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Bespoke versus off-the-shelf ankle foot orthosis for people with stroke: randomised controlled trial

Cover title: Which is the best type of AFO for people with stroke?

Authors: Sarah F Tyson^{1,2}, Andy Vail^{1,3}, Nessa Thomas^{1,2}, Kate Woodward-Nutt^{1,2}, Sarah Plant^{1,2}, Pippa J Tyrrel^{1,4},

¹Stroke Research Centre University of Manchester, Manchester Academic Health Science Centre; ²Division of Nursing, Midwifery and Social Work, University of Manchester, Manchester Academic Health Science Centre; ³Division of Population Health, Health Services Research & Primary Care University of Manchester, Manchester Academic Health Science Centre; ⁴Division of Cardiovascular, Sciences University of Manchester, Manchester Academic Health Science Centre,

Corresponding Author: Sarah F Tyson, Division of Nursing Midwifery and Social Work, Jean McFarlane Building University of Manchester, Oxford Rd, Manchester M13 9PU. Tel 44(0)7810562538. Email sarah.tyson@manchester.ac.uk

Key Words: ankle foot orthosis; AFO, orthosis, stroke; gait, mobility; randomised controlled trial

Abstract

Objective: To compare of effect of two designs of ankle foot orthosis on people with stroke.

Design: ASSESSOR-BLIND, MULTI-CENTRE RANDOMISED CONTROLLED TRIAL

SETTING: COMMUNITY STROKE SERVICES

PARTICIPANTS: 139 COMMUNITY-DWELLING STROKE SURVIVORS WITH LIMITED MOBILITY

INTERVENTIONS: The two most commonly used types of ankle foot orthosis (bespoke and off-the-shelf)

MAIN MEASURES: short (6 WEEKS) AND LONG-TERM (12 WEEKS) effect on stroke survivors' satisfaction; adverse events mobility (WALKING HANDICAP SCALE); FEAR OF FALLING (FALLS EFFICACY SCALE- INTERNATIONAL, FES-I) AND WALKING IMPAIRMENTS (GAIT SPEED AND STEP LENGTH USING THE 5M WALK TEST)

Results: Long-term satisfaction was non-significantly higher in the off-the-shelf group: 72% vs 64%; OR (95% CI) = 0.64 (0.31 to 1.3); $p=0.21$. No statistically significant differences were found between the orthoses except the off-the-shelf group had less fear of falling at short term follow-up than the bespoke group: mean difference (95% CI) = -4.6 (-7.6 to -1.6) points on the Falls Efficacy Scale–International; $p=0.003$.

Conclusions: No differences between off-the-shelf and bespoke ankle foot orthoses were found except that participants in the off-the-shelf orthosis group had less fear of falling at short-term follow up.

INTRODUCTION

Most stroke survivors' mobility is limited by enduring impairments such as weakness, spasticity and poor balance [1]. Foot drop, due to weak dorsiflexors, is common and contributes to a slow, inefficient gait and high risk of falls [2-4]. This in turn limits functional mobility, community integration and quality of life for many stroke survivors, many of whom are only able to mobilise independently using an assistive device.

One such device is an ankle foot orthosis. This is a thermoplastic moulded splint or leg brace that fits inside the user's shoe and up the back of the calf to hold the foot and ankle in the neutral position (Figure 1). Our earlier systematic reviews have shown that an ankle foot orthosis normalises the movements of the ankle and knee during swing and stance phase of gait and stabilises the foot so the user can safely transfer their weight over their foot during stance phase [5]. This has a beneficial effect on mobility, balance, gait and falls risk [6]. However, most trials have used a paired subject design (a randomised comparison with and without the ankle foot orthosis) and only looked at the immediate effects of the ankle foot orthosis. Previous The only parallel-group trial of ankle foot orthoses to date used a control group with no ankle foot orthosis (n=28) and reported better gait and mobility at 3 month follow-up [7].

This evidence supporting ankle foot orthoses is recognised in the UK's National Clinical Guidelines for Stroke [8] which recommend an ankle foot orthosis to improve balance and mobility. It further recommends that the ankle foot orthosis be individually fitted but this is based on expert opinion as there are no existing studies to inform choice of ankle foot orthosis.

