td>
<td>1) Sign. ↑ with AFO
<table><tr><th>Parameter</th><th>No AFO</th><th>AFO</th><th>p-value</th></tr><tr><td>Ashburn walking time (15m)</td><td>51,12 ± 29,34</td><td>46,27 ± 25,36</td><td>p=0,007*</td></tr><tr><td>TUG</td><td>35,49 ± 14,59</td><td>31,28 ± 15,13</td><td>p=0,005*</td></tr><tr><td>BBS Total</td><td>41,28 ± 8,61</td><td>46,26 ± 5,27</td><td>p<0,001*</td></tr><tr><td>STREAM Total (Mobility subscale)</td><td>15,93 ± 2,68</td><td>18,12 ± 1,95</td><td>p<0,001*</td></tr></table>Values are mean ± SD ; *, significant at p<0.05
BBS: items 6-14 sign. ≠ (p<0,001 – p= 0,024)
STREAM: Items placing affected foot onto first step, 3 steps backward, 3 steps to affected side, walk 10m, down 3 stairs (p=0,002 – p=0,04)
2) No sign. ≠ for: Ashburn stair climbing</td>
</tr>
<tr>
<td>S. Erel et al. 2011
Clin. Rehabil.</td>
<td>Dynamic AFO (DAFO)

- Study group(SG): Baseline testing with tennis shoes and after 3mo with dynamic AFO
- Control group(CG): Baseline testing with tennis shoes/ 3mo F-U testing also with tennis shoes

With AFO – Without AFO</td>
<td>Pts did not were AFO before study (see inclusion criteria)</td>
<td>- Balance: TUG, functional reach test (FR)
- Mobility: TUG, FR, Timed Up Stairs (TUS), Timed Down Stairs (TDS)
- Walking speed (walking 100m)
- Energy cost: Physiological Cost Index (PCI)</td>
<td><u>1) Initial assessment:</u>
- SG + CG: Only tennis shoes (S)
→ No sign. ≠ between 2 groups (homogenous groups)

<u>2) 3mo assessment:</u>
- SG: Dynamic AFO + tennis shoes
- CG: Only tennis shoes (S)
→ No sign. ≠ between the groups for FR, TUG, TDS

Sign. ≠ in favour of the AFO
<table><tr><th>Parameter</th><th>SG: S + DAFO</th><th>CG: S</th><th>p-value</th></tr><tr><td>TUS (sec)</td><td>12,00 ±10,21</td><td>15,00 ± 7,29</td><td>p=0,040*</td></tr><tr><td>Gait speed (m/sec)</td><td>0,99 ± 0,45</td><td>0,72 ± 0,20</td><td>p=0,001*</td></tr><tr><td>PCI (beats/min)</td><td>0,12 ± 0,06</td><td>0,28 ± 0,13</td><td>p=0,001*</td></tr></table>Values are mean ± SD ; *, significant at p<0.05</td>
</tr>
<tr>
<td>M. Francescchini et al. 2003
Clin. Rehabil</td>
<td>Not reported

With AFO – Without AFO</td>
<td>Not reported</td>
<td>-Gait: BTS telemetric system →spatio-temporal parameters
-Metabolic parameters: Cosmed K2
-Walking capacity: 6MWT

BTS: Bioengineering Technology and Systems</td>
<td>1) Sign↓ duration of the stride cycle with AFO
2) Sign ↓ duration of the stance phase with AFO
3) Sign ↓ duration of the DS with AFO
4) Sign↑ in the self-selected speed with AFO (p<0.001)
5) Sign ↓ in energy cost of walking with AFO (p<0.01)</td>
</tr>
</table>

<table>
<tr>
<td>S. Hesse et al. 1996
Int. J. Rehab Science</td>
<td>Valens Caliper AFO: Single strut , rigid, metal AFO attached to heel of shoe

Without AFO (barefoot) – Without AFO (Blücher-type shoe) – AFO</td>
<td>New AFO prescribed (Practiced not more than 1 week)</td>
<td>- Weight bearing: RMA Leg and trunk section (° 6 and °7)
- Walking capacity: 10mWT (at maximum speed)

RMA: Rivermead Motor Assessment</td>
<td>1) Balance (RMA):
- Barefoot: 4/19 pts could perform one motor task and 3/19 pts both 6 and 7
- Shoes: 1 more pt could perform both 6 and 7 (4/19 pts)
- AFO: 6/19 pts could perform one task and 4/19 pts both 6 and 7
2) sign. effects with an AFO on the 10mWT comparing to no AFO
<table>
<tr><th></th><th>Barefoot</th><th>Shoes</th><th>AFO</th></tr>
<tr><td>Velocity (m/s)</td><td>0,33 ± 0,17</td><td>0,43 ± 0,21*</td><td>0,55 ± 0,27*</td></tr>
<tr><td>Cadence (steps/min)</td><td>65 ± 21</td><td>70 ± 19</td><td>77 ± 22*</td></tr>
<tr><td>Stride length (m)</td><td>0,58 ± 0,16</td><td>0,69 ± 0,18*</td><td>0,80 ± 0,24*</td></tr>
</table>
Values are mean ± SD ; *, significant at p<0.006
- Wearing shoes vs. barefoot: pts walked 30,3% faster
- Wearing the AFO: additional ↑ velocity (66,6% vs. barefoot; 27,9% vs. shoes)</td>
</tr>
<tr>
<td>S. Hesse et al. 1999
American Heart Association</td>
<td>Valens caliper AFO: Single strut , rigid, metal AFO attached to heel of shoe

With AFO – Without AFO (barefoot)</td>
<td>< 1 week</td>
<td>- Walking capacity: 10mWT (at maximum speed)
- EMG</td>
<td>1) 10mWT: No sign effect of an AFO
<table>
<tr><th>Parameter</th><th>Barefoot</th><th>AFO</th><th>p-value</th></tr>
<tr><td>Velocity (m/s)</td><td>0.32 ± 0.17</td><td>0.33 ± 0.15</td><td>ns</td></tr>
<tr><td>Cadence (steps/min)</td><td>62 ± 17</td><td>63 ± 16</td><td>ns</td></tr>
<tr><td>Stride length (m)</td><td>0.62 ± 0.17</td><td>0.65 ± 0.18</td><td>ns</td></tr>
</table>
Values are mean ± SD ; *, significant at p<0.05</td>
</tr>
<tr>
<td>J-W. Hung et al. 2010
Am. J. Phys Med. Rehabil.</td>
<td>Anterior AFO (A-AFO)

With AFO – Without AFO</td>
<td>≥ 5 mo before study started</td>
<td>-Mobility: mEFAP
-Walking capacity: 6MWT
-Fall risk: FES-I

mEFAP: Modified Emory Functional Ambulation Profile
FES-I:Falls Efficacy Scale-International</td>
<td>1) Sign. ≠ mEFAP + 6MWT
<table>
<tr><th>Parameter</th><th>No A-AFO</th><th>A-AFO</th><th>p-value</th></tr>
<tr><td>Floor (sec)</td><td>19,18 ± 11,19</td><td>16,29 ± 10,18</td><td>p <0,01*</td></tr>
<tr><td>Carpet (sec)</td><td>22,62 ± 15,79</td><td>17,17 ± 10,91</td><td>p <0,01*</td></tr>
<tr><td>Up Go (sec)</td><td>35,30 ± 20,5</td><td>30,21± 17,41</td><td>p <0,01*</td></tr>
<tr><td>Obstacles (sec)</td><td>53,79 ± 31,64</td><td>45,37 ± 23,37</td><td>p <0,01*</td></tr>
<tr><td>Stairs (sec)</td><td>39,09 ± 21,64</td><td>32,54 ± 16,14</td><td>p <0,01*</td></tr>
<tr><td>6MWT (m)</td><td>121,73 ± 78,22</td><td>141,48 ± 86,06</td><td>p <0,01*</td></tr>
</table>
Values are mean ± SD ; *, significant at p<0.05
-3 Pts could not walk on carpet without AFO. With AFO they could
-7 Pts could not step over obstacles without AFO. 5 pts could with AFO
-3 Pts could not climb stairs without AFO. 1 pt could with AFO
2) Fall risk:
FES-I scores were sign. ↓ with an A-AFO compared with no A-AFO</td>
</tr>
</table>

<table>
<tr>
<td>J.A.P. Mojica et al. 1988
Tohuku J. Exp.Med.</td>
<td>- AFO from below the fibular heads to the tips of the toes and provided with Velcro straps (malleolar, metatarsal and proximal leg areas)

With AFO –
Without AFO (barefoot)</td>
<td>- Mean: 7.5 weeks
- Range: 2 days-18 weeks</td>
<td>- Walking capacity:
10mWT (at maximum speed)
- Balance: movable platform</td>
<td>1) sign. ≠: 10mWT
<table>
<tr><th>Parameter</th><th>Barefoot</th><th>AFO</th><th>p-value</th></tr>
<tr><td>Walking speed (m/min)</td><td>32.80 ± 24.94</td><td>41.58 ± 30.57</td><td>p<0.01*</td></tr>
<tr><td>Walking rate (steps/min)</td><td>91.78 ± 25.42</td><td>102.56 ± 25.77</td><td>p<0.01*</td></tr>
<tr><td>Stride length (m)</td><td>0.64 ±0.35</td><td>0.74 ± 0.39</td><td>p<0.01*</td></tr>
</table>
Values are mean ± SD

2) sign. ↓ in body sway

Sign. correlations of the mean ratio of stride length and walking rate relative to walking speed (p<0.01)</td>
</tr>
<tr>
<td>K. J. Nolan et al. 2009
Am. Academy of PM&R</td>
<td>- 16/18: Plastic rigid AFO
- 1/18:Hinged AFO
- 1/18: Dynamic AFO

With AFO –
Without AFO</td>
<td>Not reported</td>
<td>- Walking capacity:
1) Distance (m) and velocity (m/sec)
2) time (s) and velocity (m/s) during 25ftW
3) 6MWT and 25ftW grouped by time component of AI</td>
<td>1) sign. ≠
<table>
<tr><th>Parameter</th><th>No AFO</th><th>AFO</th><th>p-value</th></tr>
<tr><td>6MWT total (m)</td><td>197,49 ± 104,13</td><td>228,54 ± 103,93</td><td>p=0,002*</td></tr>
<tr><td>6MWT (m) G 1</td><td>319,18 ± 44,06</td><td>338,41 ± 66,60</td><td>ns</td></tr>
<tr><td>6MWT (m) G 2</td><td>195,86 ± 61,45</td><td>229,16 ± 65,24</td><td>p=0,069¥</td></tr>
<tr><td>6MWT (m) G 3</td><td>78,40 ± 35,87</td><td>117,66 ± 59,72</td><td>p=0,041*</td></tr>
<tr><td>25ftW time (sec)</td><td>21,22 ± 20,57</td><td>15,49 ± 14,65</td><td>p=0,01*</td></tr>
<tr><td>25ftW time (sec) G 1</td><td>7,60 ± 1,54</td><td>7,02 ± 1,67</td><td>p=0,087¥</td></tr>
<tr><td>25ftW time (sec) G 2</td><td>14,60 ± 4,55</td><td>11,45 ± 3,00</td><td>p=0,037*</td></tr>
<tr><td>25ftW time (sec) G 3</td><td>45,42 ± 26,62</td><td>30,40 ± 22,20</td><td>p=0,04*</td></tr>
</table>
Values are mean ± SD ; *, significant at p<0.05 ; ¥, borderline significant ; ns, not significant; G, group
3) 6MWT/ 25ftW: average velocity with AFO sign > without AFO</td>
</tr>
<tr>
<td>J.H. Park et al. 2009
Am. J. Phys Med. Rehabil.</td>
<td>- A-AFO: anterior leaf-type design, suitable for walking barefoot/ shoes
- PAFO: posterior leaf-type design, not suitable for barefoot

Without AFO (Barefoot) -
PAFO- (A-AFO)</td>
<td>Short time to familiarize with their newly prescribed AFO</td>
<td>- Gait: Motion analysis system (speed, stride length, velocity and double/single support)
- Balance: BBS</td>
<td>1) Sign. ↑ in cadence, stride length and velocity with A-AFO and PAFO compared with barefoot
<table>
<tr><th></th><th>Barefoot</th><th>PAFO</th><th>A-AFO</th></tr>
<tr><td>Cadence (steps/min)</td><td>63.9 ± 24.1</td><td>72.4 ± 21.4*</td><td>72.4 ± 17.8*</td></tr>
<tr><td>Stride length (cm)</td><td>56.6 ± 24.7</td><td>67.5 ± 19.9*</td><td>67.7 ± 19.9*</td></tr>
<tr><td>Velocity (cm/sec)</td><td>34.1 ± 29.0</td><td>43.2 ± 26.1*</td><td>42.9 ± 24.2*</td></tr>
<tr><td>Single support (%)</td><td>35.6 ± 19.8</td><td>24.5 ± 15.3</td><td>20.5 ± 10.8</td></tr>
<tr><td>Double support (%)</td><td>33.2 ± 18.9</td><td>46.7 ± 18.6</td><td>49.2 ± 14.5</td></tr>
</table>
Values are mean ± SD ; *, significant at p<0.05
2) Walking with AFO (A-AFO & PAFO) improved foot drop of hemiplegic ankles
3) No sign. ≠ in kinematics of hip/knee in 3 conditions, but there were diff. in favour of the AFO's</td>
</tr>
</table>

<table>
<tr><td></td><td></td><td></td><td></td><td>4) No sign. diff. in BBS scores with 3 conditions
5) 10/17 pts showed a transition in "household ambulation" (speed < 0.4m/sec= severe gait impairment) to "limited community ambulation" (speed between 0.4-0.8 m/sec =moderate gait impairment)</td></tr>
<tr><td>L.R. Sheffler et al. 2006
Neurorehabil. Neural Repair</td><td>-8/14: plastic, solid AFO
-4/14: plastic, hinged AFO
-2/14: plastic, prefabricated AFO

No device – AFO – ODFS (Odstock Dropped-Foot-Stimulator)</td><td>Prescribed AFO before study, different for each patient</td><td>- Mobility: mEFAP</td><td>1) No device vs. AFO: Sign. ≠ mEFAP (Mean differences)
<table>
<tr><th>Parameter</th><th>No device vs. AFO</th><th>p-value</th></tr>
<tr><td>Floor (sec)</td><td>2,98 ± 2,38</td><td>P<0,001*</td></tr>
<tr><td>Carpet (sec)</td><td>2,68 ± 3,47</td><td>p=0,013*</td></tr>
<tr><td>Up Go (sec)</td><td>3,0 ± 5,0</td><td>p=0,042*</td></tr>
<tr><td>Obstacle</td><td>5,68 ± 11,68</td><td>p=0,092</td></tr>
<tr><td>Stair</td><td>2,45 ± 4,95</td><td>p=0,067¥</td></tr>
</table>
Values are mean ± SD ; *, significant at p<0.05 ; ¥, borderline significant
Note: The performance with an AFO is in every item faster than with no device but not always significantly faster.
2) AFO vs. ODFS:
- mEFAP better with AFO compared with ODFS</td></tr>
<tr><td>C.D.M. Simons et al. 2009
Clin. Biomech.</td><td><u>Flexible:</u>
- 5/20: PP, non-art. AFO with small post. steel (Dynafo)
- 5/20: PP, non-art. AFO with 2 crossed post. steels, open heel (Ottobock)
<u>Rigid:</u>
* 6/20: PP, non-art. AFO with large post. steel (Camp)
* 4/20: Art. metal AFO with 2 bars (custom-made)

PP: Polypropylene

With AFO – Without AFO</td><td>-Mean: 34,7mo
-Range: 2-123 mo</td><td>- Balance: BBS, TUG, TBT
- Mobility: TUG, FAC
- Walking capacity: 10mWT (at comfortable speed)
- Dynamic balance control Posturographic tests: Force plates on movable platform

TBT: Timed Balance Test</td><td>1) Functional tests:
- Sign. effect with AFO for BBS, TUG, FAC, 10mWT in comparison without AFO
- No sign. effect with AFO for TBT in comparison without AFO. But it is borderline significant.
<table>
<tr><th></th><th>No AFO</th><th>AFO</th><th>p-value</th></tr>
<tr><td>BBS</td><td>46,2 ± 5,5</td><td>48,1 ± 4,8</td><td>p=0,001*</td></tr>
<tr><td>TUG (sec)</td><td>29,1 ± 12,9</td><td>23,4 ± 9,7</td><td>p<0,001*</td></tr>
<tr><td>10mWT (m/sec)</td><td>0,46 ±0,21</td><td>0,58 ± 0,24</td><td>p<0,001*</td></tr>
<tr><td>FAC</td><td>4,0 ±0,6</td><td>4,7 ± 0,5</td><td>p=0,001*</td></tr>
<tr><td>TBT</td><td>3,5 ± 1,0</td><td>4,0 ± 1,0</td><td>p=0,051¥</td></tr>
</table>
Values are mean ± SD ; *, significant at p<0.05 ; ¥, borderline significant
2) Posturographic tests:
- No sign. effects with AFO for weight-bearing asymmetry and dynamic balance control</td></tr>
</table>

<table>
<tr>
<td>SF Tyson & L Rogerson 2009 Archives of Physical Medicine and Rehabil.</td>
<td>Standard ossur leaf spring AFO. AFO was individually fitted for each pt.
(used also a slider shoe over their shoe to slide weak foot forward and a walking cane)

5 interventions: No device – Without AFO – Walking cane – Slider shoe – combination 3 devices</td>
<td>AFO's were fitted in the morning. Testing took place in the afternoon. Pts could practice in between as much as they wanted</td>
<td>- Mobility: FAC
- Walking capacity: 5m walk test (5mWT)</td>
<td>1) Sign. ↑ FAC with AFO – without AFO

<table>
<tr><th rowspan="2">FAC</th><th colspan="3">Comparison with no device</th></tr>
<tr><th>Median (IQR)</th><th>p-value</th><th>Effect size (% change)</th></tr>
<tr><td>AFO</td><td>2 (1-2)</td><td>p=0,0001*</td><td>1,68 (64%)</td></tr>
</table>
*, significant at p<0.05
Median FAC without device: 1 (1-1)

2) No sign. ≠ in gait with AFO vs. without device (5mWT)</td>
</tr>
<tr>
<td>SF Tyson & HA Thornton 2001 Clin. Rehabil.</td>
<td>Customised hinged AFO: metal ankle joint and adjustable PF stop, it enclosed the malleoli and sole plate extends full length of toes

