McMonagle, Christine and Rasmussen, Susan and Elliott, Mark A. and Dixon, Diane (2016) Use of the ICF to investigate impairment, activity limitation and participation restriction in people using ankle-foot orthoses to manage mobility disabilities. Disability and Rehabilitation, 38 (6). pp. 605-612. ISSN 0963-8288 , http://dx.doi.org/10.3109/09638288.2015.1055374

Use of the ICF to investigate impairment, activity limitation and participation restriction in people using ankle-foot orthoses to manage mobility disabilities

Christine McMonagle, Susan Rasmussen, Mark A. Elliott & Diane Dixon

Disability and Rehabilitation, Vol 38, pp 605-612

Main Text

Introduction

Ankle-foot orthoses (AFOs) are externally applied devices that encompass the joints of the ankle and foot. They are used to modify the structure and function of the neuromuscular and skeletal systems [1] and are used to manage mobility disabilities caused by a wide range of conditions such as stroke, cerebral palsy, spina bifida, poliomyelitis and peripheral nerve injury[2-6]. AFOs have been shown to improve timed walking speed, step length and clearance of the toe in the swing phase of gait. [2,3,5,7-14]. Whilst these outcome measures are valuable in providing evidence for orthotic intervention, they focus on specific aspects of physical activity that can be measured in a gait laboratory. Consequently, they do not provide any information about patients' use of AFOs in their day to day lives or the extent to which use of AFOs is associated with physical, psychological and social well-being. These outcomes are important because they are of value to the patient. Specifically, consideration of psychological well–being is vital because of its relationship with functional outcomes [15,16]. This paper adds to the literature by focusing on AFO use in a real life setting and by incorporating psychological measures to investigate differences in impairment, activity limitation and participation restriction across 3 groups of AFO users; people using AFOs as recommended, people using AFOs differently to recommended; and those not aware of recommendations for use.

Use of AFOs

To identify differences in outcomes across these groups, consideration should be given to other factors that could affect AFO use. Seriousness of the underlying health condition has been related to AFO use. Increased severity of Charcot-Marie-Tooth (CMT) disease [17] and greater functional impairment in stroke have also been related to increased use of AFOs by patients [18]. In addition, when provided with an orthosis a patient should be given specific wearing instructions [19], as recommended wear time may differ depending on a person's individual circumstances. It is important that people follow the recommended wear times given by the

orthotist as over use may negatively affect functional outcome [20], and under-use or non-use can lead to falls [21], progression of deformity [22], and ulceration [23]. Despite this, adherence rates are varied with Vinci [21] reporting compliance to AFOs as low as 20% for patients with CMT disease. He noted that people chose not to use orthoses because they highlighted their disability and caused discomfort. Also Bakker [24] showed a discrepancy between recommended use and actual use, reporting that 18 out of 25 patients with Duchenne Muscular Dystrophy did not use their AFOs for the recommended amount of time, with all of these participants using the AFO less than recommended. This was thought to be due to pain and patient reluctance to wear the orthotic devices; however reasons for their reluctance were not formally investigated. In summary, appropriate use of orthoses is important for optimal outcomes.

Identification of Health Outcomes

A theoretical approach to understanding use of AFOs and their impact on patient valued outcomes would be useful. Use of a theoretical framework of health outcomes would facilitate the identification of appropriate outcome measures and therefore offers a more structured approach to the development of future interventions [25].

The International Classification of Functioning, Disability and Health (ICF) [26], shown in Figure 1, identifies three distinct health outcomes, namely, impairments to body functions and structures, activity limitations (i.e. limitations in the ability to perform specific actions) and participation restrictions (i.e. restrictions in involvement in life situations). The three health outcomes are interrelated and are all influenced by personal and environmental contextual factors. Therefore the ICF can be used as a framework to examine the impact of health interventions on specific outcomes; impairment, activity limitation and participation restriction [27,28].

Insert Figure 1 here

Measurement of impairment, activity limitation and participation restrictions

When selecting outcome measures, it is important to ensure that outcomes measure the specific construct and do not overlap other constructs in the same theory [29]. If there is poor content validity and the measures used in a study do not discriminate among constructs, any identified relationships may be of questionable value [30].