Therefore we undertook the first randomised comparison of the two most commonly used types of ankle foot orthosis: a bespoke, individually fitted ankle foot orthosis and an off-the-shelf ankle foot orthosis. Both can improve walking compared with 'no ankle foot orthosis' [5-7]. The bespoke ankle foot orthosis may fit better but is more expensive and requires more time and resources to fit. Thus we wished to establish whether differences in their acceptability, safety and effectiveness would justify the current guideline.

METHOD

A phase II, assessor-blind, multi-centre randomised controlled trial to compare a bespoke versus an off-the-shelf ankle foot orthosis on short and long term satisfaction; adverse events; mobility and gait was undertaken. Recruitment and retention rates were monitored closely to assess the feasibility of a large scale, phase III trial. Ethical approval was obtained from the Lancaster Committee of the National Research Ethics Service (reference 11/NW/0352). International Standard Randomised Controlled Trial Number (ISRCTN) 98287938

Participants were community-dwelling adult stroke survivors with self-reported limited mobility, impaired dorsiflexion and no contractures at the ankle (following clinical assessment) but who could walk (at least 5m) without the assistance of another person and give informed written consent. Exclusion criteria were co-morbidities that severely limited mobility or precluded use of an ankle foot orthosis. Stroke survivors who had previously had an ankle foot orthosis but stopped using it and were willing to try again

were included. Those who currently used an ankle foot orthosis were excluded. There were no criteria regarding the participants' age or time since their stroke. They were recruited from the clinical databases of stroke, therapy or rehabilitation services of nine hospitals in England. Additionally, potential participants were contacted directly via stroke support groups and research volunteer databases using invitation letters, newsletters, websites, posters in high traffic areas (such as stroke units and out-patient clinics) and social media outlets (Twitter, Facebook and blogs).

No data were available regarding the variability of the outcome measures in a population using these ankle foot orthoses to inform sample size calculation. We initially aimed to recruit 75 participants in each group to inform sample size calculation for a Phase III trial and gain sufficient experience of logistics to assess feasibility. Follow-up of this many participants would give 95% probability of identifying an adverse event occurring in 5% or more of participants in each group. For practical reasons and blind to outcome data, we later reduced the target to a minimum of 45 per group providing outcome data.

Potential participants were given a screening letter and information sheet. Suitable participants were visited by a member of the research team to determine eligibility. Once informed consent had been obtained, a referral was made to the participant's local orthotics service. After baseline assessment, the on-line randomisation service was contacted and the orthotist informed of the group allocation. At the appointment, the treating orthotist fitted the ankle foot orthosis allocated according to their usual clinical practice. All other aspects of the participants' treatment (delivery, fitting and follow-up support) were provided in line with the orthotics services' usual practice.

Randomisation was undertaken by an independent telephone randomisation service [www.sealedenvelope.com] and was stratified according to the participants' functional mobility (household or community walker) [9], whether the participant was receiving out-patient or community based rehabilitation, and by sex.

THE ANKLE FOOT ORTHOSES: The bespoke ankle foot orthoses were prescribed, designed and fitted by a qualified orthotist. The orthotists provided the design of ankle foot orthosis they felt would best meet the patient's needs in line with their usual clinical practice. A typical design of bespoke ankle foot orthosis is shown in Figure 1.

Participants randomised to the off-the-shelf ankle foot orthosis group were fitted with a light-weight, flexible posterior leaf spring ankle foot orthosis (Figure 1). We undertook extensive consultations with orthotists and physiotherapists supplying and prescribing ankle foot orthoses to choose the off-the-shelf orthosis. Our choice was considered the off-the-shelf ankle foot orthosis of choice by most consultees and was the one most commonly used in clinical practice, as it was thought to be an effective design, of medium price and applicable to a wide range of patients. A bespoke ankle foot orthosis typically requires 2-3 visits to the orthotics department for casting, fitting and review, while an off-the-shelf ankle foot orthosis typically requires only one. Our monitoring of participants' flow through the trial therefore included waiting time for fitting.

ASSESSMENTS were undertaken at baseline, six weeks (short-term follow up) and 12 weeks (long-term follow up) later by a member of the research team. Where the process to fit and supply the ankle foot orthosis was so prolonged that it exceeded the assessment period, we followed the pragmatic principle of intention to treat. In these cases,

assessments were completed without the ankle foot orthoses as patient satisfaction with the ankle foot orthosis (or lack of it) and prevention of adverse events (such as falls) were important outcomes.