With AFO – Without AFO</td>
<td>1 mo before the study started, AFO's were fitted.</td>
<td>- Gait: paper walkways (stride length, step length, symmetry, cadence and velocity)
- Mobility: FAC</td>
<td>1) Sign. ↑ FAC with AFO
<table>
<tr><th rowspan="2">FAC</th><th colspan="2">Subject number (%)</th></tr>
<tr><th>No AFO</th><th>AFO</th></tr>
<tr><td>1</td><td>7 (28%)</td><td>1 (4%)</td></tr>
<tr><td>2</td><td>8 (32%) = median FAC</td><td>0 (0%)</td></tr>
<tr><td>3</td><td>7 (28%)</td><td>3 (12%)</td></tr>
<tr><td>4</td><td>3 (12%)</td><td>19 (76%) = median FAC</td></tr>
<tr><td>5</td><td>0 (0%)</td><td>2 (8%)</td></tr>
</table>
2) There were sign. ↑ in stride length, cadence and velocity with AFO, but not for step length and symmetry.
<table>
<tr><th>Parameter</th><th>No AFO</th><th>AFO</th><th>P-Value</th></tr>
<tr><td>Velocity (m/sec)</td><td>0,18 ± 0,1</td><td>0,25 ± 0,1</td><td>p<0,001*</td></tr>
<tr><td>Cadence (steps/min)</td><td>53,1 ± 16,8</td><td>62,5 ± 17,2</td><td>p=0,002*</td></tr>
<tr><td>Stride length aff (cm)</td><td>39,4 ± 14,3</td><td>44,3 ± 14,1</td><td>p=0,005*</td></tr>
<tr><td>Stride length unaff(cm)</td><td>39,3 ± 13,7</td><td>43,8 ± 14</td><td>p=0,014*</td></tr>
<tr><td>Step length aff (cm)</td><td>21,7 ± 9,5</td><td>23,7 ± 11,7</td><td>ns</td></tr>
<tr><td>Step length unaff (cm)</td><td>19,4 ± 9,9</td><td>20,8 ± 9,6</td><td>ns</td></tr>
</table></td>
</tr>
</table>

<table>
<tr><td></td><td></td><td></td><td></td><td>
<table>
<tr><td>Step symmetry</td><td>2,6 ± 4,9</td><td>3 ± 7,8</td><td>ns</td></tr>
</table>
Values are mean ± SD ; *, significant at p<0.05 ; ns, not significant; aff, affected side; unaff, unaffected side
</td></tr>
<tr><td>R-Y. Wang et al. 2005
Clin. Rehabil.</td><td>Standard plastic, 125g,neutral position AFO

With AFO – Without AFO</td><td>Not reported</td><td>- Balance: BBS
- Walking capacity: 10m walk (at comfortable speed)
- Static & dynamic balance: Balance Master System (BMS)
• Static balance test
• Dynamic balance test</td><td><u>1) Short duration group (SD):<6mo:</u>
AFO sign. ↑:
- Symmetry in standing (weight-bearing)
- Dynamic standing balance (Maximal excursion towards aff. side, movement velocity)
-↑ in speed / cadence (10mW)
- No effect of AFO on BBS
<u>2) Long duration group (LD):>12mo:</u>
- AFO no sign. effects on BBS, walking, static and dynamic balance (BMS)</td></tr>
<tr><td>DCM. de Wit et al. 2004
Clin. Rehabil.</td><td>Plastic, non-art. AFO
3 diff. types:
1) AFO with small posterior steel
2) AFO with big posterior steel, sometimes individually made
3) AFO with 2 crossed posterior steels, open heel

With AFO – Without AFO</td><td>Not reported</td><td>- Walking capacity: 10m walkway (at comfortable speed)
- Mobility: TUG, stairs test
- Balance: TUG, stairs test</td><td>1) Sign. ≠ in mean
<table>
<tr><th>Parameter</th><th>Mean difference AFO and no AFO</th><th>p-value</th></tr>
<tr><td>Velocity (cm/sec)</td><td>4,8 ± 8,4</td><td>p=0,02*</td></tr>
<tr><td>TUG (sec)</td><td>3,6 ± 2,5</td><td>p<0,001*</td></tr>
<tr><td>Stairs test (sec)</td><td>8,6 ± 11,8</td><td>p=0,004*</td></tr>
</table>
Values are mean ± SD ; *, significant at p<0.05
Note: Main interest of study was clinical relevance in ADL so clinical relevant effect sizes were defined before start study. When taking into account these a priori defined values, none of the effects are clinically relevant
A priori values:
- Walking speed: ≠ of 20cm/sec
- TUG: ≠ of 10sec
- Stairs Test: No a priori value set</td></tr>
</table>

AFO, Ankle-foot orthosis; AFO Time: Time with AFO before study; ≠, differences; Pts, patients; PT, physiotherapist; FAC, Functional Ambulation Categories; BBS: Berg Balance Scale; TUG, Timed Up & Go; 10mWT:10meter Walk Test; 6MWT, Six-Minute Walk Test; 5MWT, 5-Meter Walk Test; 25ftW, 25-Foot Walk; AI: Ambulation Index.

Table 7: summary of results

	BALANCE/ MOBILITY											WALKING			
	TUG	**BBS**	**mEFAP**	**FAC**	**STREAM (basic mobility)**	**Ashburn (15'walk/7 stairs)**	**FR**	**TUS**	**TDS**	**TBT**	**Stair test**	**6MWT**	**25fWT**	**10mWT**	**5m WT**
H. Abe et al. 2009				↑*											
E. Cakar et al. 2010		↑*													
A. Dogan et al. 2010	↓*	↑*			↑*	↓* ns									
S. Erel et al. 2011	ns						ns	↓*	ns						
M. Franceschini et al. 2003												↑*			
S. Hesse et al. 1996														↑*	
S. Hesse et al. 1999														ns	
J-W. Hung et al. 2010	↓*		↓*									↑*			
J.A.P. Mojica et al. 1988														↑*	
K. J. Nolan et al. 2009												↑* Total ↑* 3 / ↑¥ 2 / ns 1	↑* Total ↑* 2/3 / ↑¥ 1		
J.H. Park et al. 2009		ns													
L.R. Sheffler et al. 2006	↓*		↓*												
C.D.M. Simons et al. 2009	↓*	↑*		↑*						↑¥				↑*	
SF Tyson & L Rogerson 2009				↑*											ns
SF Tyson & HA Thornton 2001				↑*											
R-Y. Wang et al. 2005		ns												↑* acu / ns chr	
DCM. de Wit et al. 2004	↓*										↓*			↑*	

**, Statistical significant effect in favour of the AFO ; ns, not significant; TUG, Timed Up and Go; BBS, Berg Balance Scale; mEFAP, modified Emory Functional Ambulation Profile; FAC, Functional Ambulation Categories; STREAM, Stroke Rehabilitation Assessment of Movement Measure; FR, Functional Reach test; TUS, Timed Up Stairs, TDS, Timed Down Stairs; TBT, Timed Balance Test; 6MWT, SIx-Minute Walk Test; 25ftW, 25-foot Walk; 10mWT, 10- Meter Walk Test; 5mWT, 5-Minute Walk Test; 1, Group 1 (Fast pts: Walk 25ft. in ≤ 10sec); 2, Group 2(Moderate pts: Walk 25ft. in ≤ 20sec); 3, Group 3 (Slow pts: Walk 25ft. in > 20sec); Acu, acute group; Chr, chronic group; ↑¥, Borderline significance.*

5. Discussion

5.1 Reflection on quality of studies

In general the quality of the included RCT's was rather low, because blinding of the patients and practitioners is not possible in studies with regard to the use of an AFO. So, there is always a performance bias present. Further a relative low score has been assigned to the quasi-experimental studies. There is always a selection bias present, because in all the studies there is only one group investigated, or two groups which are not at random assigned. Performance biases are also present, because blinding of the patients and practitioners is not possible in studies with an AFO.

5.2 Reflection on findings in function of research question

Six out of seventeen included articles used the Timed Up & Go (TUG) as a functional mobility scale. Five of them showed significant results in favour of the AFO. Erel et al., 2011 found only borderline significant effects of an AFO on the TUG. A first possible explanation could be that they only selected patients who did not wear an AFO prior to the study, this in contrast to the other five articles. Therefore we can suggest that the included patients were good walkers (FAC score: 3-5) so they may not benefit from the use of an AFO. A second explanation could be that Erel et al., 2011 is the only article which compared two homogenous groups of different patients, whereas other studies compared the same patients with and without an AFO. Another explanation could be that the results for patients without an AFO can be due to learned compensations. Chronic patients may have developed compensation strategies over time when walking without an AFO. Therefore it could be possible that equal results were found when performing the TUG, but that the walking pattern may be worse in patients without an AFO compared to patients who walked with an AFO. A possible limitation of the TUG is that they only investigate the quantity of the performance and not the quality of movement. A fourth possible explanation could be that they were the only study that used a Dynamic AFO (DAFO). Because of the unique features of a DAFO it could be possible that it is not comparable with a regular AFO. However this DAFO had no effect on TUG, Functional Reach test and Timed Down Stairs, it had a significant effect on the Timed Up Stairs, gait velocity and Physiological Cost Index.

Five articles used the Berg Balance Scale (BBS) as an outcome measurement. Three articles, Cakar et al., 2010, Dogan et al., 2010 and Simons et al., 2009, showed significant increases in total BBS score with an AFO. The other two articles that investigated the BBS found no effects in favour of the AFO (Park et al., 2009; Wang et al., 2005). First of all, this could be explained by a shorter habituation time with the AFO. Park et al., 2009 reported only ‘a short time to familiarize’ with the AFO and Wang et al., 2005 did not report the habituation time. This in contrast to Cakar et al., 2010, Dogan et al., 2010 and Simons et al., 2009, which had an average habitation time of respectively 4 days, 1 week and 34 months. Wang et al., 2005 (only the acute patients) and

Park et al., 2009 found significant effects on velocity and cadence, but it is possible that the habituation time has a bigger impact on balance compared to walking.
Secondly, Wang et al., 2005 found significant results in weight bearing symmetry in favour of the AFO when using the Balance Master System. This is a measurement on impairment level which is often used because it isolates the effect of an AFO on the mechanisms underlying balance control. Functional balance tests (e.g. BBS) do not measure the pure mechanical effects of an AFO, but also other factors such as adaptive strategies and balance confidence can influence the performance (Geurts, de Haart, van Nes, & Duysens, 2005).
Further, it is also possible that Wang et al., 2005 and Park et al., 2009 did not found significant effects because of the differences in population compared to Cakar et al., 2010, Dogan et al., 2010 and Simons et al., 2009. The three previous studies showed comparable scores on the BBS without AFO (range of mean scores: 41.28-46.2). Wang et al., 2005 showed in both groups a mean score of 51 (range of mean scores: 36/37-56) both with and without an AFO. When looking at the mean score and range, it can be concluded that the population consists of more good patients. Possible ceiling effects of the BBS in patients with high scores on this test, could be a possible explanation for not finding any significant results in favour of the AFO (Mao, Hsueh, Tang, Sheu, & Hsieh, 2002).
A fourth possible explanation for not finding significant effects could be that Park et al., 2009 included only acute patients with a mean onset duration of 36.8 ±11.9 days and a relative low score on the BSS (mean score: 37.3) without an AFO. Moa et al., 2002 indicates a high risk of floor effects in acute patients for the BBS.
And additionally, a good score on the BBS requires a more adequate weight bearing of the affected leg or an overcompensation of the healthy side. And also, the instructions do not force the patients to support on or use both legs equally. They have the opportunity to choose which leg they use when performing the test, this could be a possible disadvantage of the BBS.

Four out of seventeen included articles investigated the Functional Ambulation Categories (FAC) (Abe et al., 2009; Simons et al., 2009; Tyson & Rogerson, 2009; Tyson & Thornton, 2001). All of them found consistent results in favour of the AFO. By this, we can conclude that an AFO has a positive effect on the functional mobility regardless of the type of AFO used in the study, habituation time (average range from a couple of hours to 34 days), the severity of stroke and time since stroke (average range from 6.5 weeks to 39 months).

Two articles used the modified Emory Functional Ambulation Profile (mEFAP) and showed significant results in total score (Hung et al., 2011; Sheffler et al., 2006). When looking at the individual items of the test, Sheffler et al., 2006 found borderline significance in one item (stair, $p=0.067$) and no significance in item "obstacle". This could be explained by the limited power of the study. The other three items showed significant effects in favour of the AFO.

Six out of the seventeen included articles investigated the 10- Meter Walk Test (10mWT) (de Wit et al., 2004; Hesse et al., 1996; Hesse et al., 1999; Mojica et al., 1988; Simons et al., 2009; Wang et al., 2005). Five of them reported significant improvements in favour of the AFO, except for the chronic patient group in Wang et al., 2005. Wang et al., 2005 provides his own explanation for the lack of significance in the chronic patient group.

This implies that structural changes of the ankle joint that occur over time, cause less improvements with an AFO. Hesse et al., 1999 was the only article that found no significant effects. No reasonable explanation could be found.
Hesse et al., 1996 found significant effects on the 10mWT in favour of the AFO and was the only article that compared walking barefoot, with shoes only and a combination of shoes and an AFO. A big difference was found between these three conditions. Compared with barefoot, patients walked 30,3% faster when wearing shoes. Further, with an AFO, patients walked 66,6% faster compared to walking barefoot and 27,9% faster compared to the shoes only condition. Therefore, we can conclude that there is an effect of shoes on the walking speed in stroke patients.
According to Collen et al., 1990, only Simons et al., 2009 used the instructions of the 10mWT. De Wit et al., 2004 and Wang et al., 2005 did not describe their test as a 10mWT. De Wit et al., 2004 used a flying start and only measured the walking speed over a distance of 7.5 meters. Wang et al., 2005 also used a flying start but walking speed was measured over a distance of 10 meters. Another issue of Wang et al., 2005 is that they only repeated the test twice, however three times is recommended by the guidelines (Collen, Wade, & Bradshaw, 1990). In contrast to the previous three articles mentioned above, Hesse et al., 1996, Hesse et al., 1999 and Mojica et al., 1988 used the maximum walking speed as an instruction instead of comfortable, self-selected walking speed. Also it was not clear if they took an average of three measurements per patient. We are aware of the differences in these instructions and did not compare the articles with instructions of maximum walking speed to articles with instructions of comfortable, self-selected walking speed.

When encompassing walking endurance besides walking speed, the Six-Minute Walk Test (6MWT) is a more appropriate measurement. Three studies used the 6MWT (Franceschini et al., 2003; Hung et al., 2011; Nolan et al., 2009). One of them, Franceschini et al., 2003 did not express the 6MWT as an outcome measurement. His experimental procedure was ‘6 minutes of continues walking at a comfortable self-selected speed. Patients walked a hospital corridor of known length’. This actually is the description of the 6MWT and therefore it was analysed as the 6MWT (Balke, 1963). These three studies all showed significant improvements in favour of the AFO. Nolan et al., 2009 divided his population in three groups based on the Ambulation Index (AI). They found only a significant result in the slow patients (group 3) and borderline significance in the moderate patients (group 2). Based on Nolan et al., 2009, it can be concluded that slower patients benefit more from the use of an AFO while walking long distances. This conclusion cannot be confirmed by the other two articles because no subgroups were made. Nolan et al., 2009 also compared the 6MWT with the 25-Foot Walk (25ftW). Here we see that there is a greater effect of the AFO in group 1 and 2 on the 25ftW compared to the 6MWT. We would expect that it would be vice versa, so more effect on the 6MWT than on the 25ftW. This because when patients walk for a short distance (25ftW) and you find an effect, you would certainty expect an effect on a longer distance (6MWT). Thereby, we cannot find a reasonable explanation for the results of this article.

The Ashburn Battery Test, the Stroke Rehabilitation Assessment of Movement (STREAM), the Functional Reach (FR), the Timed Up Stairs (TUS) and Timed Down Stairs (TDS), the Timed Balance Test (TBT), the Stairs Test and the 5-Minute Walk Test (5mWT) were each investigated by only one included article, so it is not possible to

draw conclusions out of these tests. For future research it is important to use the same outcome measurements to make comparison of results possible.

In 2013, Tyson SF & Kent RM performed a systematic review of RCT's and pooled meta-analysis which we did not include based on the guidelines of master thesis part 1. This systematic review contains thirteen RCT's, whereof eight articles were also included separately in this master thesis (de Wit et al., 2004; Hesse et al., 1996; Hesse et al., 1999; Mojica et al., 1988; Simons et al., 2009; Tyson & Rogerson, 2009; Tyson & Thornton, 2001; Wang et al., 2005). The incomplete overlap of articles is due to a difference in research questions. Both, Tyson SF & Kent RM, 2013 and this current systematic review included articles related to balance and walking. The differences are that our review focuses on functional balance and functional walking tests only and Tyson SF & Kent RM, 2013 included also instrumented balance tests and non-functional spatio-temporal gait parameter measurements. When comparing this current systematic review and the systematic review of Tyson SF & Kent RM, 2013, some results contradict each other. This is because Tyson SF & Kent RM, 2013 executed a pooled meta-analysis and we used the individual data of all articles to draw conclusions.

5.3 Reflection on strengths and weaknesses of the literature study

A first strength of our study is that an explicit research question was set up with an appropriate PICO as a guidance. Secondly, different search combinations were set up, then they were compared with each other and the most appropriate search strategy has been selected. Further, additional relevant articles were searched in the reference lists of the already included articles and in the related citations on Pubmed. In April, Pubmed and WoK were checked for new updates.
A possible weakness of our literature study could be that only two databases were searched. According to the Cochrane Checklist for Systematic Review of RCT's, MEDLINE(Pubmed) and EMBASE should be searched to obtain 90% of all relevant articles. We did not use EMBASE as a database. Therefore it is possible that appropriate articles could have been missed. Selection of articles, quality assessment and data-extraction were well reported but not performed by two independent researchers. Because of the major differences between the articles: namely the patients' characteristics, the AFO used in the study, the differences in time wearing an AFO before the study and the different outcome measures used, it is difficult to compare the results.

5.4 Recommendations for future research

Little is known about the effects of an AFO based on the severity of patients. Thus a distinction between severely impaired patients and less impaired patients should be made. Also, it could be useful to examine which patients (acute – sub-acute – post-acute – chronic) benefit the most from an AFO concerning dynamic balance and walking capacity. Furthermore, the literature is inconclusive about the optimal time wearing an AFO and at which point of time post stroke they should be prescribed. Hung et al., 2010 and Simons et al., 2009 reported patients who wore their AFO for more than one month, but they did not perform pre- and post-tests. Therefore

this is not a measure of a long term effect. So there is a need for studies with a longitudinal design which measures the effects of an AFO over time.
Another important issue is that wearing shoes could have an impact on the effects of an AFO. According to Churchill et al., 2001, the most appropriate way to measure the effects of an AFO is comparing shoes and shoes with an AFO and not walking barefoot, as in Abe et al., 2009, Hesse et al., 1996, Hesse et al., 1999, Mojica et al., 1988 and Park et al., 2009 (Churchill, Halligan, & Wade, 2003).
All included articles except for Park et al., 2009 did not compare different types of AFO. The other thirteen included articles compared no AFO with AFO and in some of them different types of AFO were used in the AFO condition (Abe et al., 2009; de Wit et al., 2004; Nolan et al., 2009; Sheffler et al., 2006; Simons et al., 2009). In this case only general conclusions can be drawn, but no specific conclusion can be made about which AFO is superior, for example a prefabricated AFO (Maramed) versus an individualised AFO (Y-tech). In conclusion: further research needs to focus on the effects of different types of AFO and a clear classification of definitions of different types of AFO should be developed.

6. Conclusion

All articles that investigated the FAC, mEFAP and 6MWT found significant effects in favour of the AFO. Although most of the articles reported significant results on the TUG, BBS and 10mWT, but the overall effect was inconclusive. The results for TUG and 10mWT are more conclusive than those for BBS. Further research is necessary to draw appropriate conclusions.

7. Reference list

(*) Included articles in the literature study

(*) Abe, H., Michimata, A., Sugawara, K., Sugaya, N., & Izumi, S. (2009). Improving gait stability in stroke hemiplegic patients with a plastic ankle-foot orthosis. *Tohoku J Exp Med, 218*(3), 193-199.