A candidate core set of outcome measures has been proposed to assess outcomes for lower limb orthotic interventions [31]. These core sets can be used to define impairment, activity limitation or participation restriction [32]. For example, Brehm [31] suggests that appropriate outcomes for the impairment component of the ICF could be gait pattern functions, pain, and exercise tolerance functions. Mobility and moving around in different locations could be used to measure activity limitation, and community, social and interpersonal interactions could be used to measure participation restrictions. However, although the most successful results are achieved in well-motivated patients [31], it appears an anomaly that psychological well-being measures are not considered as part of a core set of outcome measures in orthotic studies. As well as obvious physical factors, studies have shown that psychological factors, such as emotional well-being, cognitions and coping mechanisms can affect functional outcome [33-36]. Within the ICF psychological well-being indicators such as depression and anxiety are classified as impairments to the cognitive system. However standardised measures of psychological well-being or distress have rarely been reported in orthotic studies, and have generally focused on more complex orthoses for spinal cord injury (SCI) [37] or multidisciplinary interventions [35] including orthotic management. In summary, although there is some evidence that orthotic use is related to psychological and social well- being, few studies have used psychological well-being and distress as an outcome measure.

Aims and Hypotheses

The aims of this study were to investigate differences in impairment, activity limitation and participation restriction and psychological distress in 3 groups: participants who used AFOs as recommended, participants who did not use as recommended, and participants who were not aware of recommendations for use. The following hypotheses were tested:

1. participants using their AFOs as recommended will report lower levels of impairment than participants not using their AFOs as recommended;

2. participants using their AFOs as recommended will report lower levels activity limitation than participants not using their AFOs as recommended;

3. participants using their AFOs as recommended will report lower levels of participation restriction than participants not using their AFOs as recommended;

4. Participants using their AFOs as recommended will report lower levels of anxiety and depression than participants not using their AFOs as recommended.

Method

Participants

Participants were 157 patients who had been fitted with an AFO between 2010 and 2012 from an NHS Orthotic Service in Scotland, to manage a functional deficit affecting their lower limb. All participants were aged 18 years old or over. The mean age of the sample was 59 years old (*SD* 16.3) and 46% (n=72) were male. Participants could have been prescribed an AFO for any condition. 53.6% of participants were prescribed an AFO because of a condition caused by damage to the brain (e.g. stroke, multiple sclerosis, traumatic brain injury) and the remaining participants were prescribed an AFO because of damage to another part of the body (e.g. peripheral nerve injury, bone or soft tissue damage).

The mean length of time since the AFOs were fitted to participants was 19.1 (*SD* 11.8) months. Forty one percent of the participants (n=64) had AFOs which were fitted to the right leg; 42.7% (n=67) to the left leg and 16.6% (n=26) to both legs. A total of 183 AFOs were fitted to the sample with the following designs being used: rigid 60.7% (n=111); flexible 29.5% (n=54); ground reaction 2.2% (n=4); jointed 2.2% (n=4); other 2.2% (n=4); unknown 3.3% (n=6). Seventy one percent (n=130) of AFOs were custom made; 19.7% (n=36) were prefabricated; for 9.3% (n=17) of AFOs, it was not known if devices were custom made or prefabricated.

Forty one per cent of the participants (*n* = 64) reported that they used their AFO as recommended; 32% (n=51) reported that they did not use their AFO as recommended (29/51 reported that they did not use their AFO at all, 13/51 reported using it more than recommended and 9/51 reported using it less than recommended); 27% (n=42) did not know the recommendations for use, although all of these participants reported that they were using their AFO. A MANOVA showed that there were no significant differences between non-, under- and over-users on any of the outcome measures, F (24, 74) = 0.916, *ns*, (univariate Fs (2, 48) = 0.08 to 1.32, *ns*). Therefore, in the subsequent analyses these participants were combined into the one group, against which we compared the participants who used their AFOs as recommended and those who did not know the recommendations for use.