It was not possible to blind participants to the intervention received. Blinded assessment was maintained as far as possible by asking participants to wear trousers and a sock over the ankle foot orthosis during assessments to conceal the type of orthosis from the assessors. Participants were also requested not to discuss or reveal their type of ankle foot orthosis with the assessor.

OUTCOME MEASURES: Our primary outcome measure was long term satisfaction with the ankle foot orthosis assessed using the Patient Satisfaction Questionnaire previously developed and used by the authors [10] (Appendix 1). This outcome measure was chosen as it is well established that an ankle foot orthosis can improve gait and mobility [5,6] however if the patient is not satisfied with the ankle foot orthosis and does not wear it, then it will not be effective whatever its potential impact on gait.

Secondary outcomes were:

- recruitment and retention rates
- short-term satisfaction
- adverse events assessed through participant self-report
- clinical effects:
 - Functional mobility (Walking Handicap Scale) [9]
 - Fear of falling (Falls Efficacy Scale- International, FES-I) [11]

- Walking impairments (gait speed and step length using the 5m Walk Test [12]). The 5m Walk Test recorded the time taken to walk 5m. The number of steps taken was also counted. From this, walking speed (in metres/second) and mean step length (in metres) were calculated.

Analyses of recruitment, retention and adverse events were descriptive, citing number and percentage in each case. Clinical outcomes were compared on both an intention-to-treat and per-treatment basis. Outcome data for all participants were sought regardless of treatment adherence unless consent to follow-up was explicitly withdrawn. Regression analyses controlled for the stratification factors and, where available, baseline measures of the outcome variable. We used multiple logistic regression to give an odds ratio (95% confidence interval) for binary outcomes and linear regression to give a mean difference (95% confidence interval) for continuous outcomes. Thematic content analysis was used to analyse the responses to open questions in the satisfaction questionnaire [13].

RESULTS

139 participants were recruited. In the first six months, recruitment averaged 3 participants per month, rising to 9 per month in the final six months as our strategy developed. The most successful recruitment strategy was to approach current and former patients of stroke, therapy and rehabilitation services directly by post (Figure 2).

Patient flow through the trial is detailed in Figure 2. Retention rates were high. Most participants were fitted with the ankle foot orthosis to which they were randomised.

However, of those randomised to receive an off-the shelf ankle foot orthosis:

- Two were supplied with a bespoke ankle foot orthosis because they could not fit into an off-the-shelf orthosis due to high muscle tone (n=1) or limited dorsiflexion range (n=1)
- For the other four participants, no explanation was given.
- Two were given a different design of off-the-shelf ankle foot orthosis: a metal leg iron/ caliper.
- Seven were not given an ankle foot orthosis as the orthotist considered it unnecessary.

Of those randomised to receive a bespoke ankle foot orthosis:

- Sixteen were supplied with an off-the-shelf ankle foot orthosis because the orthotist considered a bespoke orthosis was too expensive (n=1) or too restrictive of range of movement at the ankle (n=4). Five were fitted in error and no explanation was given for the remaining six
- Five were not given an orthosis as the orthotist considered it unnecessary.

Participants' characteristics and baseline measures are detailed in Table 1. Age ranged 24-93 years and 99 (71%) were male. Most (64%) were 'community walkers'. There were no marked differences between groups at baseline. At short-term assessment, 94 (68%) participants had received their ankle foot orthosis, 40 (58%) in the bespoke orthosis group and 54 (77%) in the off-the-shelf orthosis group.

Sixty-five percent (n=26) of respondents from the bespoke group and 61% (n=33) of off-the-shelf group were satisfied or very satisfied with their ankle foot orthosis: OR (95% CI) = 1.3 (0.62 to 2.9); p=0.47. By the long-term assessment, the corresponding figures were 72% and 64% respectively: OR (95% CI) = 0.64 (0.31 to 1.3); p=0.21 (Table 2). Classifying by treatment received, satisfaction scores were 64% versus 61% at short-term and 72% versus 63% at long-term follow-up, both in favour of off-the-shelf ankle foot orthosis.