Balke, B. (1963). A Simple Field Test for the Assessment of Physical Fitness. Rep 63-6. *Rep Civ Aeromed Res Inst US*, 1-8.

(*) Cakar, E., Durmus, O., Tekin, L., Dincer, U., & Kiralp, M. Z. (2010). The ankle-foot orthosis improves balance and reduces fall risk of chronic spastic hemiparetic patients. *Eur J Phys Rehabil Med, 46*(3), 363-368.

Cho, K., & Lee, G. (2013). Impaired dynamic balance is associated with falling in post-stroke patients. *Tohoku J Exp Med, 230*(4), 233-239.

Churchill, A. J., Halligan, P. W., & Wade, D. T. (2003). Relative contribution of footwear to the efficacy of ankle-foot orthoses. *Clin Rehabil, 17*(5), 553-557.

Collen, F. M., Wade, D. T., & Bradshaw, C. M. (1990). Mobility after stroke: reliability of measures of impairment and disability. *Int Disabil Stud, 12*(1), 6-9.

Danielsson, A., & Sunnerhagen, K. S. (2004). Energy expenditure in stroke subjects walking with a carbon composite ankle foot orthosis. *J Rehabil Med, 36*(4), 165-168. doi: 10.1080/16501970410025126

(*) de Wit, D. C., Buurke, J. H., Nijlant, J. M., Ijzerman, M. J., & Hermens, H. J. (2004). The effect of an ankle-foot orthosis on walking ability in chronic stroke patients: a randomized controlled trial. *Clin Rehabil, 18*(5), 550-557.

(*) Dogan, A., Mengulluoglu, M., & Ozgirgin, N. (2011). Evaluation of the effect of ankle-foot orthosis use on balance and mobility in hemiparetic stroke patients. *Disabil Rehabil, 33*(15-16), 1433-1439. doi: 10.3109/09638288.2010.533243

(*) Erel, S., Uygur, F., Engin Simsek, I., & Yakut, Y. (2011). The effects of dynamic ankle-foot orthoses in chronic stroke patients at three-month follow-up: a randomized controlled trial. *Clin Rehabil, 25*(6), 515-523. doi: 10.1177/0269215510390719

Feigin, V. L., Lawes, C. M., Bennett, D. A., & Anderson, C. S. (2003). Stroke epidemiology: a review of population-based studies of incidence, prevalence, and case-fatality in the late 20th century. *Lancet Neurol, 2*(1), 43-53.

(*) Franceschini, M., Massucci, M., Ferrari, L., Agosti, M., & Paroli, C. (2003). Effects of an ankle-foot orthosis on spatiotemporal parameters and energy cost of hemiparetic gait. *Clin Rehabil, 17*(4), 368-372.

Geurts, A. C., de Haart, M., van Nes, I. J., & Duysens, J. (2005). A review of standing balance recovery from stroke. *Gait Posture, 22*(3), 267-281. doi: 10.1016/j.gaitpost.2004.10.002

Gok, H., Kucukdeveci, A., Altinkaynak, H., Yavuzer, G., & Ergin, S. (2003). Effects of ankle-foot orthoses on hemiparetic gait. *Clin Rehabil, 17*(2), 137-139.

(*) Hesse, S., Luecke, D., Jahnke, M. T., & Mauritz, K. H. (1996). Gait function in spastic hemiparetic patients walking barefoot, with firm shoes, and with ankle-foot orthosis. *Int J Rehabil Res, 19*(2), 133-141.

(*) Hesse, S., Werner, C., Matthias, K., Stephen, K., & Berteanu, M. (1999). Non-velocity-related effects of a rigid double-stopped ankle-foot orthosis on gait and lower limb muscle activity of hemiparetic subjects with an equinovarus deformity. *Stroke, 30*(9), 1855-1861.

(*) Hung, J. W., Chen, P. C., Yu, M. Y., & Hsieh, Y. W. (2011). Long-term effect of an anterior ankle-foot orthosis on functional walking ability of chronic stroke patients. *Am J Phys Med Rehabil, 90*(1), 8-16. doi: 10.1097/PHM.0b013e3181fc7d27

Koninklijk Nederlands Genootschap voor Fysiotherapie. (w.y.). Accessed on the 5th of May 2014, of http://www.kngfrichtlijnen.nl

Lehmann, J. F. (1979). Biomechanics of ankle-foot orthoses: prescription and design. *Arch Phys Med Rehabil, 60*(5), 200-207.

Lehmann, J. F., Condon, S. M., Price, R., & deLateur, B. J. (1987). Gait abnormalities in hemiplegia: their correction by ankle-foot orthoses. *Arch Phys Med Rehabil, 68*(11), 763-771.

Mao, H. F., Hsueh, I. P., Tang, P. F., Sheu, C. F., & Hsieh, C. L. (2002). Analysis and comparison of the psychometric properties of three balance measures for stroke patients. *Stroke, 33*(4), 1022-1027.

(*) Mojica, J. A., Nakamura, R., Kobayashi, T., Handa, T., Morohashi, I., & Watanabe, S. (1988). Effect of ankle-foot orthosis (AFO) on body sway and walking capacity of hemiparetic stroke patients. *Tohoku J Exp Med, 156*(4), 395-401.

Neumann, D. (2002). *Kinesiology of the Musculoskeletal System: Foundations for Rehabilitation.* St. Louis, Missouri: Elsevier.

(*) Nolan, K. J., Savalia, K. K., Lequerica, A. H., & Elovic, E. P. (2009). Objective assessment of functional ambulation in adults with hemiplegia using ankle foot orthotics after stroke. *PM R, 1*(6), 524-529. doi: 10.1016/j.pmrj.2009.04.011

O'Sullivan, S. (2007). *Physical Rehabilitation*. Philadelphia: Davis Company.

(*) Park, J. H., Chun, M. H., Ahn, J. S., Yu, J. Y., & Kang, S. H. (2009). Comparison of gait analysis between anterior and posterior ankle foot orthosis in hemiplegic patients. *Am J Phys Med Rehabil, 88*(8), 630-634. doi: 10.1097/PHM.0b013e3181a9f30d

Pollock, C., Eng, J., & Garland, S. (2011). Clinical measurement of walking balance in people post stroke: a systematic review. *Clin Rehabil, 25*(8), 693-708. doi: 10.1177/0269215510397394

(*) Sheffler, L. R., Hennessey, M. T., Naples, G. G., & Chae, J. (2006). Peroneal nerve stimulation versus an ankle foot orthosis for correction of footdrop in stroke: impact on functional ambulation. *Neurorehabil Neural Repair, 20*(3), 355-360. doi: 10.1177/1545968306287925

(*) Simons, C. D., van Asseldonk, E. H., van der Kooij, H., Geurts, A. C., & Buurke, J. H. (2009). Ankle-foot orthoses in stroke: effects on functional balance, weight-bearing asymmetry and the contribution of each lower limb to balance control. *Clin Biomech (Bristol, Avon), 24*(9), 769-775. doi: 10.1016/j.clinbiomech.2009.07.006

(*) Tyson, S. F., & Rogerson, L. (2009). Assistive walking devices in nonambulant patients undergoing rehabilitation after stroke: the effects on functional mobility, walking impairments, and patients' opinion. *Arch Phys Med Rehabil, 90*(3), 475-479. doi: 10.1016/j.apmr.2008.09.563

(*) Tyson, S. F., & Thornton, H. A. (2001). The effect of a hinged ankle foot orthosis on hemiplegic gait: objective measures and users' opinions. *Clin Rehabil, 15*(1), 53-58.

(*) Wang, R. Y., Yen, L., Lee, C. C., Lin, P. Y., Wang, M. F., & Yang, Y. R. (2005). Effects of an ankle-foot orthosis on balance performance in patients with hemiparesis of different durations. *Clin Rehabil, 19*(1), 37-44.

Excluded articles:

New devices compensate for foot drop. Nerve stimulation can help many people walk normally again (2012). *Harv.Heart Lett., 23,* 6.

Bayram, S., Sivrioglu, K., Karli, N., & Ozcan, O. (2006). Low-dose botulinum toxin with short-term electrical stimulation in poststroke spastic drop foot: a preliminary study. *Am.J.Phys.Med.Rehabil., 85,* 75-81.

Black, C., Liu, D., Petrash, H., & Warga, G. (2008). The Knee Nook. *Top.Stroke Rehabil., 15,* 146-150.

Bosch, PR., Harris, JE., Wing, K. (2014). Review of Therapeutic Electrical Stimulation for Dorsiflexion Assist and Orthotic Substitution From the American Congress of Rehabilitation Medicine Stroke Movement Interventions Subcommittee. *Archives of physical medicine and rehabilitation*.,95(2),390-6.

Bregman, D. J., de, G., V, Van, D. P., Meulman, H., Houdijk, H., & Harlaar, J. (2010). Polypropylene ankle foot orthoses to overcome drop-foot gait in central neurological patients: a mechanical and functional evaluation. *Prosthet.Orthot.Int., 34,* 293-304.

Bregman, D. J., van der Krogt, M. M., de, G., V, Harlaar, J., Wisse, M., & Collins, S. H. (2011). The effect of ankle foot orthosis stiffness on the energy cost of walking: a simulation study. *Clin.Biomech.(Bristol., Avon.), 26,* 955-961.

Bulley, C., Shiels, J., Wilkie, K., & Salisbury, L. (2011). User experiences, preferences and choices relating to functional electrical stimulation and ankle foot orthoses for foot-drop after stroke. *Physiotherapy., 97,* 226-233.

Burridge, J., Haugland, M., Larsen, B., Pickering, RM., Svaneborg, N., Iversen, HK. (2007). Phase II trial to evaluate the ActiGait implanted drop-foot stimulator in established hemiplegia. *Journal of Rehabilitation Medicine.*, 39(3), 212-8.

Caillet, F., Mertens, P., Rabaseda, S., & Boisson, D. (2003). [Three dimensional gait analysis and controlling spastic foot on stroke patients]. *Ann.Readapt.Med.Phys., 46,* 119-131.

Carda, S., Invernizzi, M., Cognolato, G., Piccoli, E., Baricich, A., & Cisari, C. (2012). Efficacy of a hip flexion assist orthosis in adults with hemiparesis after stroke. *Phys.Ther., 92,* 734-739.

Carse, B., Bowers, R. J., Meadows, B. C., & Rowe, P. J. (2011). Visualisation to enhance biomechanical tuning of ankle-foot orthoses (AFOs) in stroke: study protocol for a randomised controlled trial. *Trials, 12,* 254.

Chen, C. C., Hong, W. H., Wang, C. M., Chen, C. K., Wu, K. P., Kang, C. F. et al. (2010). Kinematic features of rear-foot motion using anterior and posterior ankle-foot orthoses in stroke patients with hemiplegic gait. *Arch.Phys.Med.Rehabil., 91,* 1862-1868.

Chen, C. H., Lin, K. H., Lu, T. W., Chai, H. M., Chen, H. L., Tang, P. F. et al. (2010). Immediate effect of lateral-wedged insole on stance and ambulation after stroke. *Am.J.Phys.Med.Rehabil., 89,* 48-55.

Chen, C. K., Hong, W. H., Chu, N. K., Lau, Y. C., Lew, H. L., & Tang, S. F. (2008). Effects of an anterior ankle-foot orthosis on postural stability in stroke patients with hemiplegia. *Am.J.Phys.Med.Rehabil., 87,* 815-820.

Chen, C. L., Yeung, K. T., Wang, C. H., Chu, H. T., & Yeh, C. Y. (1999). Anterior ankle-foot orthosis effects on postural stability in hemiplegic patients. *Arch.Phys.Med.Rehabil., 80,* 1587-1592.

Chen, G. & Patten, C. (2006). Treadmill training with harness support: selection of parameters for individuals with poststroke hemiparesis. *J.Rehabil.Res.Dev., 43,* 485-498.

Cheng, H. S., Ju, M. S., & Lin, C. C. (2003). Improving elbow torque output of stroke patients with assistive torque controlled by EMG signals. *J.Biomech.Eng, 125,* 881-886.

Chisholm, A. E. & Perry, S. D. (2012). Ankle-foot orthotic management in neuromuscular disorders: recommendations for future research. *Disabil.Rehabil.Assist.Technol., 7,* 437-449.

Churchill, A. J., Halligan, P. W., & Wade, D. T. (2003). Relative contribution of footwear to the efficacy of ankle-foot orthoses. *Clin.Rehabil., 17,* 553-557.

Coenen, P., van, W. G., van Nunen, M. P., Van Dieen, J. H., Gerrits, K. H., & Janssen, T. W. (2012). Robot-assisted walking vs overground walking in stroke patients: an evaluation of muscle activity. *J.Rehabil.Med., 44,* 331-337.

Danielsson, A. & Sunnerhagen, K. S. (2004). Energy expenditure in stroke subjects walking with a carbon composite ankle foot orthosis. *J.Rehabil.Med., 36,* 165-168.

de Seze, M. P., Bonhomme, C., Daviet, J. C., Burguete, E., Machat, H., Rousseaux, M. et al. (2011). Effect of early compensation of distal motor deficiency by the Chignon ankle-foot orthosis on gait in hemiplegic patients: a randomized pilot study. *Clin.Rehabil., 25,* 989-998.

Dobkin, B. H., Firestine, A., West, M., Saremi, K., & Woods, R. (2004). Ankle dorsiflexion as an fMRI paradigm to assay motor control for walking during rehabilitation. *Neuroimage., 23,* 370-381.

Eckhardt, M. M., Mulder, M. C., Horemans, H. L., van der Woude, L. H., & Ribbers, G. M. (2011). The effects of high custom made shoes on gait characteristics and patient satisfaction in hemiplegic gait. *Gait.Posture., 34,* 543-547.

Everaert, DG., Stein, RB., Abrams, GM., Dromerick, AW., Francisco, GE., Hafner, BJ., et al. (2013). Effect of a Foot-Drop Stimulator and Ankle-Foot Orthosis on Walking Performance After Stroke: A Multicenter Randomized Controlled Trial. *Neurorehabilitation and neural repair.,* 27(7), 579-91.

Fatone, S., Hansen, AH. (2007). Effect of ankle-foot orthosis on roll-over shape in adults with hemiplegia. *Journal of rehabilitation research and development.*, 44(1), 11-20.

Fatone, S., Gard, S. A., & Malas, B. S. (2009). Effect of ankle-foot orthosis alignment and foot-plate length on the gait of adults with poststroke hemiplegia. *Arch.Phys.Med.Rehabil., 90,* 810-818.

Femery, VG., Moretto, PG., Hespel, JMG., Thevenon, A., Lensel, G. (2004) A real-time plantar pressure feedback device for foot unloading. *Archives of physical medicine and rehabilitation*., 85(10), 1724-8.

Fernandes, M. R., Carvalho, L. B., & Prado, G. F. (2006). A functional electric orthesis on the paretic leg improves quality of life of stroke patients. *Arq Neuropsiquiatr., 64,* 20-23.

Fish, D. J., Crussemeyer, J. A., & Kosta, C. S. (2001). Lower extremity orthoses and applications for rehabilitation populations. *Foot Ankle Clin., 6,* 341-369.

Guillebastre, B., Calmels, P., Rougier, P. (2013). Effects of muscular deficiency on postural and gait capacities in patients with charcot-marie-tooth disease. *Journal of Rehabilitation Medicine.*, 45(3), 314-7.

Han, S. H., Kim, T., Jang, S. H., Kim, M. J., Park, S. B., Yoon, S. I. et al. (2011). The effect of an arm sling on energy consumption while walking in hemiplegic patients: a randomized comparison. *Clin.Rehabil., 25,* 36-42.

Harlaar, J., Brehm, M., Becher, JG., Bregman, DJJ., Buurke, J., Holtkamp, F., et al. (2010). Studies examining the efficacy of Ankle Foot Orthoses should report activity level and mechanical evidence. *Prosthetics and orthotics international.*, 34(3), 327-35.

Hase, K., Suzuki, E., Matsumoto, M., Fujiwara, T., & Liu, M. (2011). Effects of therapeutic gait training using a prosthesis and a treadmill for ambulatory patients with hemiparesis. *Arch.Phys.Med.Rehabil., 92,* 1961-1966.

Herr, H., Kornbluh, R. (2004). New horizons for orthotic and prosthetic technology: artificial muscle for ambulation. *The International Society for Optical Engineering.*, 53852004, p. 1-9.

Hesse, S. (2008). Treadmill training with partial body weight support after stroke: a review. *NeuroRehabilitation., 23,* 55-65.

Hesse, S., Tomelleri, C., Bardeleben, A., Werner, C., & Waldner, A. (2012). Robot-assisted practice of gait and stair climbing in nonambulatory stroke patients. *J.Rehabil.Res.Dev., 49,* 613-622.

Hiengkaew, V., Jitaree, K., & Chaiyawat, P. (2012). Minimal detectable changes of the Berg Balance Scale, Fugl-Meyer Assessment Scale, Timed "Up & Go" Test, gait speeds, and 2-minute walk test in individuals with chronic stroke with different degrees of ankle plantarflexor tone. *Arch.Phys.Med.Rehabil., 93,* 1201-1208.

Hornby, T. G., Campbell, D. D., Kahn, J. H., Demott, T., Moore, J. L., & Roth, H. R. (2008). Enhanced gait-related improvements after therapist- versus robotic-assisted locomotor training in subjects with chronic stroke: a randomized controlled study. *Stroke, 39,* 1786-1792.

Hoyer, E., Jahnsen, R., Stanghelle, J. K., & Strand, L. I. (2012). Body weight supported treadmill training versus traditional training in patients dependent on walking assistance after stroke: a randomized controlled trial. *Disabil.Rehabil., 34,* 210-219.

Husemann, B., Muller, F., Krewer, C., Heller, S., & Koenig, E. (2007). Effects of locomotion training with assistance of a robot-driven gait orthosis in hemiparetic patients after stroke: a randomized controlled pilot study. *Stroke, 38,* 349-354.

Hwang, Y. I., An, D. H., & Yoo, W. G. (2012). Effects of the Dual AFO on gait parameters in stroke patients. *NeuroRehabilitation., 31,* 387-393.

Hwang, Y. I., Yoo, W. G., & An, D. H. (2013). Effects of the Elastic Walking Band on gait in stroke patients. *NeuroRehabilitation., 32,* 317-322.

Iwata, M., Kondo, I., Sato, Y., Satoh, K., Soma, M., & Tsushima, E. (2003). An ankle-foot orthosis with inhibitor bar: effect on hemiplegic gait. *Arch.Phys.Med.Rehabil., 84,* 924-927.

Knarr, BA., Reisman, DS., Binder-Macleod, SA., Higginson, JS. (2013). Understanding compensatory strategies for muscle weakness during gait by simulating activation deficits seen post-stroke. *Gait & posture.*, 38(2), 270-5.

Kobayashi, T., Leung, AKL., Hutchins, SW. (2011). Techniques to measure rigidity of ankle-foot orthosis: A review. *Journal of rehabilitation research and development*., 48(5),565-76.

Kobayashi, T., Leung, A. K., Akazawa, Y., & Hutchins, S. W. (2013). The effect of varying the plantarflexion resistance of an ankle-foot orthosis on knee joint kinematics in patients with stroke. *Gait.Posture., 37,* 457-459.

Kosak, M. C. & Reding, M. J. (2000). Comparison of partial body weight-supported treadmill gait training versus aggressive bracing assisted walking post stroke. *Neurorehabil.Neural Repair, 14,* 13-19.