Design and Procedure

A cross-sectional design was used. Postal questionnaires were sent to a consecutive sample of *n*=966 adults, drawn from a database held by the Orthotics Service. The questionnaires asked participants to provide information about their demographic and clinical status, their AFO usage, and contained established scales to measure a range of health outcomes that (a) have previously been used to measure the three ICF health outcomes; impairments, activity limitations and participation restrictions, and psychological distress, and (b) could potentially be improved through use of an AFO by patients with a functional impairment of the lower limb. The questionnaire was sent by the Orthotics Service along with an information sheet about the

study. The information sheet stated that participation was voluntary, that there were no right or wrong answers to any of the questions, and that all information would be treated confidentially, and participants were encouraged to answer honestly. Participants returned their completed questionnaire to the research team at the University of Strathclyde using an enclosed stamped addressed envelope. One hundred and sixty one participants (17%) returned the questionnaire. This response rate is broadly comparable with previous postal surveys of patient groups with complex health conditions [38,39]. Out of the 161 participants who responded, 4 did not indicate if they used their orthoses as recommended, and were excluded from any further analysis leaving a final sample of 157. Ethical approval for this study was obtained from NHS West of Scotland Research Ethics Committee (11/AL/0263) and the University of Strathclyde Ethics Committee (UEC 110102).

Measures

Demographic and Clinical Measures

Participants were asked to state their age, gender, and postcode sector. Postcode sector was recoded into a deprivation score, using the Carstairs Scores, a measure which reflects access to material resources [40]. These scores provide a summary measure applied to populations rather than a measure of deprivation experienced by an individual. These scores ranged from 1, the most affluent postcode sector to 7, the most deprived. Participants were also asked to state the condition which led to them being prescribed an AFO, and any co-morbidities that they had. Participants were asked to rate the perceived seriousness of their primary condition for which the AFO was prescribed and perceived seriousness of any co-morbidities on a scale of 0 to 3, with 0 being not serious at all and 3 being extremely serious. Perceived seriousness of condition is known to affect physical and psychological health outcomes across a number of conditions [41,42]. Furthermore, many patients using AFOs present with co-morbidities which could also explain higher levels of impairment and activity limitations.

Impairments

Items from the RAND-36 Item Short Form Health Survey [43] were used to measure 4 aspects of impairment namely: General Health Impairment (items 1, 33, 34, 35, 36); pain impairment (items 21,22); Fatigue/energy impairment (items 23,27,29,31); and impairment to emotional wellbeing (items 24,25,26,28,30). All these impairment outcomes have been shown to measure impairment with discriminant validity [44]. The RAND-36 is an established measure of health-related quality of life in which responses to every item are coded from 0 to 100. The mean of all items in the same sub-scale is used as a composite measure for subsequent analyses. All items are scored so that a more positive score indicates a more favourable health status. Five items measure general health (e.g., "In general, would you say your health is: excellent [scored 100], very good [scored 75], good [scored 50], fair [scored 25] or poor [scored 0]"). Two items measure pain (e.g., "How much bodily pain have you had during the past 4 weeks: none [scored 100], very mild [scored 80], mild [scored 60], moderate [scored 40], severe [scored 20] or very severe [scored 0]"). Four items measure energy/fatigue (e.g., "Did you have a lot of energy: all of the time [scored 100], most of the time [scored 80], a good bit of the time [scored 60], some of the time [scored 40], a little bit of the time [scored 20], none of the time [scored 0]"). Five items measure emotional well-being (e.g. "How much of the time during the past 4 weeks have you felt calm and peaceful?: all of the time [100], most of the time [80], a good bit of the time [60], some of the time [40], a little of the time [20], none of the time [0]").The mean of the general health items produced a reliable composite scale (α= 0.84), as did the mean of the pain (α= 0.91), the energy/fatigue (α= 0.74), and the emotional well-being (α= 0.86) items.

Activity Limitations

Seven items from the RAND-36 (items 6-12) physical functioning sub-scale were used to measure activity limitations with discriminant validity (α= 0.91). These items measured the extent to which participant's health limits them in a range of activities (e.g., "Does your health now limit you in walking several blocks (about ½ a mile): a lot [scored 0], a little [scored 50], Not at all [scored 100]"). Questions 3-5 in the RAND 36 have been identified as reflecting a

combination of both impairment and activity limitation constructs and were therefore not considered to be pure measures of activity limitation and were not included in the analysis [44].