Questions of comfort and convenience are reported in Table 3. We did not statistically compare these secondary outcomes but all observed differences favoured the off-the-shelf ankle foot orthosis. Responses did not change materially between short-term and long-term follow-up. Analysis of the open questions in the satisfaction questionnaire indicated that participants felt the main benefit of an orthosis was that it improved their walking by improving the alignment of their foot and ankle. It stopped their foot turning over (inversion), enabled them to put their foot down first (heel strike) safely and gave them confidence that they would not trip. The off-the-shelf ankle foot orthosis group more frequently reported a beneficial effect on foot posture and alignment (n=38 vs 17).

Sixty-four orthosis-related adverse events were reported and are detailed in Table 4. The most serious adverse events; a head injury and a fractured neck of femur following a fall, both occurred whilst the participant was waiting for their ankle foot orthosis be fitted. Of the remaining falls causing severe events, only one participant was wearing their orthosis

at the time. Of the falls causing moderate adverse events, all occurred while the participant was active (eg negotiating stairs, walking on a moving train or attending a football match). Half occurred while they were wearing the orthosis and three while awaiting receipt of the orthosis. Of the falls causing mild adverse events, 12 occurred while the participant was wearing the orthosis and four while waiting for the orthosis to be fitted. In total 10 participants (five in each group) reported abandoning their orthosis because of adverse events. We did not statistically compare the number of adverse events between groups.

Both groups improved in all measures of clinical effectiveness between baseline and both short-term and long-term follow-up. There were no substantive differences between allocated groups in functional mobility, gait speed, step length or longer-term falls efficacy (Table 5). At short-term follow-up, fear of falling was significantly lower in the off-the-shelf ankle foot orthosis group: mean difference (95% CI) = -4.6 (-7.6 to -1.6); $p=0.003$. Conclusions were not materially altered when comparing groups according to treatment as received.

DISCUSSION

This is the first RCT to compare the effects of different types of ankle foot orthosis. We found that both groups' mobility, gait and fear of falling improved compared to baseline at both short-term and long-term follow-up. This concurs with previous reports [5]. However we did not find any benefits of a bespoke ankle foot orthosis over off-the-shelf ankle foot orthosis in terms of patient satisfaction, adverse events or clinical effects.

Although most participants were satisfied with their ankle foot orthosis, the rate of reported difficulties is of concern. Approximately 50% of participants had a problem of some description with their orthosis, many of which were considered serious. Discomfort, skin problems, difficulty getting the ankle foot orthosis on and off, and fitting it in their shoes were common complaints. There are no accepted minimal levels of satisfaction for health care interventions, but these levels are clearly unacceptable. Further research is needed to develop more comfortable, better fitting and convenient designs of ankle foot orthosis.

One of the aims of this trial was to ascertain whether further trials were feasible or necessary. Given that we did not have a sample size calculation (as no previous data existed), one explanation for the lack of difference between groups may be that the trial was under-powered. Using the data from this trial indicates that a sample size of at least 1,300 would be needed for a Phase III trial of clinical effectiveness where functional mobility (Walking Handicap Scale, [9]) was the primary outcome for 80% power to detect a large effect size ($OR=0.75$). The timescale and cost of such a Phase III trial is likely to be prohibitive given the relatively low cost of the interventions. If a future trial design focused on efficacy, then gait speed could be considered as the primary outcome; the minimal clinically important difference of which is 0.2m/sec [9]. Our trial has already excluded a difference of even half of this magnitude in either direction when analysed by either 'intention to treat' or 'treatment as received'. We therefore believe there is little chance of demonstrating a clinical benefit of bespoke ankle foot orthosis use in this population.

The main limitation of this trial is that the outcome assessors successfully identified the type of ankle foot orthosis with which most participants had been fitted. It is difficult to know what further measures we could have taken to blind the assessors. Rather, we feel that like

many complex interventions, it is not possible to effectively blind assessors, and the risk of bias this presents needs to be accepted as inevitable in this type of intervention.

The high number of allocation deviations may be considered a limitation but we completed the analyses on the basis of intention-to-treat and per-treatment and found no difference in the outcomes. Thus it appears that the deviations did not affect the findings or conclusions of the trial.

A bespoke ankle foot orthosis costs three to five times more than an off-the-shelf one and requires additional resource to fit. There is an obvious cost-advantage to an off-the-shelf orthosis with no evidence to support the more expensive option. If anything, there may be an advantage to the off-the-shelf orthosis as they are quicker to provide and thus reduce risk of falls more quickly. The imperative to fit ankle foot orthosis speedily was starkly illustrated by the two most serious adverse events (head injury and fractured neck of femur) which occurred while awaiting fitting.