Kottink, A. I., Oostendorp, L. J., Buurke, J. H., Nene, A. V., Hermens, H. J., & IJzerman, M. J. (2004). The orthotic effect of functional electrical stimulation on the improvement of walking in stroke patients with a dropped foot: a systematic review. *Artif.Organs, 28,* 577-586.

Kottink, A. I., Hermens, H. J., Nene, A. V., Tenniglo, M. J., Groothuis-Oudshoorn, C. G., & IJzerman, M. J. (2008). Therapeutic effect of an implantable peroneal nerve stimulator in subjects with chronic stroke and footdrop: a randomized controlled trial. *Phys.Ther., 88,* 437-448.

Kottink, A., Tenniglo, MJB., de Vries, WHK., Hermens, HJ., Buurke, JH. (2012). Effects of an implantable two-channel peroneal nerve stimulator versus conventional walking device on spatiotemporal parameters and kinematics of hemiparetic gait. *Journal of Rehabilitation Medicine.*, 44(1), 51-7.

Krishnamoorthy, V., Hsu, W. L., Kesar, T. M., Benoit, D. L., Banala, S. K., Perumal, R. et al. (2008). Gait training after stroke: a pilot study combining a gravity-balanced orthosis, functional electrical stimulation, and visual feedback. *J.Neurol.Phys.Ther., 32,* 192-202.

Lairamore, C., Garrison, M. K., Bandy, W., & Zabel, R. (2011). Comparison of tibialis anterior muscle electromyography, ankle angle, and velocity when individuals post stroke walk with different orthoses. *Prosthet.Orthot.Int., 35,* 402-410.

Langhammer, B. & Stanghelle, J. K. (2010). Exercise on a treadmill or walking outdoors? A randomized controlled trial comparing effectiveness of two walking exercise programmes late after stroke. *Clin.Rehabil., 24,* 46-54.

Magagnin, V., Bo, I., Turiel, M., Fornari, M., Caiani, E. G., & Porta, A. (2010). Effects of robot-driven gait orthosis treadmill training on the autonomic response in rehabilitation-responsive stroke and cervical spondylotic myelopathy patients. *Gait.Posture., 32,* 199-204.

Maguire, C., Sieben, J. M., Frank, M., & Romkes, J. (2010). Hip abductor control in walking following stroke -- the immediate effect of canes, taping and TheraTogs on gait. *Clin.Rehabil., 24,* 37-45.

Maguire, C., Sieben, J. M., Erzer, F., Goepfert, B., Frank, M., Ferber, G. et al. (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 acute stroke. A study protocol for a multi-centre, single blind, randomised control trial. *BMC.Neurol., 12,* 18.

Malezic, M., Bogataj, U., Gros, N., Decman, I., Vrtacnik, P., Kljajic, M. et al. (1992). Application of a programmable dual-channel adaptive electrical-stimulation system for the control and analysis of gait. Journal of rehabilitation research and development., 29(4), 41-53.

Mankala, KK., Banala, SK., Agrawal, SK. (2009). Novel swing-assist un-motorized exoskeletons for gait training. *Journal of Neuroengineering and Rehabilitation*., 6.

Mayr, A., Kofler, M., Quirbach, E., Matzak, H., Frohlich, K., & Saltuari, L. (2007). Prospective, blinded, randomized crossover study of gait rehabilitation in stroke patients using the Lokomat gait orthosis. *Neurorehabil.Neural Repair, 21,* 307-314.

Mehrholz, J., Werner, C., Kugler, J., & Pohl, M. (2007). Electromechanical-assisted training for walking after stroke. *Cochrane.Database.Syst.Rev.,* CD006185.

Mehrholz, J. & Pohl, M. (2012). Electromechanical-assisted gait training after stroke: a systematic review comparing end-effector and exoskeleton devices. *J.Rehabil.Med., 44,* 193-199.

Mehrholz, J., Elsner, B., Werner, C., Kugler, J., & Pohl, M. (2013). Electromechanical-assisted training for walking after stroke. *Cochrane.Database.Syst.Rev., 7,* CD006185.

Mehrholz, J., Pohl, M., Elsner, B. (2014). Treadmill training and body weight support for walking after stroke. *Cochrane Database of Systematic Reviews*., (1).

Moseley, A. M., Stark, A., Cameron, I. D., & Pollock, A. (2003). Treadmill training and body weight support for walking after stroke. *Cochrane.Database.Syst.Rev.,* CD002840.

Moseley, A. M., Stark, A., Cameron, I. D., & Pollock, A. (2005). Treadmill training and body weight support for walking after stroke. *Cochrane.Database.Syst.Rev.,* CD002840.

Mulroy, S. J., Eberly, V. J., Gronely, J. K., Weiss, W., & Newsam, C. J. (2010). Effect of AFO design on walking after stroke: impact of ankle plantar flexion contracture. *Prosthet.Orthot.Int., 34,* 277-292.

Muto, T., Herzberger, B., Hermsdoerfer, J., Miyake, Y., & Poeppel, E. (2012). Interactive cueing with Walk-Mate for hemiparetic stroke rehabilitation. *J.Neuroeng.Rehabil., 9,* 58.

Nolan, K. J., Savalia, K. K., Yarossi, M., & Elovic, E. P. (2010). Evaluation of a dynamic ankle foot orthosis in hemiplegic gait: A case report. *NeuroRehabilitation., 27,* 343-350.

Nolan, K. J. & Yarossi, M. (2011). Weight transfer analysis in adults with hemiplegia using ankle foot orthosis. *Prosthet.Orthot.Int., 35,* 45-53.

Pohl, M. & Mehrholz, J. (2006). Immediate effects of an individually designed functional ankle-foot orthosis on stance and gait in hemiparetic patients. *Clin.Rehabil., 20,* 324-330.

Ring, H., Treger, I., Gruendlinger, L., & Hausdorff, J. M. (2009). Neuroprosthesis for footdrop compared with an ankle-foot orthosis: effects on postural control during walking. *J.Stroke Cerebrovasc.Dis., 18,* 41-47.

Sale, P., Franceschini, M., Waldner, A., & Hesse, S. (2012). Use of the robot assisted gait therapy in rehabilitation of patients with stroke and spinal cord injury. *Eur.J.Phys.Rehabil.Med., 48,* 111-121.

Salisbury, L., Shiels, J., Todd, I., & Dennis, M. (2013). A feasibility study to investigate the clinical application of functional electrical stimulation (FES), for dropped foot, during the sub-acute phase of stroke - A randomized controlled trial. *Physiother.Theory.Pract., 29,* 31-40.

Schmidt, H., Werner, C., Bernhardt, R., Hesse, S., & Kruger, J. (2007). Gait rehabilitation machines based on programmable footplates. *J.Neuroeng.Rehabil., 4,* 2.

Schwartz, I., Sajin, A., Fisher, I., Neeb, M., Shochina, M., Katz-Leurer, M. et al. (2009). The effectiveness of locomotor therapy using robotic-assisted gait training in subacute stroke patients: a randomized controlled trial. *PM.R., 1,* 516-523.

Scivoletto, G., Cosentino, E., Mammone, A., Molinari, M. (2008). Inflammatory myelopathies and traumatic spinal cord lesions: Comparison of functional and neurological outcomes. *Physical therapy.*, 88(4), 471-84.

Sereda, V. G., Drygant, L. P., Ingula, N. I., Kravchuk, N. A., Tkachenko, V. V., Babirad, A. M. et al. (2012). [Vertical integration--an important component of rehabilitation of patients with stroke]. *Lik.Sprava.,* 170-172.

Sheffler, L. R., Bailey, S. N., Wilson, R. D., & Chae, J. (2013). Spatiotemporal, kinematic, and kinetic effects of a peroneal nerve stimulator versus an ankle foot orthosis in hemiparetic gait. *Neurorehabil.Neural Repair, 27,* 403-410.

Shimada, Y., Matsunaga, T., Misawa, A., Ando, S., Itoi, E., Konishi, N. (2006). Clinical application of peroneal nerve stimulator system using percutaneous intramuscular electrodes for correction of foot drop in hemiplegic patients. *Neuromodulation.*, 9(4), 320-7.

Sivan, M. & Bhakta, B. (2008). Restoring mobility: theories, technologies and effective treatments. *Clin.Med., 8,* 596-600.

Stein, RB., Everaert, DG., Thompson, AK., Chong, SL., Whittaker, M., Robertson, J. et al. (2010). Long-Term Therapeutic and Orthotic Effects of a Foot Drop Stimulator on Walking Performance in Progressive and Nonprogressive Neurological Disorders. *Neurorehabilitation and neural repair.*, 24(2), 152-67.

Sungkarat, S., Fisher, B. E., & Kovindha, A. (2011). Efficacy of an insole shoe wedge and augmented pressure sensor for gait training in individuals with stroke: a randomized controlled trial. *Clin.Rehabil., 25,* 360-369.

Sutliff, MH., Naft, JM., Stough, DK., Lee, JC., Arrigain, SS., Bethoux, FA. (2008). Efficacy and safety of a hip flexion assist orthosis in ambulatory multiple sclerosis patients. *Archives of physical medicine and rehabilitation.*, 89(8), 1611-7.

Taylor, P. N., Burridge, J. H., Dunkerley, A. L., Lamb, A., Wood, D. E., Norton, J. A. et al. (1999). Patients' perceptions of the Odstock Dropped Foot Stimulator (ODFS). *Clin.Rehabil., 13,* 439-446.

Teasell, R. W., McRae, M. P., Foley, N., & Bhardwaj, A. (2001). Physical and functional correlations of ankle-foot orthosis use in the rehabilitation of stroke patients. *Arch.Phys.Med.Rehabil., 82,* 1047-1049.

Thijssen, D. H., Paulus, R., van Uden, C. J., Kooloos, J. G., & Hopman, M. T. (2007). Decreased energy cost and improved gait pattern using a new orthosis in persons with long-term stroke. *Arch.Phys.Med.Rehabil., 88,* 181-186.

Tilson, JK., Settle, SM., Sullivan, KJ. (2008). Application of evidence-based practice strategies: Current trends in walking recovery interventions poststroke. *Topics in stroke rehabilitation.*, 15(3), 227-46.

Tyson, S. F. & Kent, R. M. (2009). WITHDRAWN: Orthotic devices after stroke and other non-progressive brain lesions. *Cochrane.Database.Syst.Rev.,* CD003694.

Tyson, S. F. & Kent, R. M. (2009). Orthotic devices after stroke and other non-progressive brain lesions. *Cochrane.Database.Syst.Rev.,* CD003694.

Tyson, S. F. & Kent, R. M. (2013). Effects of an ankle-foot orthosis on balance and walking after stroke: a systematic review and pooled meta-analysis. *Arch.Phys.Med.Rehabil., 94,* 1377-1385.

Van Peppen, R. P., Kwakkel, G., Wood-Dauphinee, S., Hendriks, H. J., Van der Wees, P. J., & Dekker, J. (2004). The impact of physical therapy on functional outcomes after stroke: what's the evidence? *Clin.Rehabil., 18,* 833-862.

van, S. R., Vloothuis, J., den, B. J., Weerdesteyn, V., & Geurts, A. C. (2010). Is transcutaneous peroneal stimulation beneficial to patients with chronic stroke using an ankle-foot orthosis? A within-subjects study of patients' satisfaction, walking speed and physical activity level. *J.Rehabil.Med., 42,* 117-121.

van, S. R., van Duijnhoven, H. J., den, B. J., Geurts, A. C., & Weerdesteyn, V. (2012). Effect of peroneal electrical stimulation versus an ankle-foot orthosis on obstacle avoidance ability in people with stroke-related foot drop. *Phys.Ther., 92,* 398-406.

Verma, R., Arya, K. N., Sharma, P., & Garg, R. K. (2012). Understanding gait control in post-stroke: implications for management. *J.Bodyw.Mov Ther., 16,* 14-21.

Waters, R. L. & Mulroy, S. (1999). The energy expenditure of normal and pathologic gait. *Gait.Posture., 9,* 207-231.

Wong, C. K., Bishop, L., & Stein, J. (2012). A wearable robotic knee orthosis for gait training: a case-series of hemiparetic stroke survivors. *Prosthet.Orthot.Int., 36,* 113-120.

Xu, G. Q., Lan, Y., Huang, D. F., Chen, Z. H., & Ding, M. H. (2011). [Effects of ankle-foot orthosis on gait stability and balance control in patients with hemiparetic stroke]. *Zhonghua Yi.Xue.Za Zhi., 91,* 890-893.

Yamamoto, S., Fuchi, M., & Yasui, T. (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. *Prosthet.Orthot.Int., 35,* 350-359.

Yamanaka, T., Akashi, K., & Ishii, M. (2004). Stroke rehabilitation and long leg brace. *Top.Stroke Rehabil., 11,* 6-8.

Yamanaka, T., Ishii, M., & Suzuki, H. (2004). Short leg brace and stroke rehabilitation. *Top.Stroke Rehabil., 11,* 3-5.

Yavuzer, G. & Ergin, S. (2002). Effect of an arm sling on gait pattern in patients with hemiplegia. *Arch.Phys.Med.Rehabil., 83,* 960-963.

Zancan, A., Beretta, M. V., Schmid, M., & Schieppati, M. (2004). A new hip-knee-ankle-foot sling: kinematic comparison with a traditional ankle-foot orthosis. *J.Rehabil.Res.Dev., 41,* 707-712.

PART 2: RESEARCH PROTOCOL

This research protocol was mainly developed by Dorine Tancsik, who wrote this in the academic year (AY) 2012-13 in frame of her master thesis part 1. The master thesis of Dorine Tancsik focussed particularly on the effects of AFO's on spatio-temporal gait parameters, while our master thesis will focus on the effects on dynamic balance and both walking capacity measured by functional walking tests. Both study parts are conducted as one study based on this research protocol during the AY 2013-14 by all students. During AY 2013-14 the protocol of Dorine Tancsik was updated by us. This protocol was approved in June 2013 by the committee of Medical Ethics of the hospital Ziekenhuis Oost-Limburg and the University of Hasselt.

1. Introduction

Walking or ambulation is the most common activity that we do during the day. It is the individual need to move safely and efficient from one place to another (Neumann D., 2002). Stroke patients often have an altered gait pattern related to a number of factors: "muscle weakness, alterations in tone, abnormal synergy patterns, abnormal reflexes, altered coordination, altered motor programming and disturbances in balance" ((Abe et al., 2009; Esquenazi, Ofluoglu, Hirai, & Kim, 2009) and O'Sullivan S., 2007). These impairments lead to unsafe walking and to an increased fall risk. Dependent on the individual and unique problems of each patient, an ankle-foot orthosis (AFO) can be prescribed, to promote a better and safer walking pattern. Many types of AFO exist, all with their own specific functionalities. There is also the possibility to adapt the AFO's according to the individual needs before and during the rehabilitation process. The AFO can be adapted by optimal shaping to the foot characteristics and by changing the position and rigidity of the ankle joint. During the rehabilitation process in the hospital or rehabilitation centre, physical therapists in the clinical setting use various ways to determine the gait and balance problems in stroke patients. They investigate these problems to optimize the rehabilitation process and to determine the degree of recovery.

Many instruments exist to determine the spatio-temporal gait parameters. Previously, some techniques as paper walkways with ink patches attached underneath the feet of the patients and foot- switches, etc. have been used, but they provide only a small amount of parameters. Motion Analysis Systems (VICON, RIVCAM), electronic walkways (GAITRite®, GAITMat®), force plates, etc. provide a broader range and more precise description of gait parameters (Rao et al., 2008). Based on the literature search of Dorine Tancsik; following results were found: gait velocity, cadence, stride length and step length were often reported as well consistent in results. Other gait parameters were often divergent and inconsistent in results.

Balance is also important for an optimal gait pattern and is hypothesized to be also influenced by an AFO. The balance can be measured with clinical tests. Pollock et al., 2011 listed a number of useful clinical tests to determine the balance in stroke patients (Pollock, Eng, & Garland, 2011). They subdivided the tests in two groups: the multiple- and single task measures. The multiple-task tests give a better representation of the

balance needed in the community level of walking. Not only the clinical tests but also instrumented tests exist to determine the balance. For example: the balance master (Wang, Lin, Lee, & Yang, 2007). The balance master can be used as a test, and as a training method to improve the balance. This technique provides a good representation of the balance but is expensive, not easily transferable, etc.
Following amounts of articles were found with regard to balance, mobility and walking. Only one article (Park et al., 2009) compared different types of AFO's with each other, seven articles investigated the effects of an AFO on balance or mobility (Abe et al., 2009; Cakar et al., 2010; Dogan et al., 2011; Erel et al., 2011; Park et al., 2009; Sheffler et al., 2006; Tyson & Thornton, 2001) and two articles investigated the effects on functional walking ability only (Franceschini et al., 2003; Nolan et al., 2009). Five articles tested the patients on both balance and walking (de Wit et al., 2004; Hung et al., 2011; Simons et al., 2009; Tyson & Rogerson, 2009; Wang et al., 2005). Finally, three articles tested patients on trajectories longer than ten meters (Franceschini et al., 2003; Hung et al., 2011; Nolan et al., 2009).

Based on the literature search, yet no classification has been made based on the severity of patients. However this could be important to determine which patients could benefit the most from a particular AFO. Most of the articles were measured at comfortable walking speed, but little is known about the effect of the AFO at fastest speed. Many types of AFO exist and are developed to help the stroke patients normalize or improve the gait pattern. Many studies have investigated the effect of a custom- molded, plastic AFO on walking and balance, but further research is necessary to compare the effects of an individualized-, versus a standardized AFO and no AFO. We are mainly interested in the spatio- temporal gait parameters, functional balance tests and functional walking tests.

2. Purpose research

2.1. Research questions

1) Does an individualized AFO (Y-tech) change the gait pattern and the gait speed of persons with a stroke, compared to not wearing an AFO? And is this effect different from a standard prefabricated AFO (Maramed)?
2) Has an individualized AFO (Y-tech) a positive effect on the dynamic balance of persons with a stroke, compared with the standard prefabricated AFO (Maramed)?
3) Has an individualized AFO (Y-tech) a positive effect on the functional walking capacity of persons with a stroke, compared with the standard prefabricated AFO (Maramed)?

2.2. Hypotheses

1) The Y-tech and the Maramed have both positive impact on the gait parameters, dynamic balance and functional walking ability compared with not wearing an AFO.
2) The Y-tech leads to better results on the gait parameters compared with the Maramed.
3) The Y-tech leads to better results in the dynamic balance and functional walking capacity compared with the Maramed.

3. Method

3.1. Research design

The testing will be performed in the Rehabilitation Department of ZOL (Ziekenhuis Oost-Limburg) in Lanaken. Fifteen patients will be tested each in three days over a 3-week period. In our experiment, all the individuals will receive the same interventions *(see tables 1 and 2).* There are three testing conditions: condition 1 without an AFO, condition 2 with a standardized AFO (Maramed) and condition 3 with an individualized AFO (Y-tech). All these three conditions are randomized for all tests (GAITRite® measurements, balance testing on day 2 and Six-Minute Walking Test (6MWT) on day 3). Before the start of the tests, patients will have the opportunity to familiarize themselves with the devices by walking once on the GAITRite®. All the patients will receive standard instructions, dependent on the test or item to be taken. During the rest period, the AFO will be removed or changed in another condition, with the assistance of the testing person.