Participation Restrictions

Participation (i.e. involvement in life situations) was measured using the social functioning sub scale of the RAND-36 (items 20,32), which contains 2 items (α= 0.86) (e.g., “During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities: all of the time [scored 0], most of the time [scored 20], some of the time [scored 50], a little bit of the time [scored 75], none of the time [scored 100]”).

Mixed Measures –Activity limitations and Participation Restrictions

The RAND-36 contains items that measure both activity limitations and participation restrictions. These mixed items were scored separately from the pure activity and participation items. These measures were role limitations due to physical health problems (items 13-16) and role limitations due to emotional problems (items 17-19). . Four items (α= 0.86) measured role limitations due to physical health problems (e.g., “During the past 4 weeks, have you accomplished less than you would like as a result of your physical health: Yes [scored 0], No [scored 100]”). Three items (α= 0.87) measured role limitations due to emotional problems (e.g., “During the past 4 weeks, have you cut down the amount of time you spent on work or other activities, as a result of any emotional problems: Yes [scored 0], No [scored 100]”).

Psychological Distress - Hospital Anxiety and Depression Scale (HADS)

The HADS [45] was used to measure anxiety and depression; two further indicators of psychological impairment. The HADS includes 14 items; each measured on a 4-point scale and scored from 0-3. Seven items measure anxiety (e.g., "I can sit at ease and feel relaxed”: definitely [scored 3]; usually [scored 2]; not often [scored1]; not at all [scored 0]) and 7 items measure depression (e.g., “I feel cheerful”: not at all [scored 3]; not often [scored 2]; sometimes

[scored 1]; or most of the time [scored 0]. The sum of the 7 anxiety items (α= 0.77) and the sum of the 7 depression items (α= 0.86) produced reliable composite scales.

Statistical Analysis

All questionnaire data were coded and entered into SPSS® Version 20. Descriptive statistics (means and standard deviations) were computed for all measures for the full sample and separately for participants who used their AFOs as recommended, those who did not use as recommended and those who did not know recommendations for use. Differences between these groups in demographic, clinical status and the three health outcomes (impairment, activity limitations and participation restrictions) were tested using a series of between-subjects Analyses Of Variance (ANOVA) for continuous data, and Pearson's chi squared test for nominal data. Planned follow up comparisons were used to test the primary hypotheses using between subjects t-tests. Alpha was set at $\alpha = 0.05$ for all statistical tests.

Results

Demographic and Clinical Characteristics of Sample

The demographic and clinical characteristics of the 3 groups are shown in Table 1.

Insert Table 1 here

There were no significant differences in demographic or clinical characteristics between participants who used their AFO as recommended, those who did not use their AFO as recommended and those who did not know recommendations for use. Therefore, the subsequently reported differences between these participant groups on the ICF outcomes and HADS cannot be attributed to any between-group differences in demographic or clinical status.

Descriptive Statistics

The means and standard deviations in Table 2 show that the sample as a whole scored below the scale mid-points for energy levels, general health, physical functioning and role limitations due to physical problems indicating that the sample in general had moderate to low levels of general health, energy and physical functioning and a high level of role limitations due to physical problems. The sample means were above the scale mid-points for pain, social functioning, role limitations due to emotional problems and emotional well-being indicating that the sample, on average, had moderate levels of pain, moderate to high levels of social functioning, high levels of emotional well-being and a low to moderate level of role limitations due to emotional problems. The mean anxiety and depression scores as measured by HADS were below 8, the value at which clinical levels of anxiety and depression are considered present, indicating that on average participants did not experience clinical levels of anxiety and depression [45].

In line with the study hypotheses, participants who used their AFO as recommended reported less impairment, lower activity limitations and lower participation restrictions than those who did not use their AFO as recommended and those who did not know recommendations for use.