We recommend that, unless contra-indicated, stroke survivors with limited mobility (plus dorsiflexor weakness and a plantargrade position) should be offered a light-weight, flexible off-the-shelf ankle foot orthosis such as the one used in this trial in the first instance. A bespoke ankle foot orthosis should be considered if an off-the shelf one proves unsuccessful. It is important to note that this recommendation refers to the type of light-weight, flexible off-the-shelf ankle foot orthosis used in this trial. It cannot be assumed that all off-the-shelf ankle foot orthosis will be similarly effective or safe. It is incumbent on manufacturers of the more expensive, bespoke ankle foot orthoses to demonstrate sufficient clinical superiority of their product to justify the increased waiting time and costs.

CLINICAL MESSAGES

- Mobility, gait and fear of falling improved with both a bespoke and an off-the-self orthosis.
- There were no differences between orthoses.
- Problems with the orthosis were common including falls, skin breakdown/ rubbing and discomfort. The more severe adverse events happened while waiting for the orthosis to be fitted

Authors Contributions: SFT, AV and PJT contributed to the trial design, analysis and production of the manuscript. NT, KWN and SP were responsible for the data collection, contributed to the analysis and commented on the manuscript.

Declaration of Conflicts of Interest: None

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Table 1 Description of the groups at baseline assessment. Figures are n (%) mean (sd), range or interquartile range as appropriate.

	Bespoke ankle foot orthosis (n=69)	Off-the-Shelf ankle foot orthosis (n=70)
Sex (Male: Female)	49:20	50:20
Age (years)	64.7 (12.6), 29-87	67.0 (11.8), 24-93
Median (IRQ) Time since stroke (weeks)	112 (38-213)	83 (5-166)
Mobility		
Physiological walker	2 (3%)	3 (4%)
Limited household walker	11 (16%)	12 (17%)
Unlimited household walker	9 (13%)	13 (19%)
Most limited Community walker	17 (25%)	11 (16%)
Least limited Community walker	10 (14%)	14 (20%)
Unlimited Community walker	20 (29%)	17 (24%)
Stage of rehabilitation when recruited		
In-patient	4 (6%)	4 (6%)
Out-patient or community therapy	18 (26%)	19 (27%)
No therapy	47 (68%)	47 (67%)
Falls efficacy Scale	38.8 (11.5), 16- 61	39 (11.8), 16-63
Gait speed (m/s)	0.52 (0.27), 0.04-1.06	0.47 (0.24), 0.12-0.97
Step length (metres)	0.37 (0.13), 0.09-0.70	0.34 (0.11), 0.15-0.53
Do you use a walking aid? (yes)	43 (62%)	35 (50%)

Table 2. Showing participants' satisfaction with their ankle foot orthosis at long term (primary outcome) and short term follow up assessment.

	Bespoke AFO at long-term follow up (n=50)	Off-the-shelf AFO at long-term follow up (n=57)	Total at long-term follow up (n=107)	Bespoke AFO at short-term follow up (n=40)	Off-the-shelf AFO at short-term follow up (n=54)	Total at short-term follow up (n=94)
Very satisfied	16	25	41	16	17	33
satisfied	16	16	32	10	16	26
Neutral	6	2	8	3	7	10
Unsatisfied	8	6	14	6	5	11
Very Unsatisfied	4	8	12	5	9	14

AFO = ankle foot orthosis;

Table 3 showing participants' views of using the AFO at short-term and long term (shaded) follow up