Day one will be a preparatory session (session 1), descriptive outcome measures will be collected and each experimental clinical test will be demonstrated and practiced. All tests will be performed without an orthosis and with standardized shoes, which will be fitted that day. Patients also performed the Timed Up and Go (TUG) three times without an AFO but with the standardised shoes. The TUG is used as an objective criterion for the use of an assistive device. Based on the results of this test, patients will use a standardised cane during testing day 2 and day 3. Patients who will score > 20 seconds on the TUG, will use the cane and patients who will score ≤ 20 seconds will be tested without assistive device. Except for the Step Test (ST) (day 2) and some items of the Brunel Balance Assessment (BBA) (day 2), no assistive device is allowed for both groups and this according to the test instructions of the ST and BBA.

On the second day of testing (session 2), the tests consist of walking on the GAITRite® first (to detect the spatio-temporal changes) and four clinical tests (to examine the balance). In all conditions, the patient will walk twice on the GAITRite® at comfortable walking speed, followed by walking at fastest speed twice. The clinical tests for functional balance are the TUG, ST, Four Square Step Test (FSST) and the BBA. These tests will be applied immediately after the GAITRite® measurements. After the clinical balance tests in each condition the Visual Analogue Scale (VAS) questionnaire will be filled out. Between test conditions, a rest period of ten minutes will take place. The GAITRite® will be positioned in a room, where is enough space to allow a dynamic start over the instrumented section of the carpet. The patient will start two meters before the carpet and continues walking two meters after the carpet. These extra walking spaces are foreseen so that patients will walk at constant walking speed and these spaces will be marked with a white tape. The patients will be positioned with their toes just behind the tape, and instructed to walk across the mat just behind the marked tape.

On testing day 3 (session 3) patients will perform the 6MWT three times, once in each condition. A new randomisation will be carried out before the start of the tests. Before and after each test, patients will walk once over the GAITRite® carpet (to detect spatio-temporal changes) at the same speed as they will complete the 6MWT. After this, patients will fill out the VAS questionnaire. Heart rate will be monitored during the whole test with a finger pulse oximeter. Between each testing condition a standardized resting period of 15 minutes will take place.

Table 1: Study design (day 2, session 2)

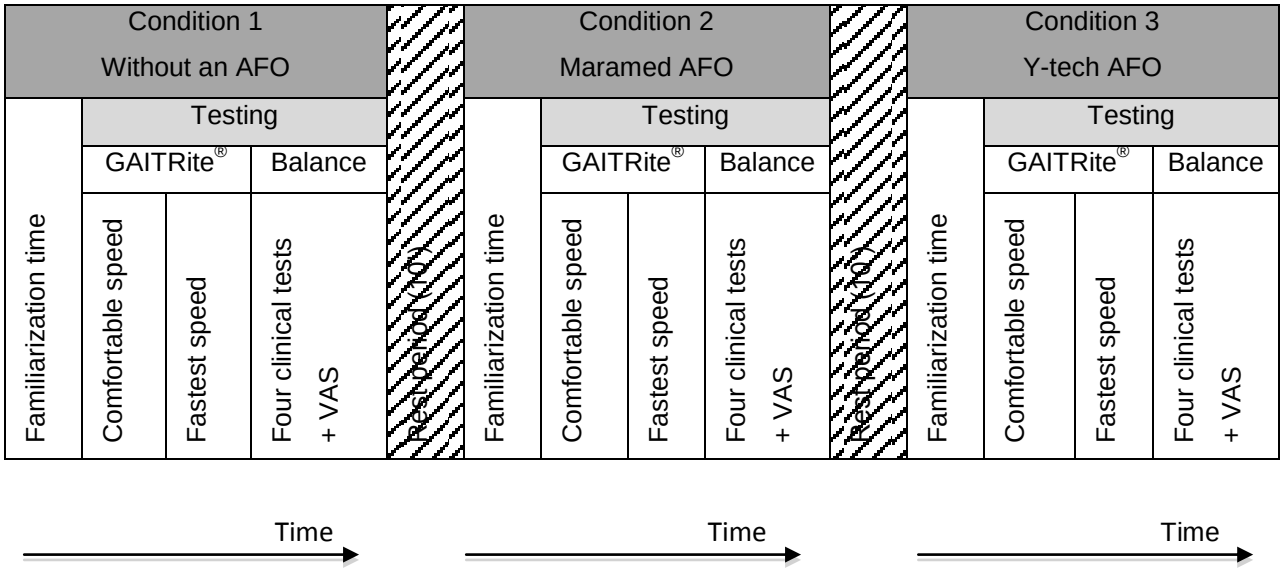
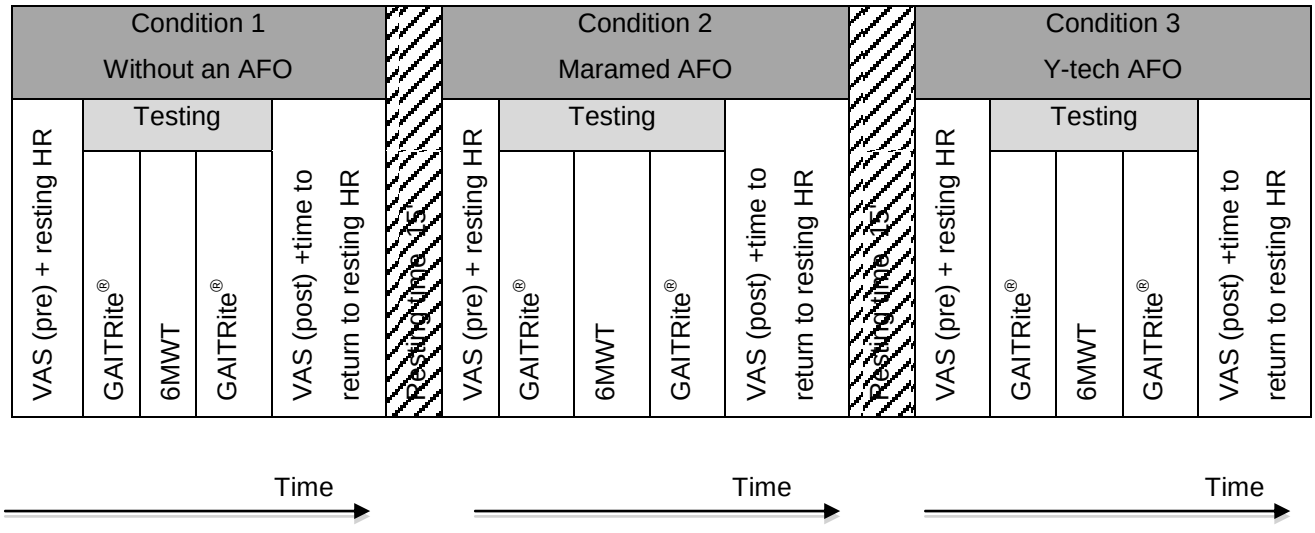


Table 2: Study design (day 3, session 3)



3.2. Participants

We aim to include fifteen subjects in this study.

3.1.1. Inclusion criteria

- Diagnosis of hemi-paresis caused by a Cerebro-Vascular Accident (CVA)
- Chronic stroke patients (>3 months, post-onset)
- Unilateral assistive devices are allowed (eg. cane)
- Patients can understand simple instructions
- Familiar with wearing an AFO (Y-tech) since at least one month

3.1.2. Exclusion criteria

- Bilateral assistive devices needed for walking
- History of orthopaedic problems (related to lower extremities) that would interfere with gait performance

3.1.3. Recruitment

The patients will be recruited from the outpatient services of the Rehabilitation Department of ZOL (Ziekenhuis Oost-Limburg) in Lanaken. The co-promoter (a physical therapist), who works in this hospital, is going to recruit the patients in collaboration with medical responsible Dr. P. Hallet. Only patients who are/ have been in the rehabilitation over the last year, will be included.

3.3. Medical ethics

The documents needed to complete the study are prepared for approval by the Committee Medical Ethics of the hospital (ZOL) and university (Hasselt). All the participants that will be included in the experiment, will have read and approved the Informed Consent.

3.4. Intervention

In this experiment two different types of AFO will be used: a Maramed and a Y-tech. The Maramed *(see figure 1)* is a prefabricated AFO. These orthoses are made of polypropylene plastic and are fabricated in a neutral dorsi-flexed position. This orthosis has a thin and limited width of material behind the ankle, which leads to a limited stability in the ankle. For the experiment, three different sizes will be available. The patients will wear the orthosis that fits the best. The hybrid Y-tech *(see figure 2)* is an individualized AFO from the company V!GO©. Each patient who we will include for the experiment already had his or her own Y-tech. These AFO's are adapted according to the individual needs of the patient. These ankle-foot orthosis consist of a polypropylene sheet (4-5mm) with integrated thermoplastic carbon reinforcement and a strap to fixate the foot/ankle in the AFO. Both AFO's will be fitted in a preparatory session. The patients will also receive standardized shoes, so that all the patients will use the same shoes in each condition.

Figure 1: Maramed

Figure 2: Y-Tech

3.5. Outcome measures

3.5.1. Descriptive outcome measures

Following descriptive outcome measures will be collected from the patients: demographic data and tests (both on function and activity level) to evaluate the severity of stroke. These tests will be applied during session 1 preceding the experimental testing.

Demographic data: gender (male/female), weight (kg), height (cm), birth date, stroke onset (months), location of stroke (right/left hemisphere, brain trunk, cerebellum, other), type of stroke (infarction/haemorrhagic), lateralisation of stroke (right/ left), time of wearing AFO before study, AFO size and shoe size.

Tests to evaluate the severity of the motor and sensory dysfunction: the degree of spasticity (Modified Ashworth Scale and Tardieu Scale), balance (Berg Balance Scale), reflex activity, synergies, coordination and sensory of the lower extremities (Fugl-Meyer Assessment), sensory extinction (Sensory Extinction Test), independence of walking (Functional Ambulation Categories), strength of lower extremities (Motricity Index), and active/ passive range of motion of the ankle in knee flexion and extension. Timed Up and Go (TUG) will be performed three times and is used for dividing patients in two groups: patients who will score >20sec on the TUG, will use an assistive device and patients who will score ≤ 20sec, will walk without an assistive device. An overview of the descriptive outcome measures is given in *table 3 (see p.58)*. Balance and walking tests will be performed wearing standardized shoes (and no AFO).

The Modified Ashworth Scale (MAS) is a 5-point ordinal scale (0-4 points). A score of 0 indicates: no increased muscle tone. A score of 4 indicates: the affected body part is rigid in flexion or extension. Neumann D., 2002 reported a good intra-rater reliability [ICC 0.84] and a good inter-rater reliability [ICC 0.83] . Li F et al., 2014 showed a quit good inter- and intra-rater reliability [ICC 0.66 and 0.69] for the elbow flexors and a fair inter- and intra-rater reliability [ICC 0.48 and 0.48] for the plantar flexors in stroke patients (Li, Wu, & Li, 2014).

The Tardieu Scale (TS) is a 6-point ordinal scale (0-5 points). A score of 0 indicates: no resistance throughout the course of the passive movement. A score of 5 indicates: the joint is immovable. The measurements take place at three velocities; V1: as slow as possible (slower than the natural drop of the limb segment under gravity), V2: speed of the limb segment falling under gravity and V3: as fast as possible (faster than the rate of the natural drop of the limb segment under gravity). All the tests are taken in supine position. Li F et al., 2014 showed a quit good inter- and intra-rater reliability for the elbow flexors [ICC 0.73 and 0.73] and a quit good inter- and intra-rater reliability [ICC 0.82 and 0.79] for the ankle flexors in stroke patients.

The Berg Balance Scale (BBS) is a 14-items test. Each item is scored using a 5-point ordinal scale (0-4 points). A score of 4 indicates: independent function. A score of 0 indicates: unable to complete the task. In total there are 56 items to achieve. A score of < 45 represents a risk of falling (KNGF Guidelines of Stroke). Blum et al., 2008, a systematic review reported an inter-rater reliability of [0.95-0.98], an intra-rater reliability of [0.97], a test-retest reliability of [0.98] and floor/ceiling effects (Blum & Korner-Bitensky, 2008). Pollock et al., 2011 reported a limited content validity (single-leg stance task and turning) (Pollock, Eng, & Garland, 2011).

The Fugl-Meyer Assessment of lower extremities (FMA-LE) is a 3-point ordinal scale (0-2 points). The tests of the lower extremity include: reflex activity of the m. triceps surae/quadriceps femoris, random movement in the flexion/extension synergy, possibility to combine the flexion/extension synergy, full dissociation of synergies is possible, normal reflex activity, coordination and sensation. Sanford et al., 1993 reported a reliability of [ICC 0.96] in acute stroke patients (Sanford, Moreland, Swanson, Stratford, & Gowland, 1993).

The Sensory Extinction test is a 2-point nominal scale. This test was used to identify neglect for light tough on the patient's thighs.

The Functional Ambulation Categories (FAC) is a 6-point ordinal scale (0-5 points). A score of 0 indicates: the patient cannot walk, or needs assistance of two or more persons. A score of 5 indicates: the per- son can walk independent on a flat surface, uneven surfaces, inclinations and stairs. Viosca et al., 2005 reported a good inter-rater reliability [K = 0.74] (Viosca, Martinez, Almagro, Gracia, & Gonzalez, 2005).

The Motricity Index (MI) is a 6-point ordinal scale (0, 11, 19, 22, 26 and 33 points). When there is a total score of the leg part (99 points), one point can be added (total points 100). This test mainly evaluates the maximal isometric strength or minimal active amplitude of both the upper and lower limbs. Fayazi et al., 2012 reported a high test-retest reliability [ICC 0.93] with one-week interval. Only the lower limb part will be used in this study (Fayazi, Dehkordi, Dadgoo, & Salehi, 2012).

During the TUG, the patients will have to rise from an armchair, walk three meters, turn, walk back to the starting point (chair) and sit. The time to complete the trial will be measured with a stopwatch (ratio scale). Ng et al., 2005 reported a good to excellent reliability [ICC range 0.69- 0.99], test-retest [ICC 0.95] for chronic stroke patients (Ng & Hui-Chan, 2005). The concurrent validity with the Berg Balance Scale [ICC 0.81] and Barthel

Index [ICC 0.78] has been reported in O'Sullivan S. 2007. Pollock et al., 2011 reported a content validity (speed of walking and tuning). This test predicts the fall risk in elderly subjects. A score of <20 seconds represents that patients are independent for most transfers, a score of >30 stated that patients are dependent in most activities in daily life, this according to Stroke Engine (http://www.strokengine.ca). Concurrent validity is reported for the Berg Balance Scale (ICC: 0.81) and the Barthel Index (ICC: 0.78). The articles also reported an inter-rater reliability of (ICC: 0.99) and an intra-rater reliability of (ICC: 0.98). In our protocol, the test will be performed three times and an average will be calculated. This average score will be used for dividing patients in 2 groups: With (>20sec) and without (≥ 20sec) assistive device according to a selected cut-off score of 20 seconds.

3.5.2. Experimental outcome measures

3.5.2.1. Primary outcome measures

During the Step Test (ST), the patient will be instructed to maintain the balance on one leg, while he/ she has to place the opposite foot on and off a 10cm high and 5 cm in front positioned box. The patient has to complete two trials: once maintaining balance on the affected side and once on the non-affected side. The numbers of steps completed in 15 seconds are recorded (ratio scale) (Pollock et al., 2011). Pollock et al., 2011 reported an excellent test-retest reliability [ICC 0.93] for the affected leg, and [ICC 0.94] for the non-affected leg in older patients. They also reported a limited content validity (single leg stance task) and no ceiling effect for the stroke population, during inpatient rehabilitation, mean age 72.2 years.

In the Four Square Step Test (FSST), the patient starts in square one, facing square two. The patient has to step forward (to square two), sideward to the right (to square three), backward (to square four), sideward to the left (to square one) and again in the other direction as fast and safely as possible. During the paces, they also have to step over a low obstacle (two canes). These canes are placed in a cross, so that the patients have to step over the obstacles in all the directions *(see figure 3).* The patients are instructed as following: “try to complete the sequence as fast and as safely as possible without touching the sticks. Both feet must take contact with the floor in each square. If possible, face forward during the entire sequence” (Blennerhassett & Jayalath, 2008). The time to complete the trial is measured with a stopwatch (ratio scale). The time from the initial contact of the first step to the initial contact of the final step, is measured (Blennerhassett & Jayalath, 2008; Dite & Temple, 2002). Blennerhassett et al., 2008 reported an excellent agreement between two repeated test trials for both tests (Four Square Step Test and Step Test) [ICC 0.94- 0.99] and no practice effect between two repeated successful trial scores (p-value 0.16-0.84) in chronic stroke patients. Pollock et al., 2011 reported a ceiling effect (in younger adults, age 52 years) and some content validity (turning and obstacle avoidance). Goh E.Y. et al., 2013 showed a good intra [ICC 0.82-0.83] and inter-rater reliability [ICC >0.99] in persons with chronic stroke. A cut off score of 11 seconds was found to make a distinction in dynamic balance of healthy persons and chronic post stroke patients (Goh, Chua, Hong, & Ng, 2013).

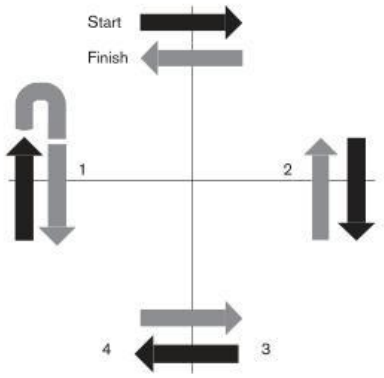


Figure 3: Sequence of steps (FSST)

The TUG has been explained in section: *3.5.1. Descriptive outcome measures.* The only difference in performing the test as a descriptive outcome measure and an experimental outcome measure is that in this last the test will be performed only twice.

In the Brunel Balance Assessment (BBA), the patient has to complete some items, which are hierarchically ordered, ranging from easy to difficult. The items range from: sit to stand, stepping to walking and lowering/ raising the base of support (BOS) by stepping on objects. “The scoring utilizes a pass/ fail structure based on performance or time standards which dictates minimal detectable change on the scale (ordinal scale)”. When a patient fails one item, the patient will automatically fail all the other items. Then the test can be stopped. An example: level one (supported sitting- timed test), the patient passes this test when he/ she can balance for 30 seconds or more and fails when he/ she cannot balance for 30 seconds. The score is noted, so that we can see the difference between the previous and the next test. Tyson et al., 2004 reported a high inter-test and test-retest reliability with 100% agreement [Kappa coefficient =1] in stroke patients. They also reported a good concurrent validity with the sitting Motor Assessment Scale [0.83], Berg Balance Scale [0.97], and the Rivermead Mobility Index [0.95] (Tyson & DeSouza, 2004).

During the Six-minute walk test (6MWT), patients' physical endurance is tested. Patients are instructed to walk as far as possible during the six minutes. Patients are scored based on the distance covered in these six minutes on a hard, flat surface along a 25 meters marked walkway. To mark every 5 meters of the walkway, tape on the floor is used. During the test, covered distance and hart rate will be recorded every minute. The patient is allowed to rest if needed but has to stay upright. The use of an assistive device is obligated when patients had a score of >20 seconds on the descriptive TUG. Eng et al., 2004 and Flansbjer et al., 2005 reported an excellent test-retest reliability of the 6MWT for distance covered in meters [ICC 0.99] (Eng, Dawson, & Chu, 2004; Flansbjer, Holmback, Downham, Patten, & Lexell, 2005). According to Kosak & Smith, 2005, the intra-rater reliability was adequate [ICC 0.74] and the inter-rater reliability was found to be good [ICC 0.78] (Kosak & Smith, 2005).