Insert Table 2 here

Testing between group differences in impairment, activity limitation, participation restriction and psychological distress

There were significant between-group differences in one measure of impairment, namely energy/ fatigue $F(2,147)= 3.45$, $p=0.03$, Cohen's f=0.22 (see Table 2). In line with hypothesis 1, planned comparisons indicated that participants using AFOs as recommended reported significantly higher levels of energy $t(df=147)=2.57$, $p<0.01$, $d=0.64$ than participants not using AFOs as recommended. There were also significant between group differences in activity levels, as measured by physical functioning, $F(2,146)= 3.95$, $p=0.02$, Cohen's f=0.23. In line with hypothesis 2, follow-up t-tests demonstrated that participants using AFOs as

recommended reported higher physical functioning *t*(df =146)= 2.57, *p*<0.01, *d*=0.63. Contrary to hypothesis 3, we did not find any differences in the pure construct of participation restrictions, as measured by social functioning between the three groups. Role limitations due to emotional problems *F*(2,125)= 5.27, *p*=0.01, Cohen's f=0.29 demonstrated a significant difference between groups. Follow-up t-tests indicated lower role limitations due to emotional problems *t*(df=89.54)=3.25, *p*<0.01, *d*=0.91. However because this is a combined measure of activity and participation, hypothesis 3 was not supported. There was a significant between-group difference in anxiety *F*(2,148)= 3.70, *p*=0.03, Cohen's f=0.22 (see Table 2). Follow-up t-tests indicated and significantly lower levels of anxiety *t*(df=148)=2.71, *p*<0.01, *d*=0.91, providing some support for hypothesis 4.

Discussion

The aims of this study were to investigate differences in the three ICF outcomes of impairment, activity limitation and participation restriction, and psychological distress in participants using AFOs as recommended, participants who did not use AFOs as recommended, and participants not aware of recommendations for use. Specifically, differences between participants using AFOs as recommended and those not using AFOs as recommended were examined.

For impairment outcomes, participants using their AFO as recommended reported higher levels of energy (a medium to large effect size [46]), when compared to participants who did not use AFOs as recommended. The patients' higher energy levels are supported by experimental studies of AFO use which have found reduced energy expenditure when walking with AFOs [14,47,48]. In this study, people using AFOs as recommended did not report lower pain levels compared to the other 2 groups. In contrast, reduction in pain following use of AFOs has been reported in other studies [49-51] with Jagadamma [49] reporting the importance of appropriate tuning of the AFO-footwear combination in reducing knee pain. However, due to the research design, we were not able to ascertain if the AFOs had been appropriately tuned. Also, participants using their AFOs as recommended may actually use the AFO to reduce their pain to

a more manageable level; i.e. participants using AFOs as recommended may have a higher level of pain when not using their AFO, compared to the group who did not use AFOs as recommended, which may explain why we did not see any significant differences. There was no difference in general health between the groups. A generic measure of health in such a heterogeneous group, with a range of co-morbidities has value in providing an indicator of overall health status. However it may be too generic an outcome measure to be associated with AFO use.

Participants who reported using their AFOs as recommended also reported lower activity limitations than those not using their AFOs as recommended. This finding is consistent with a systematic review and pooled meta-analysis [52] demonstrating significant improvements in objective measures of balance and walking activity when using an AFO after stroke. Key measures used in this review, such as, timed walk tests (walking speed), timed up and go test (mobility), time to ascend and descend stairs (mobility), postural sway and weight distribution (balance), focus on the performance of the patient in the gait laboratory. The measure of physical functioning used in the current study captures use of AFOs while carrying out a range of activities of daily living, and because it is a patient reported measure, may be more likely to be associated with the patient's decision to use the AFO as recommended.

Higher scores in role limitations due to emotional problems (a large effect size) were seen in participants who used AFOs as recommended meaning that daily activities were significantly less likely to be limited by emotional problems. However this measure is not a pure measure of activity limitation but a combination of activity and participation restrictions. Previous studies which have investigated role limitations due to emotional problems in people with mobility disabilities [53] have not specifically investigated any relationship with AFO use. While this is an important finding, the lack of discriminant validity poses challenges in understanding the relationship between ICF constructs.

Contrary to our hypothesis we did not find a significant difference in the pure measure participation restrictions between the three groups, as measured by social functioning. The lack of difference between groups however can be explained by consideration of the ICF model, which suggests that other factors, such as personal and environmental factors as well as impairment can influence social participation. Another possible reason for a lack of significance in this current study may be that people using AFOs as recommended may have lower participation levels if they do not use their AFOs as recommended, compared to the group who do not use as recommended, and this therefore is a motivation to use the AFO. A prospective study would be useful to investigate this. Lack of literature in this area does suggest that participation has been overlooked as an appropriate outcome measure and should be used more routinely.