	“Yes”	“No”	“Sometimes”
Short-term follow up			
Is the splint comfortable?	Total =58/90 (64%) Bespoke =22/35 (63%) Off-the-shelf =36/55 (65%)	Total =20/90 (23%) Bespoke =7/35 (20%) Off-the-shelf =13/55 (24%)	Total =12/90 (13%) Bespoke =6/35 (17%) Off-the-shelf =6/55 (11%)
Does the splint rub?	Total = 46/92 (50%) Bespoke =18/35 (51%) Off-the-shelf =28/56 (50%)	Total =33/92 (36%) Bespoke =14/35 (40%) Off-the-shelf =19/56 (34%)	Total = 12/92 (13%) Bespoke =3/35 (9%) Off-the-shelf =9/56 (16%)
Is the splint easy to don and doff?	Total =66/92 (72%) Bespoke =24/36 (67%) Off-the-shelf =42/56 (75%)	Total =16/92 (17%) Bespoke =9/36 (25%) Off-the-shelf =7/56 (12.5%)	Total =10/92 (11%) Bespoke =3/36 (8%) Off-the-shelf =7/56 (12.5%)
Can you fit the splint in to your shoes?	Total =20/92 (22%) Bespoke =7/36 (19%) Off-the-shelf =13/56 (23%)	Total = 69/92 (75%) Bespoke =27/36 (75%) Off-the-shelf =42/56 (75%)	Total =3/92 (3%) Bespoke =2/36 (6%) Off-the-shelf =1/56 (2%)
Do you find the	Total =5/91 (5%)	Total =79 (87%)	Total =7 (8%)

appearance of the splint	Bespoke =3/35 (9%)	Bespoke =30/35 (90%)	Bespoke =2/35 (1%)
off-putting?	Off-the-shelf =2/56 (4%)	Off-the-shelf =49/56 (88%)	Off-the-shelf =5/56 (9%)
Long-term follow up			
Is the splint comfortable?	Total =64/106 (60%) Bespoke =26/50 (52%) Off-the-shelf =38/56 (68%)	Total =30/106 (28%) Bespoke =18/50 (36%) Off-the-shelf =12/56 (21%)	Total =12/106 (11%) Bespoke =6/50 (12%) Off-the-shelf =6/56 (11%)
Does the splint rub?	Total =52/108 (48%) Bespoke =24/52 (46%) Off-the-shelf =28/56 (50%)	Total =35/108 (32%) Bespoke =17/52 (33%) Off-the-shelf =18/56 (32%)	Total =21/108 (19%) Bespoke =11/52 (21%) Off-the-shelf =10/56 (18%)
Is the splint easy to don and doff?	Total =70/107 (65%) Bespoke = 29/52 (56%) Off-the-shelf =41/55 (75%)	Total =19/107 (18%) Bespoke =13/52 (25%) Off-the-shelf =6/55 (11%)	Total =18/107 (17%) Bespoke =10/52 (19%) Off-the-shelf =19/55 (35%)
Can you fit the splint in to your shoes?	Total =20/108 (19%) Bespoke =9/52 (17%) Off-the-shelf =11/56 (20%)	Total =84/108 (78%) Bespoke =40/52 (77%) Off-the-shelf =44/56 (79%)	Total =4/108 (4%) Bespoke =3/52 (6%) Off-the-shelf =1/56 (18%)
Do you find the	Total =8/108 (7%)	Total =94/108 (87%)	Total =6/108 (6%)

appearance of the splint	Bespoke =5/52 (10%)	Bespoke =43/52 (83%)	Bespoke =4/52 (8%)
off-putting?	Off-the-shelf =3/56 (5%)	Off-the-shelf =51/56 (91%)	Off-the-shelf =2/56 (4%)

Table 4 detailing the adverse effects reported by participants

	Severe	Moderate	Mild
Total number	12	25	27
Falls	7, all injurious No. admitted = 6	10, all non-injurious No. admitted = 0	16, all non-injurious No. admitted = 0
Skin breakdown and rubbing	3	11	10
Pain	2	4	1

Definition of a severe adverse event = definitely discomforting and preventing normal everyday activities. Definition of a moderate adverse event = causing moderately discomfort and/or interferes with normal everyday activities. Definition of a mild adverse event = causing minimal discomfort that does not interfere with everyday activities)