3.5.2.2. Secondary outcome measures

The GAITRite® system is used to detect changes in the spatio-temporal gait parameters. This system is a computer based instrumented walkway. It consists of a carpet and a computer. The flexible roll-up carpet, available in various lengths, is embedded with sensors. The GAITRite® that we use is 5.37 meters long. The sensors are activated by mechanical pressure, when a subject walks across the carpet. The GAITRite® has also the ability to connect two cameras. This provides additional information about the gait pattern. We will only use one camera because of practical reasons. We will position the camera in a position between the frontal and sagittal plane of the patient walking across the carpet. The data arrived from the pressure sensors and video camera, will be collected and stored by a connected computer. The computer software displays automatically the spatio-temporal parameters and video material. The GAITRite® provides following bilateral parameters: step length (cm), single support time (%GC) and double support time (%GC). The other parameters include: distance (cm), velocity (cm/sec) and cadence (steps/min). Bilney et al., 2003 showed a good test-retest reliability, when patients were tested in three consecutive measurements on one day (Bilney, Morris, & Webster, 2003). Van Uden et al., 2004 reported a high test-retest reliability of spatio-temporal parameters, over a one week period in healthy subjects (van Uden & Besser, 2004). They also reported an [ICC: 0.92] at preferred walking speed, and an [ICC: 0.89] at fast walking speed. MCDonough et al., 2001 reported also a good reliability and validity for measuring spatio-temporal parameters. There was a concurrent validity with a paper pencil method [ICC: 0.95] and with a video-based analysis [ICC: 0.93] (McDonough, Batavia, Chen, Kwon, & Ziai, 2001).

A Visual Analogue Scale (VAS) will be used to evaluate the experienced comfort in walking. This instrument consists of a straight line with on the extreme ends opposite claims. The patients will mark on the line the point that they feel that represents their perception of their current state. The VAS score is determined by measuring in millimetres from the left hand end of the line to the point that the patient marks. For session 2, the questions are: ‘How comfortable is your walking now?’ and ‘How confident are you in your walking now?’. For session 3, the question is: ‘How fatigued are you feeling now?’.

Before the 6MWT resting heart rate will be measured. Every minute of the test, the heart rate will be monitored to check for alternations of the heart rhythm in response of the effort. Afterwards the time to return to the resting heart rate will be determined. During the measurements, patients will continuously wear a finger pulse oximeter. Iyriboz Y. et al., 1991 reported a good correlation ($r=0.91$, $p<0.0001$) between pulse oximeter and ECG measurements in healthy subjects at rest and during exercise (Iyriboz, Powers, Morrow, Ayers, & Landry, 1991). An overview of the experimental outcome measures is given in *table 3*.

Table 3: Overview of the descriptive and experimental outcome measures.

Descriptive outcome measures	
Demographic data	Gender (male/ female), weight (kg), height (cm), birth date, stroke onset (months), location of stroke (right/ left hemisphere, brain trunk, cerebellum, other), type of stroke (infarction/ haemorrhagic), lateralisation of stroke (right/ left), time of wearing AFO before study, AFO size and shoe size.
Evaluation of the severity of motor dysfunction	Modified Ashworth Scale (MAS) Tardieu Scale (TS) Berg Balance scale (BBS) Fugl-Meyer Assessment lower extremity (FMA-LE): motor control and sensation Sensory Extinction test (SE) Functional Ambulation Categories (FAC) Motricity Index (MI) Active/ Passive ROM of the ankle (with knee flexed and extended) Timed Up and Go (TUG)
Experimental outcome measures	
Primary outcome measures	
Dynamic balance	Step Test (ST) Four Square Step Test (FSST) Timed Up and Go test (TUG) Brunel Balance Assessment (BBA)
Functional walking	6MWT
Secondary outcome measures	
Spatio-temporal parameters	GAITRite®
Subjective findings	VAS
Heart rate	Finger pulse oximeter

3.6. Data analysis

Statistical analyses will be carried out with STATISTICA 7.

The results of the parameters in the three conditions will be compared for the total group of subjects as well for two groups (with assistive device and without assistive device). Despite our relative small sample size, we will use parametric tests to allow for two-way ANOVA. Repeated measures ANOVA will be used for the total group analysis and a two group by three conditions ANOVA to investigate the interaction effects between the groups. The reason for parametric testing is because we would like to know how the subgroups will behave relative to each other. The analysis is performed for each experimental outcome measure. Non-parametric tests will be used as a control because of the relative small sample size.

4. Time planning

Planning	
Task	Date
Request Ethical committee	May - June, 2013
Preparation of instruction forms	July - August, 2013
Experimental tests	September 2013 - January 2014
Data processing & interpretation	February - March, 2014
Article writing	March - May, 2014

5. References

Abe, H., Michimata, A., Sugawara, K., Sugaya, N., & Izumi, S. (2009). Improving gait stability in stroke hemiplegic patients with a plastic ankle-foot orthosis. *Tohoku J Exp Med, 218*(3), 193-199.

Balke, B. (1963). A Simple Field Test for the Assessment of Physical Fitness. Rep 63-6. *Rep Civ Aeromed Res Inst US*, 1-8.

Bilney, B., Morris, M., & Webster, K. (2003). Concurrent related validity of the GAITRite walkway system for quantification of the spatial and temporal parameters of gait. *Gait Posture, 17*(1), 68-74.

Blennerhassett, J. M., & Jayalath, V. M. (2008). The Four Square Step Test is a feasible and valid clinical test of dynamic standing balance for use in ambulant people poststroke. *Arch Phys Med Rehabil, 89*(11), 2156-2161. doi: 10.1016/j.apmr.2008.05.012

Blum, L., & Korner-Bitensky, N. (2008). Usefulness of the Berg Balance Scale in stroke rehabilitation: a systematic review. *Phys Ther, 88*(5), 559-566. doi: 10.2522/ptj.20070205

Cakar, E., Durmus, O., Tekin, L., Dincer, U., & Kiralp, M. Z. (2010). The ankle-foot orthosis improves balance and reduces fall risk of chronic spastic hemiparetic patients. *Eur J Phys Rehabil Med, 46*(3), 363-368.

Cho, K., & Lee, G. (2013). Impaired dynamic balance is associated with falling in post-stroke patients. *Tohoku J Exp Med, 230*(4), 233-239.

Churchill, A. J., Halligan, P. W., & Wade, D. T. (2003). Relative contribution of footwear to the efficacy of ankle-foot orthoses. *Clin Rehabil, 17*(5), 553-557.

Collen, F. M., Wade, D. T., & Bradshaw, C. M. (1990). Mobility after stroke: reliability of measures of impairment and disability. *Int Disabil Stud, 12*(1), 6-9.

Danielsson, A., & Sunnerhagen, K. S. (2004). Energy expenditure in stroke subjects walking with a carbon composite ankle foot orthosis. *J Rehabil Med, 36*(4), 165-168. doi: 10.1080/16501970410025126

de Wit, D. C., Buurke, J. H., Nijlant, J. M., Ijzerman, M. J., & Hermens, H. J. (2004). The effect of an ankle-foot orthosis on walking ability in chronic stroke patients: a randomized controlled trial. *Clin Rehabil, 18*(5), 550-557.

Dite, W., & Temple, V. A. (2002). A clinical test of stepping and change of direction to identify multiple falling older adults. *Arch Phys Med Rehabil, 83*(11), 1566-1571.

Dogan, A., Mengulluoglu, M., & Ozgirgin, N. (2011). Evaluation of the effect of ankle-foot orthosis use on balance and mobility in hemiparetic stroke patients. *Disabil Rehabil, 33*(15-16), 1433-1439. doi: 10.3109/09638288.2010.533243

Eng, J. J., Dawson, A. S., & Chu, K. S. (2004). Submaximal exercise in persons with stroke: test-retest reliability and concurrent validity with maximal oxygen consumption. *Arch Phys Med Rehabil, 85*(1), 113-118.

Erel, S., Uygur, F., Engin Simsek, I., & Yakut, Y. (2011). The effects of dynamic ankle-foot orthoses in chronic stroke patients at three-month follow-up: a randomized controlled trial. *Clin Rehabil, 25*(6), 515-523. doi: 10.1177/0269215510390719

Esquenazi, A., Ofluoglu, D., Hirai, B., & Kim, S. (2009). The effect of an ankle-foot orthosis on temporal spatial parameters and asymmetry of gait in hemiparetic patients. *PM R, 1*(11), 1014-1018. doi: 10.1016/j.pmrj.2009.09.012

Fayazi, M., Dehkordi, S. N., Dadgoo, M., & Salehi, M. (2012). Test-retest reliability of Motricity Index strength assessments for lower extremity in post stroke hemiparesis. *Med J Islam Repub Iran, 26*(1), 27-30.

Feigin, V. L., Lawes, C. M., Bennett, D. A., & Anderson, C. S. (2003). Stroke epidemiology: a review of population-based studies of incidence, prevalence, and case-fatality in the late 20th century. *Lancet Neurol, 2*(1), 43-53.

Flansbjer, U. B., Holmback, A. M., Downham, D., Patten, C., & Lexell, J. (2005). Reliability of gait performance tests in men and women with hemiparesis after stroke. *J Rehabil Med, 37*(2), 75-82. doi: 10.1080/16501970410017215

Franceschini, M., Massucci, M., Ferrari, L., Agosti, M., & Paroli, C. (2003). Effects of an ankle-foot orthosis on spatiotemporal parameters and energy cost of hemiparetic gait. *Clin Rehabil, 17*(4), 368-372.

Geurts, A. C., de Haart, M., van Nes, I. J., & Duysens, J. (2005). A review of standing balance recovery from stroke. *Gait Posture, 22*(3), 267-281. doi: 10.1016/j.gaitpost.2004.10.002

Goh, E. Y., Chua, S. Y., Hong, S. J., & Ng, S. S. (2013). Reliability and concurrent validity of Four Square Step Test scores in subjects with chronic stroke: a pilot study. *Arch Phys Med Rehabil, 94*(7), 1306-1311. doi: 10.1016/j.apmr.2013.01.027

Gok, H., Kucukdeveci, A., Altinkaynak, H., Yavuzer, G., & Ergin, S. (2003). Effects of ankle-foot orthoses on hemiparetic gait. *Clin Rehabil, 17*(2), 137-139.

Hesse, S., Luecke, D., Jahnke, M. T., & Mauritz, K. H. (1996). Gait function in spastic hemiparetic patients walking barefoot, with firm shoes, and with ankle-foot orthosis. *Int J Rehabil Res, 19*(2), 133-141.
Hesse, S., Werner, C., Matthias, K., Stephen, K., & Berteanu, M. (1999). Non-velocity-related effects of a rigid double-stopped ankle-foot orthosis on gait and lower limb muscle activity of hemiparetic subjects with an equinovarus deformity. *Stroke, 30*(9), 1855-1861.
Hung, J. W., Chen, P. C., Yu, M. Y., & Hsieh, Y. W. (2011). Long-term effect of an anterior ankle-foot orthosis on functional walking ability of chronic stroke patients. *Am J Phys Med Rehabil, 90*(1), 8-16. doi: 10.1097/PHM.0b013e3181fc7d27
Iyriboz, Y., Powers, S., Morrow, J., Ayers, D., & Landry, G. (1991). Accuracy of pulse oximeters in estimating heart rate at rest and during exercise. *Br J Sports Med, 25*(3), 162-164.
Kosak, M., & Smith, T. (2005). Comparison of the 2-, 6-, and 12-minute walk tests in patients with stroke. *J Rehabil Res Dev, 42*(1), 103-107.
Lehmann, J. F. (1979). Biomechanics of ankle-foot orthoses: prescription and design. *Arch Phys Med Rehabil, 60*(5), 200-207.
Lehmann, J. F., Condon, S. M., Price, R., & deLateur, B. J. (1987). Gait abnormalities in hemiplegia: their correction by ankle-foot orthoses. *Arch Phys Med Rehabil, 68*(11), 763-771.
Li, F., Wu, Y., & Li, X. (2014). Test-retest reliability and inter-rater reliability of the Modified Tardieu Scale and the Modified Ashworth Scale in hemiplegic patients with stroke. *Eur J Phys Rehabil Med, 50*(1), 9-15.
Mao, H. F., Hsueh, I. P., Tang, P. F., Sheu, C. F., & Hsieh, C. L. (2002). Analysis and comparison of the psychometric properties of three balance measures for stroke patients. *Stroke, 33*(4), 1022-1027.
McDonough, A. L., Batavia, M., Chen, F. C., Kwon, S., & Ziai, J. (2001). The validity and reliability of the GAITRite system's measurements: A preliminary evaluation. *Arch Phys Med Rehabil, 82*(3), 419-425. doi: 10.1053/apmr.2001.19778
Mojica, J. A., Nakamura, R., Kobayashi, T., Handa, T., Morohashi, I., & Watanabe, S. (1988). Effect of ankle-foot orthosis (AFO) on body sway and walking capacity of hemiparetic stroke patients. *Tohoku J Exp Med, 156*(4), 395-401.
Ng, S. S., & Hui-Chan, C. W. (2005). The timed up & go test: its reliability and association with lower-limb impairments and locomotor capacities in people with chronic stroke. *Arch Phys Med Rehabil, 86*(8), 1641-1647. doi: 10.1016/j.apmr.2005.01.011
Nolan, K. J., Savalia, K. K., Lequerica, A. H., & Elovic, E. P. (2009). Objective assessment of functional ambulation in adults with hemiplegia using ankle foot orthotics after stroke. *PM R, 1*(6), 524-529. doi: 10.1016/j.pmrj.2009.04.011
Park, J. H., Chun, M. H., Ahn, J. S., Yu, J. Y., & Kang, S. H. (2009). Comparison of gait analysis between anterior and posterior ankle foot orthosis in hemiplegic patients. *Am J Phys Med Rehabil, 88*(8), 630-634. doi: 10.1097/PHM.0b013e3181a9f30d
Pollock, C., Eng, J., & Garland, S. (2011). Clinical measurement of walking balance in people post stroke: a systematic review. *Clin Rehabil, 25*(8), 693-708. doi: 10.1177/0269215510397394
Rao, N., Chaudhuri, G., Hasso, D., D'Souza, K., Wening, J., Carlson, C., & Aruin, A. S. (2008). Gait assessment during the initial fitting of an ankle foot orthosis in individuals with stroke. *Disabil Rehabil Assist Technol, 3*(4), 201-207. doi: 10.1080/17483100801973023
Sanford, J., Moreland, J., Swanson, L. R., Stratford, P. W., & Gowland, C. (1993). Reliability of the Fugl-Meyer assessment for testing motor performance in patients following stroke. *Phys Ther, 73*(7), 447-454.
Sheffler, L. R., Hennessey, M. T., Naples, G. G., & Chae, J. (2006). Peroneal nerve stimulation versus an ankle foot orthosis for correction of footdrop in stroke: impact on functional ambulation. *Neurorehabil Neural Repair, 20*(3), 355-360. doi: 10.1177/1545968306287925
Simons, C. D., van Asseldonk, E. H., van der Kooij, H., Geurts, A. C., & Buurke, J. H. (2009). Ankle-foot orthoses in stroke: effects on functional balance, weight-bearing asymmetry and the contribution of each lower limb to balance control. *Clin Biomech (Bristol, Avon), 24*(9), 769-775. doi: 10.1016/j.clinbiomech.2009.07.006
Tyson, S. F., & DeSouza, L. H. (2004). Development of the Brunel Balance Assessment: a new measure of balance disability post stroke. *Clin Rehabil, 18*(7), 801-810.
Tyson, S. F., & Rogerson, L. (2009). Assistive walking devices in nonambulant patients undergoing rehabilitation after stroke: the effects on functional mobility, walking impairments, and patients' opinion. *Arch Phys Med Rehabil, 90*(3), 475-479. doi: 10.1016/j.apmr.2008.09.563
Tyson, S. F., & Thornton, H. A. (2001). The effect of a hinged ankle foot orthosis on hemiplegic gait: objective measures and users' opinions. *Clin Rehabil, 15*(1), 53-58.

van Uden, C. J., & Besser, M. P. (2004). Test-retest reliability of temporal and spatial gait characteristics measured with an instrumented walkway system (GAITRite). *BMC Musculoskelet Disord, 5*, 13. doi: 10.1186/1471-2474-5-13

Viosca, E., Martinez, J. L., Almagro, P. L., Gracia, A., & Gonzalez, C. (2005). Proposal and validation of a new functional ambulation classification scale for clinical use. *Arch Phys Med Rehabil, 86*(6), 1234-1238. doi: 10.1016/j.apmr.2004.11.016

Wang, R. Y., Lin, P. Y., Lee, C. C., & Yang, Y. R. (2007). Gait and balance performance improvements attributable to ankle-foot orthosis in subjects with hemiparesis. *Am J Phys Med Rehabil, 86*(7), 556-562. doi: 10.1097/PHM.0b013e31806dd0d3

Wang, R. Y., Yen, L., Lee, C. C., Lin, P. Y., Wang, M. F., & Yang, Y. R. (2005). Effects of an ankle-foot orthosis on balance performance in patients with hemiparesis of different durations. *Clin Rehabil, 19*(1), 37-44.

6. Appendices

6.1 Appendix 1: Progress form

universiteit hasselt | FACULTEIT GENEESKUNDE EN LEVENSWETENSCHAPPEN
www.uhasselt.be/glw
postadres: Universiteit Hasselt | Martelarenlaan 42 | BE-3500 Hasselt
bezoekadres: Universiteit Hasselt | Agoralaan, gebouw D | BE-3590 Diepenbeek
T +32(0)11 26 85 36 | F +32(0)11 26 85 99 | E-mail: glw@uhasselt.be

VOORTGANGSFORMULIER MASTERPROEF DEEL 1

DATUM	OVERLEG	HANDTEKENINGEN
10/10/2013	Bespreking testinstructies	Promotor: Student: Student:
30/10/2013	Bespreking Literature search (zoekstrategie)	Promotor: Student: Student:
29/11/2013	Bespreking Literature search (zoekstrategie + voorlopige resultaten)	Promotor: Student: Student:
04/02/2014	Nabespreking v/h onderzoek uitgevoerd in Lanaken	Promotor: Student: Student:
13/02/2014	Bespreking resultaten v/d literature search.	Promotor: Student: Student:
25/02/2014	Bespreking resultaten v/h onderzoek en statistische analyse	Promotor: Student: Student:
27/02/2014	Bespreking resultaten v/h onderzoek en statistische analyse + resultaten literature search	Promotor: Student: Student:
14/03/2014	Bespreking: 1e versie inleiding, methode-sectie en resultatensectie.	Promotor: Student: Student:
01/04/2014	Bespreking: resultaten en discussie.	Promotor: Student: Student:
24/04/2014	Bespreking: 1e versie volledige MP 1	Promotor: Student: Student:
		Promotor: Student: Student:
		Promotor: Student: Student:
		Promotor: Student: Student:

6.2 Appendix 2: Quality assessment of the included RCT's

1. Erel S. et al 2010: *The effects of dynamic ankle-foot orthoses in chronic stroke patients at three-month follow-up: a randomized controlled trial.*

1 Randomisation	32 Subjects underwent block randomization and were divided in a control and an intervention group.
2 Concealment of allocation	The participants were assigned to interventions by concealed block randomization carried out by a colleague unaware of the nature of the study.
3 Blinding of pts	It was not possible to blind the patients or therapist to the treatment because of the nature of the intervention.
4 Blinding of practitioner	It was not possible to blind the patients or therapist to the treatment because of the nature of the intervention.
5 Blinding of out-come assessor	The outcome assessor knew which group the patient was in.
6 Homogeneity of groups	At the initial assessment no difference was found between the groups for any of the measured parameters (P>0.05). This result showed that the groups were homogeneous.
7 Loss-to-follow-up	One subject from the study group was lost to follow-up, because he moved house and one subject in the control group died.
8 Intention-to-treat	One subject in the control group and one in the study group withdrew from the study for no given reason soon after randomization. No patients changed from groups.
9 Comparability intervention	Both groups received the same treatment, except for the randomisation.
10 Selection bias	Absent. Both groups were homogenous and ad random allocated and there was concealment of allocation.
11 Performance bias	Present. There is no blinding of pts and practitioners. It's not possible because of the nature of the study; wearing an AFO is always visible.
12 Exclusion bias	Absent. There were 2 pts who dropped out without any valid reason (1 in each group), but the article reported these losses.
13 Detection bias	Present. There was no blinding of the outcome assessor.
14 Conclusion	Because of the nature of the study, blinding of patients, practitioners and outcome assessor was not possible, because you can't mask if a patient wears an AFO. Only a small number of patients were included (32), but only 28 patients finished the study. Every aspect in the study was reported well.

2. De Wit DCM et al 2003: *The effect of an ankle-foot orthosis on walking ability in chronic stroke patients: a randomized controlled trial.*

1 Randomisation	The order of testing was randomized. It was not mentioned how the randomisation took place. It's possible that it was quasi randomisation. 20 patients were registered and randomized in 2 groups; group 1 walked with AFO first and group 2 walked without AFO first
2 Concealment of allocation	Not mentioned in the article.
3 Blinding of pts	Not mentioned in the article. It is not possible to blind the assessors nor the patients while testing with/without AFO. It is not possible to mask if someone is wearing an AFO or not.
4 Blinding of practitioner	Not mentioned in the article. It is not possible to blind the assessors nor the patients while testing with/without AFO. It is not possible to mask if someone is wearing an AFO or not.
5 Blinding of out-come assessor	Not mentioned in the article.
6 Homogeneity of groups	The 2 groups were comparable for baseline characteristics (age, time since stroke, time wearing AFO, kind of stroke, affected hemisphere, median UCO, median MMSE, median MI, median FAC).
7 Loss-to-follow-up	20 Patients were included in the study, from all of them , they received outcome data. There was no loss-to-follow-up.
8 Intention-to-treat	Not mentioned in the article.
9 Comparability intervention	Both groups received the same treatment, except for the randomisation.
10 Selection bias	Possible. There was not enough mentioned about concealment of allocation.
11 Performance bias	Present. There is no blinding of pts and practitioners. Not possible because of the nature of the study (comparing AFO/ no AFO).
12 Exclusion bias	Absent. There were no drop outs.
13 Detection bias	Possible. There was not enough information in the article.
14 Conclusion	The quality of this article is inadequate, but meanly because they did not reported about randomisation, blinding and intention-to-treat. The sample size was also too small. Positive about this article: the groups were homogenous and the intervention was comparable.

6.3 Appendix 3: Quality assessment of the included quasi-experimental articles

1. Abe et al., 2009: *Improving gait stability in stroke hemiplegic patients with a plastic ankle-foot orthosis.*

1 Randomisation	The order of testing was randomized (with PAFO/ without PAFO).
2 Homogeneity of pts	There was a big range in time since stroke, but other characteristics showed homogeneity.
3 Homogeneity between groups	N/A
4 Use of different AFO types	In the study pts wore different types of PAFO in the AFO condition.
5 Selection bias	Present. There is only 1 group of pts in the study.
6 Performance bias	Present. There is no blinding of pts and practitioners possible.
7 Exclusion bias	Absent. There were no drop outs.
8 Detection bias	Possible. There is not enough information in the article.

2. Cakar et al., 2010: *The ankle-foot orthosis improves balance and reduces fall risk in chronic spastic hemi paretic patients.*

1 Randomisation	There was no randomisation for conditions. Pts were first tested without AFO.
2 Homogeneity of pts	All characteristics showed homogeneity.
3 Homogeneity between groups	N/A
4 Use of different AFO types	Pts wore the same AFO's in the study.
5 Selection bias	Present. There is only 1 group of pts in the study.
6 Performance bias	Present. There is no blinding of pts and practitioners possible
7 Exclusion bias	Absent. There were no drop outs.
8 Detection bias	Possible .There is not enough information in the article.

3. Dogan et al., 2011: *Evaluation of the ankle-foot orthosis use on balance and mobility in hemi paretic stroke patients.*

1 Randomisation	First patients were tested with their sports shoes or orthopaedic shoes used during their rehabilitation and then with AFO specially designed for each patient.
2 Homogeneity of pts	There was a big range in time since stroke, but other characteristics showed quite some homogeneity.
3 Homogeneity between groups	N/A
4 Use of different AFO types	Pts wore the same AFO's in the study.
5 Selection bias	Present. There is only 1 group of pts in the study.

6 Performance bias	Present. There is no blinding of pts and practitioners possible
7 Exclusion bias	Absent, because there were no drop outs.
8 Detection bias	Possible, there not enough information in the article.

4. Franceschini et al., 2003: *Effects of an ankle-foot orthosis on spatiotemporal parameters and energy cost of hemiparetic gait.*

1 Randomisation	Not reported
2 Homogeneity of pts	There was a big range in time since stroke, but other characteristics showed homogeneity.
3 Homogeneity between groups	N/A
4 Use of different AFO types	Not reported in the study.
5 Selection bias	Present. There is only 1 group of pts in the study.
6 Performance bias	Present. There is no blinding of pts and practitioners possible
7 Exclusion bias	Absent. There were no drop outs.
8 Detection bias	Possible. There is not enough information in the article.

5. Hesse et al., 1996: *Gait function in spastic hemiparetic patients walking barefoot, with firm shoes, and with ankle-foot orthosis*

1 Randomisation	Not reported
2 Homogeneity of pts	No, there were 9/19 pts with sensory impairment, 3/19 pts with signs of sensorimotor neglect syndrome and 8/19 pts with achilles tendon cloni occurring in walking barefoot, wide range in time since stroke (1,5 tot 16mo).
3 Homogeneity between groups	N/A
4 Use of different AFO types	Only Valens Caliper AFO was used in the study.
5 Selection bias	Present. There is only 1 group of pts in the study.
6 Performance bias	Present. There is no blinding of pts and practitioners possible
7 Exclusion bias	Absent. There were no drop outs.
8 Detection bias	Possible, there is not enough information in the article.

6. Hesse et al., 1999: *Non-velocity-related effects of a rigid double-stopped ankle-foot orthosis on gait and lower limb muscle activity of hemiparetic subjects with an equinovarus deformity.*

1 Randomisation	Not reported in the article.
2 Homogeneity of pts	No, there were 7/21 pts with marked plantar flexion spasticity, 3/21 pts with signs of sensorimotor neglect syndrome and 7/21 pts with Achilles tendon cloni occurring in walking barefoot, wide range in time since stroke. (1,5 tot 16mo).
3 Homogeneity	N/A

between groups	
4 Use of different AFO types	Only Valens Caliper AFO was used in the study.
5 Selection bias	Present. There is only 1 group of pts in the study.
6 Performance bias	Present. There is no blinding of pts and practitioners possible
7 Exclusion bias	Absent. There were no drop outs.
8 Detection bias	Possible, there is not enough information in the article.

7. Hung et al., 2010: *Long-term effect of an anterior ankle-foot orthosis on functional walking ability of chronic stroke patients.*

1 Randomisation	No randomisation for conditions, only for test sequence.
2 Homogeneity of pts	All characteristics showed homogeneity.
3 Homogeneity between groups	N/A
4 Use of different AFO types	All pts wore their own anterior AFO in the study. It is not known if all AFO's were the same.
5 Selection bias	Present. There is only 1 group of pts in the study.
6 Performance bias	Present. There is no blinding of pts and practitioners possible
7 Exclusion bias	Absent. There were no drop outs.
8 Detection bias	Possible, there not enough information in the article.

8. Mojica et al., 1988: *Effect of ankle-foot orthosis (AFO) on body sway and walking capacity of hemiparetc stroke patients.*

1 Randomisation	There was a randomisation for conditions and tests
2 Homogeneity of pts	There was a heterogeneity of patients
3 Homogeneity between groups	N/A
4 Use of different AFO types	Pts wore the same type of AFO's in the study.
5 Selection bias	Present. There is only 1 group of pts in the study.
6 Performance bias	Present. There is no blinding of pts and practitioners possible.
7 Exclusion bias	Absent. There were no drop outs.
8 Detection bias	Possible, there not enough information in the article.

9. Nolan et al., 2009: *Objective assessment of functional ambulation in adults with hemiplegia using ankle-foot orthotics after stroke.*

1 Randomisation	Pts performed the test with ad random selected conditions.
2 Homogeneity of	There was a big range in time since stroke. There were insufficient demographic data

pts	available.
3 Homogeneity between groups	N/A
4 Use of different AFO types	Pts wore different types of AFO's. AFO type was not standardized.
5 Selection bias	Present. There is only 1 group of pts in the study.
6 Performance bias	Present. There is no blinding of pts and practitioners possible
7 Exclusion bias	Absent. There were two losses in the study, but the article reported this. These two pts were not able to fully complete the study.
8 Detection bias	Possible, there not enough information in the article.

10. Park et al., 2009: *Comparison of gait analysis between anterior and posterior ankle foot orthosis in hemiplegic patients.*

1 Randomisation	Gait was measured while each subject was walking with an anterior AFO, a posterior AFO, and barefoot. No randomisation.
2 Homogeneity of pts	There is a good homogeneity in this article.
3 Homogeneity between groups	N/A
4 Use of different AFO types	Pts wore the same AFO's in the study.
5 Selection bias	Present. There is only 1 group of pts in the study.
6 Performance bias	Present. There is no blinding of pts and practitioners possible
7 Exclusion bias	Absent. There were no drop outs.
8 Detection bias	Possible, there not enough information in the article.

11. Sheffler et al., 2006: *Peroneal nerve stimulation versus an ankle foot orthosis for correction of footdrop in stroke: impact on functional ambulation.*

1 Randomisation	Pts performed the test with ad random selected conditions.
2 Homogeneity of pts	They only reported only the average score of the demographic data.
3 Homogeneity between groups	N/A
4 Use of different AFO types	Pts wore different types of AFO's in the study.
5 Selection bias	Present. There is only 1 group of pts in the study.
6 Performance bias	Present. There is no blinding of pts and practitioners possible
7 Exclusion bias	Absent. There were 4 drop out (3 pts with medical issues and one with improved DF strength), but these losses were described in the article.
8 Detection bias	Possible, there not enough information in the article.

12. Simons et al., 2009: Ankle-foot orthoses in stroke: *Effects on functional balance, weight-bearing asymmetry and the distribution of each lower limb to balance control.*

1 Randomisation	Pts performed the tests with ad random selected AFO conditions.
2 Homogeneity of pts	There was a big range in time since stroke, but other characteristics showed quite some homogeneity.
3 Homogeneity between groups	N/A
4 Use of different AFO types	Pts wore four different types of AFO's in the study.
5 Selection bias	Present. There is only 1 group of pts in the study.
6 Performance bias	Present. There is no blinding of pts and practitioners possible.
7 Exclusion bias	Absent. There were 3 drop outs (2 pts had an epileptic insult and 1 pt was not able to perform the tests),but these losses were described in the article.
8 Detection bias	Possible, there is not enough information in the article.

13. Tyson & Thornton, 2001: *The effect of a hinged ankle foot orthosis on hemiplegic gait: objective measure and users' opinions.*

1 Randomisation	The order of testing was randomized.
2 Homogeneity of pts	There was a big range in time since stroke, but other characteristics showed homogeneity.
3 Homogeneity between groups	N/A
4 Use of different AFO types	Pts wore the same type of AFO's in the study.
5 Selection bias	Present. There is only 1 group of pts in the study.
6 Performance bias	Present. There is no blinding of pts and practitioners possible.
7 Exclusion bias	Absent. There were no drop outs.
8 Detection bias	Possible, there not enough information in the article.

14. Tyson & Rogerson, 2009: *Assistive walking devices in non-ambulant patients undergoing rehabilitation after stroke: the effects on functional mobility, walking impairments, and patients' opinion.*

1 Randomisation	Pts performed the tests with ad random selected AFO conditions, and allocation was concealed. Concealed envelopes were used.
2 Homogeneity of pts	There was a big range in time since stroke, but other characteristics showed homogeneity.
3 Homogeneity between groups	N/A
4 Use of different AFO types	Pts wore the same type of AFO in the study.

5 Selection bias	Present. There is only 1 group of pts in the study.
6 Performance bias	Present. There is no blinding of pts and practitioners possible.
7 Exclusion bias	Absent. There were no drop outs.
8 Detection bias	Possible, there not enough information in the article.

15. Wang et al., 2005: *Effects of an ankle foot orthosis on balance performance in patients with hemiparesis of different durations.*

1 Randomisation	The testing sequences were randomized.
2 Homogeneity of pts	N/A
3 Homogeneity between groups	Two groups were made in this article based on time since stroke (acute and chronic). There were no differences between these groups for hemi paretic side and age. Significant differences were seen for gender.
4 Use of different AFO types	Pts wore the same type of AFO in the study.
5 Selection bias	Present. Groups were divided based on time since stroke.
6 Performance bias	Present. There is no blinding of pts and practitioners possible.
7 Exclusion bias	Absent. There were no drop outs.
8 Detection bias	Possible, there not enough information in the article.

6.4 Appendix 4: Cochrane Checklist for Randomized Controlled Trials

FORMULIER II

voor het beoordelen van een

RANDOMISED CONTROLLED TRIAL

(RCT)

Evidence-Based Richtlijn Ontwikkeling

Formulier II: beoordeling randomised controlled trial (RCT)

Dit formulier is bestemd voor het beoordelen van randomised controlled trials (RCT's). RCT's worden uitgevoerd ter bepaling van het effect van een therapeutische of preventieve interventie. Soms wordt het effect van een diagnostische interventie ook door middel van een RCT onderzocht.

Dit formulier is ontwikkeld door een werkgroep bestaande uit vertegenwoordigers van het Dutch Cochrane Centre, het Kwaliteitsinstituut voor de Gezondheidszorg CBO, het Nederlands Huisartsen Genootschap, het institute for Medical Technology Assessment, de Werkgroep Onderzoek Kwaliteit, het College voor Zorgverzekeringen, Zorgonderzoek Nederland (ZonMw) en de Orde van Medisch Specialisten en wordt ondersteund door het Nederlands Paramedisch Instituut, de Vereniging voor Integrale Kankercentra en de Werkgroep Infectieziektenpreventie.

Voor het beoordelen van de kwaliteit van andere typen onderzoek zijn eveneens formulieren ontwikkeld. Deze staan samengevat in onderstaande tabel.

Type onderzoek	Formulier
Dwarsdoorsnedeonderzoek (waarde diagnostische test)	I
Randomised controlled trial (RCT)	II
Cohortonderzoek	III
Patiënt-controleonderzoek	IV
Systematische review van	
RCT's (therapie en preventie)	Va
diagnostisch onderzoek	Vb
observationeel onderzoek (etiologie/"harm"/prognose)	Vc
Economische evaluatie	VI
Richtlijn	AGREE

Instructie beoordeling

- De bruikbaarheid van een publicatie voor een richtlijn wordt in de formulieren op drie facetten beoordeeld: validiteit, toepasbaarheid in de praktijk en toepasbaarheid in de Nederlandse gezondheidszorg
- Daarnaast wordt gevraagd om de belangrijkste kwantitatieve gegevens te extraheren en op een uniforme wijze te presenteren.
- De opmaak van de beoordelingsformulieren maakt het u makkelijk:
  a) op diverse plaatsen is een beslismoment ingebouwd: indien een publicatie op dat moment niet aan de vereisten van validiteit of toepasbaarheid voldoet hoeft u met de beoordeling niet verder te gaan.
  b) de criteria en manier van data-extractie worden telkens op de tegenoverliggende pagina kort toegelicht.

Zend opmerkingen of suggesties aangaande dit formulier naar cochrane@amc.uva.nl.

Vraag 1. *Randomisatie*. Randomisatie is een methode waarbij gebruikgemaakt wordt van het toeval om de te onderzoeken interventie en de controlebehandeling(en) toe te wijzen aan de patiënt. Randomisatie houdt in dat ieder individu (of andere eenheid van randomisatie) een gelijke kans heeft om elk van de interventies te krijgen. Een goede randomisatie kan bijvoorbeeld gebruikmaken van een tabel met aselecte (random) getallen of van een door een computer aangemaakte randomisatielijst.
Er dient gewaarschuwd te worden voor andere methoden van allocatie die soms wel als randomisatie beschreven zijn, maar dit niet echt zijn: allocatie op geboortedatum, volgorde van binnenkomst, dag van de week, maand van het jaar, dossiernummer. Deze methoden heten wel “quasi random”. In dat geval is het belangrijk om extra aandacht te geven aan de vergelijkbaarheid van de groepen (vraag 6).

Vraag 2. *Blindering van de randomisatie*. Procedure waarbij wordt voorkomen dat degene die de patiënt beoordeelt en insluit op de hoogte kan zijn van de randomisatievolgorde. Goede manieren zijn: gebruik van centrale randomisatieschema’s; randomisatieschema’s die door een trial-apotheek worden beheerd; genummerde en gecodeerde verpakkingen met identieke placebo- en verum- medicatie (= werkzame medicatie); genummerde, niet-doorzichtige enveloppen; een op locatie aanwezige computer waarvan de randomisatievolgorde pas wordt vrijgegeven na opgave van de patiëntenkarakteristieken.
De in de toelichting bij vraag 1 genoemde “quasi random” procedures zijn per definitie niet blind voor randomisatie omdat degene die de patiënt in het onderzoek insluit, kan voorzien welke behandeling de patiënt zal krijgen.
Blindering van randomisatie *(concealment of allocation)* dient te worden onderscheiden van blindering van patiënten, behandelaars en effectbeoordelaars.

Vraag 3. *Blindering patiënten*. Door blindering van de patiënt wordt voorkomen dat: a) deze bewust of onbewust een grotere compliance met het protocol zal hebben, b) de uitkomstmeting door voorkeuren voor behandeling wordt beïnvloed. Blindering van de patiënt wordt bereikt door de verumbehandeling (= werkzame behandeling) en placebobehandeling identiek te maken. Medicatie moet dezelfde kleur, grootte, smaak en consistentie hebben. Ook niet-medicamenteuze placebo-interventies, zoals bijvoorbeeld fysiotherapie of ruggordels, dienen voldoende identiek te zijn om geloofwaardig over te komen. Evaluatie van het succes van blindering is gewenst, maar is voor dit item niet noodzakelijk. Indien een onderzoek als dubbelblind wordt beschreven dient u goed na te gaan om wie het gaat: patiënt, behandelaar en/of effectbeoordelaar. Dit is op voorhand niet altijd duidelijk.