Table 5. Clinical effects

Outcome	Level	Bespoke	Off-the-shelf	Effect* (95% CI)	p
SHORT-TERM FOLLOW-UP (6 WEEKS) n=126					
Walking Category	Physiological	0 (0%)	0 (0%)	1.3	0.52
	Limited household	8 (13%)	5 (8%)	(0.63 to 2.5)	
	Unlimited household	6 (10%)	11 (17%)		
	Most limited community	15 (24%)	13 (20%)		
	Least limited community	10 (16%)	13 (20%)		
	Unlimited community	23 (37%)	22 (34%)		
	Total	62	64		
FES-I	Mean (SD), range	39.2 (11.7) 16 to 60	33.7 (10.9) 16 to 58	-4.6 (-7.6 to -1.6)	0.003
Gait speed	Mean (SD), range	0.62 (0.29) 0.08 to 1.31	0.58 (0.26) 0.06 to 1.30	0.03 (-0.02 to 0.09)	0.23
Step length	Mean (SD), range	0.41 (0.13) 0.15 to 0.74	0.41 (0.12) 0.10 to 0.64	0.02 (-0.01 to 0.04)	0.18
LONG-TERM FOLLOW UP (12 WEEKS) n=123					
Walking Category	Physiological	0 (0%)	0 (0%)	1.5 (0.74 to 3.1)	0.26
	Limited household	4 (8%)	7 (10%)		
	Unlimited household	8 (17%)	4 (6%)		
	Most limited community	7 (15%)	13 (19%)		
	Least limited community	10 (21%)	12 (18%)		
	Unlimited community	19 (40%)	32 (47%)		
	Total	48	68		

FES-I	Mean (SD), range	35.4 (11.4), 18 to 59	32.5 (11.2) 16 to 58	-1.4 (-4.5 to 1.7)	0.38
Gait speed	Mean (SD), range	0.65 (0.27) 0.09 to 1.25	0.62 (0.28) 0.08 to 1.32	0.04 (-0.02 to 0.10)	0.21
Step length	Mean (SD), range	0.43 (0.12) 0.17 to 0.74	0.41 (0.12) 0.17 to 0.61	0.00 (-0.02 to 0.03)	0.71

* Effect is 'Odds Ratio' from ordinal logistic or 'Mean Difference' from linear regression, adjusting for stratification criteria in the randomisation routine and baseline value of each outcome.

Table 6. Clinical effects by treatment as received

Outcome	Level	Bespoke	Off-the-shelf	Effect* (95% CI)	p
SHORT-TERM FOLLOW-UP (6 WEEKS) n=98					
Walking Category	Physiological	0 (0%)	0 (0%)	1.3 (0.69 to 2.5)	0.40
	Limited household	8 (27%)	5 (7%)		
	Unlimited household	4 (13%)	12 (18%)		
	Most limited community	13 (43%)	15 (22%)		
	Least limited community	5 (17%)	13 (19%)		
	Unlimited community	20 (67%)	23 (34%)		
	Total	30	68		
FES-I	Mean (SD), range	38.1 (12.4), 16 to 61	34.1 (10.7), 16 to 58	-3.8 (-6.7 to -0.9)	0.01
Gait speed (m/s)	Mean (SD), range	0.62 (0.29), 0.07 to 1.31	0.56 (0.27), 0.06 to 1.30	0.03 (-0.03 to 0.08)	0.34
Step length (m)	Mean (SD), range	0.41 (0.13), 0.10 to 0.74	0.39 (0.12), 0.13 to 0.64	0.01 (-0.02 to 0.03)	0.45
LONG-TERM FOLLOW-UP (12 WEEKS) n=117					
Walking Category	Physiological	0 (0%)	0 (0%)	1.3 (0.68 to 2.6)	0.41
	Limited household	4	7 (12%)		
	Unlimited household	8	5 (9%)		
	Most limited community	9	13 (23%)		
	Least limited community	13	9 (16%)		
	Unlimited community	26	29 (51%)		

	Total	60	57		
FES-I	Mean (SD), range	34.2 (11.5) 16 to 59	33.1 (11.3), 16 to 58	-1.4, (-4.3 to 1.6)	0.37
Gait speed(m/s)	Mean (SD), range	0.65 (0.27), 0.09 to 1.25	0.61 (0.30), 0.08 to 1.32	0.04 (-0.03 to 0.10)	0.27
Step length (m)	Mean (SD), range	0.43 (0.12), 0.17 to 0.74	0.40 (0.12), 0.17 to 0.61	0.01 (-0.02 to 0.03)	0.52

* Effect is 'Odds Ratio' from ordinal logistic or 'Mean Difference' from linear regression, adjusting for stratification criteria in the randomisation routine and baseline value of each outcome.

Figure 1. The ankle foot orthoses used in the trial: A typical example of the bespoke ANKLE FOOT ORTHOSIS (left) and an off-the shelf ANKLE FOOT ORTHOSIS (left)

Figure 2. Participant flow