Vraag 4. *Blindering behandelaars*. Door blindering van de behandelaar wordt voorkomen dat deze, omdat hij op de hoogte is van de aard van de toegewezen behandeling: a) een bepaald enthousiasme zal uitstralen (selectieve vergroting van het placebo-effect), b) verschillende mate van adherentie aan het onderzoeksprotocol zal hebben (door bijvoorbeeld aan de placebogroep aanvullende behandeling aan te bieden). Evaluatie van het succes van blindering is gewenst, maar is voor dit item niet noodzakelijk.
Indien een onderzoek als dubbelblind wordt beschreven dient u goed na te gaan om wie het gaat: patiënt, behandelaar en/of effectbeoordelaar. Dit is op voorhand niet altijd duidelijk.

Vraag 5. *Blindering effectbeoordelaars.* Door blindering van de effectbeoordelaar wordt voorkomen dat deze de effecten van interventie en controlebehandeling verschillend zal beoordelen. Evaluatie van het succes van blindering is gewenst, maar is voor dit item niet noodzakelijk.
Indien een onderzoek als dubbelblind wordt beschreven dient u goed na te gaan om wie het gaat: patiënt, behandelaar en/of effectbeoordelaar. Dit is op voorhand niet altijd duidelijk.

Beoordeling van de kwaliteit van een randomised clinical trial (RCT)

Naam beoordelaar:..... Datum:..... Titel:

..... Auteurs:

..... Bron:

.....

Beoordeling van de validiteit

Korte beschrijving van de interventie: .....

..... Korte

beschrijving van de controlebehandeling(en): .....

.....

VALIDITEIT

1. Was de toewijzing van de interventie aan de patiënten gerandomiseerd?
   [ ] Ja
   [ ] Nee
   [ ] Te weinig informatie in het artikel om dit te beantwoorden

2. Degene die patiënten in het onderzoek insluit hoort niet op de hoogte te zijn van de randomisatievolgorde. Was dat hier het geval?
   [ ] Ja
   [ ] Nee
   [ ] Te weinig informatie in het artikel om dit te beantwoorden

3. Waren de patiënten geblindeerd voor de behandeling?
   [ ] Ja
   [ ] Nee
   [ ] Te weinig informatie in het artikel om dit te beantwoorden

4. Waren de behandelaars geblindeerd voor de behandeling?
   [ ] Ja
   [ ] Nee
   [ ] Te weinig informatie in het artikel om dit te beantwoorden

5. Waren de effectbeoordelaars geblindeerd voor de behandeling?
   [ ] Ja
   [ ] Nee
   [ ] Te weinig informatie in het artikel om dit te beantwoorden

Vraag 6. *Vergelijkbaarheid groepen.* De groepen moeten aan het begin van het onderzoek op belangrijke prognostische kenmerken voldoende gelijk zijn. Theoretisch zou alleen de toegewezen behandeling tussen de groepen verschillend moeten zijn.
Bij beoordeling kan worden gelet op:

a) Belangrijke prognostische variabelen, waaronder bijvoorbeeld ziekteduur, ernst, co-medicatie, co- morbiditeit
b) Uitgangswaarden van de belangrijksteuitkomstmaten
c) Demografische gegevens (geslacht, leeftijd)

Kleine verschillen kunnen op basis van toeval optreden. Bij grote verschillen dient beredeneerd te worden in welke mate en in welke richting de resultaten beïnvloed kunnen worden.
Er kan door de onderzoekers ook door middel van multivariate analyses gecorrigeerd zijn voor verschillen in prognostische factoren tussen de groepen.

NB: Als sprake is van *quasi randomisation* (zie vraag 1), is het belangrijk om extra aandacht te geven aan de vergelijkbaarheid van de groepen.

Vraag 7. *Loss-to-follow-up.* Het is belangrijk om per groep de aantallen patiënten bij randomisatie en bij follow-up te vergelijken. Relatief grote uitval (loss-to-follow-up) maakt een onderzoek gevoelig voor selectieve loss-to-follow-up. Aantallen en redenen voor uitval dienen gerapporteerd te zijn. Ook als er geen uitvallers waren dient dit te zijn beschreven.
Indien de redenen van uitval uit het onderzoek of de absolute aantallen uitvallers tussen de groepen verschillend zijn en tot een vertekening van de uitkomsten kunnen leiden, heet dit selectieve loss-to- follow-up.
Het is niet mogelijk om op voorhand per indicatiegebied aan te geven welk percentage loss-to-follow- up nog acceptabel is.

Vraag 8. *Intention-to-treat analyse.* Bij de analyse dient de allocatie door randomisatie gerespecteerd te worden. De patiënt hoort bij de oorspronkelijk door randomisatie gevormde groep, ongeacht eventuele co-interventies, non-compliance en dergelijke (zie vraag 9).
Naast intention-to-treat analyse kan ook nog een per-protocol analyse worden gepresenteerd. Hierbij worden alleen gegevens van patiënten gebruikt die volgens het onderzoeksprotocol zijn behandeld. Bedenk, dat een per-protocolanalyse zeer misleidend kan zijn.

Vraag 9. *Vergelijkbaarheid behandeling.* De behandeling van de patiënten in de verschillende groepen dient behalve het door randomisatie beoogde contrast geen verschillen te vertonen. Bij goed geblindeerde behandelingen is de vergelijkbaarheid van behandelingen in de regel geen probleem.
Bij de beoordeling kan worden gelet op:

a) Co-interventies. Verdeling van behandelingen anders dan de door randomisatie toegewezen. Soms worden deze door de onderzoekers onder controle en dus gelijk gehouden. In andere gevallen worden de co-interventies per groep gerapporteerd. Indien er geen melding van co-interventies wordt gemaakt dient men op de hoede te zijn.
b) Contaminatie. In geval van contaminatie krijgt of zoekt de patiënt in de loop van het onderzoek precies de behandeling die eigenlijk aan de andere groep toegewezen is.
c) Compliance. Indien de compliance met de toegewezen behandeling in de ene groep veel groter is dan in de andere kan dit de interpretatie van de gegevens verstoren.

Vraag 10. *Algemeen oordeel*. Hier wordt een inschatting van de validiteit en toepasbaarheid gevraagd. Let hierbij ook op eventuele fouten in het onderzoek die funest zijn voor de validiteit ervan (*red flags, fatal flaws*). Er zijn geen regels te geven voor welke items positief gescoord moeten worden of welk aantal items tenminste positief gescoord moeten worden. Dit is deels afhankelijk van de “state-of-the- art” met betrekking tot het betreffende onderwerp. Het gaat er hier om het samenvattend oordeel van wat de beoordelaar de werkgroep zou willen mededelen over de bruikbaarheid van het artikel voor de besluitvorming.

6. Waren de groepen aan het begin van de trial vergelijkbaar? [ ] Ja
   [ ] Nee, maar in de analyses is hiervoor wel gecorrigeerd
   [ ] Nee, en in de analyses is hiervoor niet gecorrigeerd
   [ ] Te weinig informatie in het artikel om dit te beantwoorden

7. Is van een voldoende proportie van alle ingesloten patiënten een volledige follow-up beschikbaar?
   [ ] Ja
   [ ] Nee ⇐ Is selectieve loss-to-follow-up voldoende uitgesloten?
   [ ] Ja
   [ ] Nee
   [ ] Te weinig informatie in het artikel om dit te beantwoorden / loss-to-follow-up niet beschreven

8. Zijn alle ingesloten patiënten geanalyseerd in de groep waarin ze waren gerandomiseerd?
   [ ] Ja
   [ ] Nee
   [ ] Te weinig informatie in het artikel om dit te beantwoorden

9. Zijn de groepen, afgezien van de interventie, gelijk behandeld? [ ] Ja
   [ ] Nee
   [ ] Te weinig informatie in het artikel om dit te beantwoorden

TUSSENOORDEEL

10. Zijn de resultaten van het onderzoek valide en toepasbaar?

[ ] Voldoende valide en toepasbaar	⇐ ga verder bij 11
[ ] Twijfelachtig	⇐ ga verder bij 11
[ ] Onvoldoende valide en toepasbaar	U kunt stoppen met het invullen van de checklist, tenzij er geen betere artikelen op dit gebied zijn (terugkoppelen naar de werkgroep)

Vraag 11. *Resultaten*

Keuze uitkomst en follow-up duur. Auteurs zijn soms geneigd de meest in het oog springende (significante) resultaten als belangrijkste te presenteren. Het is als beoordelaar belangrijk om vooraf een indruk te vormen van de klinisch of beleidsmatig meest relevante uitkomst(en) en follow- upmoment. Dit zijn de belangrijkste parameters die meegenomen dienen te worden in de rapportage naar de groep. Pas ervoor op niet slechts op de hiërarchie van de auteurs van het artikel af te gaan.

Dichotome uitkomsten. In geval van dichotome uitkomsten (uitkomsten die slechts 2 waarden kunnen aannemen, bijvoorbeeld wel of niet genezen) kunnen verschillende associatiematen berekend worden: relatieve risico, relatieve risicoreductie, absolute risicoreductie en number needed to treat. Als de oorspronkelijke getallen gepresenteerd worden (voor notatie: zie Tabel), kan men deze associatie- maten zelf berekenen. Is dit niet het geval, dan moet men volstaan met het overnemen van de door de auteurs gepresenteerde associatiemaat (inclusief het 95%-betrouwbaarheidsinterval). Dit moet u ook doen, indien de auteurs een multivariate statistische analyse hebben uitgevoerd ter correctie voor verschillen in prognostische factoren tussen de groepen.
De formules voor het zelf berekenen van een 95%-betrouwbaarheidsinterval staan in de appendix. (Zie ook de verschillende rekenmachientjes op internet, bijv. op http://minerva.minervation.com/cebm/ of http://www.cebm.utoronto.ca/practise/ca/statscal/.)

Formules voor het berekenen van verschillende associatiematen in een RCT	Uitkomst * aanwezig	afwezig	Totaal
Interventiegroep	a	b	a + b
Controlegroep	c	d	c + d
Kans op gebeurtenis (risico) in de interventiegroep	a / (a + b)		
Kans op gebeurtenis (risico) in de controlegroep	c / (c + d)		
Absolute risico reductie (ARR)	a/(a + b) – c/(c + d)		
Number needed to treat (NNT)	1/ ARR = 1 / [| a/(a + b) – c/(c + d) |]		
Relatieve risico (RR)	[a/(a + b)] / [c/(c + d)]		
Relatieve risico reductie (RRR):			
- in geval van een ongunstige uitkomst	1 – RR		
- in geval van een gunstige uitkomst	RR – 1		

* *De uitkomst (of het eindpunt) kan zowel gewenst (bijvoorbeeld genezing) als ongewenst zijn (bijvoorbeeld bijwerking van een medicijn, overleden).*
Absolute risico reductie (ARR) = risicoverschil = verschil in absolute risico op de uitkomst tussen de interventie- en controlegroep. Indien de bestudeerde uitkomst (eindpunt) een gunstige is (genezen), wordt ook wel gesproken van een *absolute benefit increase (ABI).*
Number needed to treat (NNT) = aantal patiënten dat met de interventie behandeld dient te worden om één ongewenste gebeurtenis minder of één gewenste gebeurtenis meer te bereiken dan met de controlebehandeling verkregen zou zijn.
Relatieve risico (RR) = verhouding van absolute risico op de uitkomst tussen interventie- en controlegroep. Indien de bestudeerde uitkomst (eindpunt) een gunstige is (genezen), wordt ook wel gesproken van een *benefit ratio (BR).*
Relatieve risico reductie (RRR) = relatieve risicoverschil. In geval van een ongunstige uitkomst (bijv. overleden) en een gunstig effect van de onderzochte interventie (RR < 1 en ARR < 0) is RRR de proportionele verlaging van het risico op de slechte uitkomst (dan: RRR = 1 – RR). Bij een gunstige uitkomst (bijv. genezen) en een gunstig effect van de onderzochte interventie (RR > 1 en ARR > 0) spreekt men van “relative benefit increase” (RBI). RBI is de proportionele verhoging van het “risico” (kans) op de gunstige uitkomst (dan: RBI = RR – 1).
Continue uitkomsten. Bij continue uitkomsten wordt per behandelarm het gemiddelde effect berekend. De hier van toepassing zijnde associatiemaat is het verschil van beide gemiddelden. Voor het berekenen van een 95%-betrouwbaarheidsinterval zijn ook nog – per behandelarm – de standaard- deviatie (SD) en het aantal patiënten nodig (N). NB: Let er bij de dataextractie voor op dat de standaarddeviatie [SD] iets anders is dan de standard error (of the mean) [SE(M)]! De standaard- deviatie is de standard error of the mean maal de wortel uit het aantal patiënten in de groep. In formule: $SD = SEM * \sqrt{N}$

11. Resultaten

In de onderstaande tabellen kunt u de meest relevante resultaten weergeven. Niet alle parameters zullen echter in het artikel vermeld staan. Deze zijn echter vaak zelf uit te rekenen met de gegevens uit het artikel (zie toelichting).

DICHOTOME UITKOMSTEN (genezen / niet-genezen; in leven / overleden)

Uitkomst: ..... Follow-up:

..... weken / maanden / jaar

Groep	Uitkomst aanwezig	afwezig	Totaal
Interventiegroep			
Controlegroep			

Kans op gebeurtenis in de interventiegroep	
Kans op gebeurtenis in de controlegroep	
Absolute risico reductie (ARR)	
Number needed to treat (NNT)	
Relatieve risico (RR)	
Relatieve risico reductie (RRR)	

CONTINUE UITKOMSTEN (bijvoorbeeld bloeddruk, pijnscore, kwaliteit-van-leven score)

Uitkomst: ..... Follow-up:

..... weken / maanden / jaar

Groep	Gemiddelde	SD	Aantal (N)
Interventiegroep			
Controlegroep			
Verschil van gemiddelden + 95%-BI			

Vraag 12 en 13. *Toepasbaarheid in de Nederlandse gezondheidszorg.* Beide vragen zijn een belangrijk onderdeel van richtlijnontwikkeling en dienen daarom in de werkgroep bediscussieerd te worden.

Vraag 14. *Conclusie met betrekking tot het artikel en de waarde van de interventie*

Geef hier een globale samenvatting van het eindoordeel over het artikel. Probeer, indien aanwijzingen bestaan voor vertekening van de resultaten, tenminste een inschatting te maken van de richting van de vertekening (overschatting of onderschatting van het effect van de interventie) en zo mogelijk ook over de grootte van de vertekening. Eventuele aanwijzingen voor mogelijke belangenverstrengeling van de auteurs met belanghebbende opdrachtgevers, kunt u hier ook rapporteren. Ook is het verstandig ingezonden brieven en/of redactionele commentaren op het hier door u beoordeelde onderzoek te raadplegen bij het formuleren van uw conclusie.

Voorbeeld: “Eindoordeel voldoende. Goed opgezet artikel. Door de aard van de interventie (oefentherapie bij lage rugpijn) is blindering van de behandelaar en patiënt vrijwel onmogelijk. Door te vergelijken met een gespreksgroep wordt echter wel goed gecorrigeerd voor aandachtseffecten. Oefentherapie lijkt effectief bij subacute en chronische lage rugpijn”.

TOEPASBAARHEID IN DE NEDERLANDSE GEZONDHEIDSZORG

12. Kan het gevonden resultaat worden toegepast op de Nederlandse situatie?
(hierbij valt bijvoorbeeld te denken aan de beschikbare therapeutische faciliteiten)

[ ] Ja
[ ] Nee
[ ] Te weinig informatie in het artikel om dit te beantwoorden

13. Op welk(e) echelon(s) kan het resultaat worden toegepast?
(meerdere opties tegelijk mogelijk)

[ ] algemene bevolking
[ ] eerste lijn
[ ] tweede lijn
    [ ] academische ziekenhuizen
    [ ] perifere ziekenhuizen
[ ] derde lijn

CONCLUSIE

14. Conclusie met betrekking tot het artikel en de waarde van de interventie

APPENDIX:

Formules voor het zelf berekenen van een 95%-betrouwbaarheidsinterval (95%-BI)

DICHOTOME UITKOMSTEN:

NB : op diverse internetsites zijn voor deze berekeningen ook rekenmachientjes beschikbaar
bijvoorbeeld op http://minerva.minervation.com/cebm/
of http://www.cebm.utoronto.ca/practise/ca/statscal/

Absolute risicoreductie (ARR):

$SE[ARR] = \sqrt{[\ ab / (a+b)^3 + cd / (c+d)^3\ ]}$

95%-BI voor ARR: $ARR \pm 1{,}96 * SE[ARR]$

Relatieve Risico (RR) (via natuurlijke log-transformatie): SE[LN(RR)]

$= \sqrt{[\ 1/a - 1/(a+b) + 1/c - 1/(c+d)\ ]}$

95%-BI voor RR: $e^{LN(RR) \pm 1{,}96 * SE[LN(RR)]}$

CONTINUE UITKOMSTEN:

Verschil van gemiddelden:

$SD_P = \sqrt{\ [\ ((N_I - 1) * SD^2_I + (N_C - 1) * SD^2_C) / (N_I + N_C - 2)\ ]}$

95%-BI voor verschil van gemiddelden:

$Gemiddelde_{\ I} - Gemiddelde_{\ C} \pm t_{0,975} * SD_P * \sqrt{[\ 1/N_I + 1/N_C\ ]}$

I = Interventiegroep; C = Controlegroep; $t_{0,975}$ = benodigde waarde van t-verdeling met (N_I+N_C-2) vrijheidsgraden (opzoeken in tabel van t-verdelingen)

Auteursrechtelijke overeenkomst

Ik/wij verlenen het wereldwijde auteursrecht voor de ingediende eindverhandeling:
What is the effect of an ankle-foot orthosis (AFO) on the dynamic balance and walking capacity in stroke patients?

Richting: **master in de revalidatiewetenschappen en de kinesitherapie-revalidatiewetenschappen en kinesitherapie bij musculoskeletale aandoeningen**
Jaar: **2014**

in alle mogelijke mediaformaten, - bestaande en in de toekomst te ontwikkelen - , aan de Universiteit Hasselt.

Niet tegenstaand deze toekenning van het auteursrecht aan de Universiteit Hasselt behoud ik als auteur het recht om de eindverhandeling, - in zijn geheel of gedeeltelijk -, vrij te reproduceren, (her)publiceren of distribueren zonder de toelating te moeten verkrijgen van de Universiteit Hasselt.

Ik bevestig dat de eindverhandeling mijn origineel werk is, en dat ik het recht heb om de rechten te verlenen die in deze overeenkomst worden beschreven. Ik verklaar tevens dat de eindverhandeling, naar mijn weten, het auteursrecht van anderen niet overtreedt.

Ik verklaar tevens dat ik voor het materiaal in de eindverhandeling dat beschermd wordt door het auteursrecht, de nodige toelatingen heb verkregen zodat ik deze ook aan de Universiteit Hasselt kan overdragen en dat dit duidelijk in de tekst en inhoud van de eindverhandeling werd genotificeerd.

Universiteit Hasselt zal mij als auteur(s) van de eindverhandeling identificeren en zal geen wijzigingen aanbrengen aan de eindverhandeling, uitgezonderd deze toegelaten door deze overeenkomst.

Voor akkoord,

Schaekers, Lotte **Meuws, Leni**