Participants using their AFO as recommended reported significantly lower levels of anxiety than participants who did not use their AFO (a large effect size [46]), although a difference in depression levels was not seen. Psychological outcomes in orthotics are rarely assessed. However an earlier descriptive study has shown that 58% of participants reported that AFO use was linked to reduced distress and 64% reported that the AFO made them feel better about themselves [2].

In summary, lower levels of impairment, activity limitations and anxiety were found in people using AFOs as recommended compared to people not using AFOs as recommended, not explained by demographic or clinical differences. This suggests the need to investigate more specifically why appropriate AFOs use is associated with reduced impairment, activity limitations and anxiety; and to investigate why some people adhere to use of AFOs as recommended and others do not. This could offer potential opportunities to reduce impairment, and improve activity levels and psychological well-being by identification of strategies to increase the number of patients who use orthoses as recommended.

The high number of participants (n=42, 27%) who were not aware of recommendations for use of their AFO is worth comment. The way in which AFOs are used is of crucial importance in achieving the optimum outcome for patients. While acknowledging that some participants in this sample may also have had cognitive challenges, due to their underlying pathology, and may not have been able to recall recommendations for use, no differences in use were seen between participants whose condition was caused by brain damage and those whose condition was not. When compared with data reported in the Best Practice Statement of 2008 [2], which found that approximately 50% of respondents claimed they did not get any information about the AFO and 40% felt they did not receive clear information, this figure of 27% suggests some improvement in information levels supplied to participants about their AFOs. However the high number of participants who remained unaware of recommendations for use highlights the need for improved communication and information, both verbal and written to assist patients in appropriate use of AFOs.

Use of the ICF

This study has explored differences between participants who used AFOs as recommended and those who do not, using the ICF to identify outcome measures. There is still much work to be done in how the ICF components can be effectively operationalized and related specifically to orthotic use. The relationship between impairment, activity limitations and participation are complex, with the personal and environmental factors adding increased complexity. The role of personal and environmental factors allow the possibility that interventions which aim to reduce impairment, may have a weak impact on activity limitation and participation restriction, and may only affect participation indirectly [54]. Brehm noted that currently there is no consensus on the most appropriate outcome measures, and further work is needed to identify suitability of instruments to the context being investigated [31]. The results of this study suggest the need to incorporate psychological health and well-being measures from the ICF such as energy and drive, and emotional functions to better understand AFO use. The patient's decision to use an

AFO can be considered a behaviour, and therefore psychological theories may also be useful in understanding AFO use and adherence, particularly the cognitive processes underlying AFO use. Therefore further studies investigating AFO use should consider use of social cognitive theories or an integrated ICF model which includes psychological theory [55,56].

Limitations

This study is the first study, to our knowledge, to explore differences in ICF outcomes of impairment, activity limitation and participation restrictions in different groups of AFO users. However this study has a number of limitations. The cross sectional nature of design does not allow causation to be identified. The response rate of 17% suggests that caution should be used in interpreting the results, due to possible sampling bias. The poor response rate may be indicative of a patient group with a high level of physical and psychological co-morbidities which is difficult to recruit. However, a large sample size was selected to deal with an expected low response rate and the number of participants (n=157) is considered a large group of participants for a study about AFOs, compared to other surveys [2,57,58]. Furthermore we consider inclusion of non-users of AFOs as an important strength of this study. Non-users, people who have been prescribed orthoses but choose not to use them, are a challenging group to recruit, and also are unlikely to obtain any benefit in participating, but their inclusion has allowed us to identify important differences between the groups.

Another limitation was that this research was carried out with participants living in a particular area of Scotland, who were provided with AFOs from one orthotic department. Therefore we cannot be sure if the findings would be generalisable to other locations in Scotland, or elsewhere in the UK. As with any questionnaire design, participants in this study used self-reported measures of use. However we feel that participant anonymity and wording in the questionnaire *"Many people find a way of using their orthoses which suits them, or choose not to use them. This may differ from the instructions you have been given"*, may have allowed an honest response regarding use from participants.

While use of AFOs as recommended is recognised as important to outcomes, recommendations for use tend to be based on orthotists' experience rather than evidence. An assumption was made that orthotists who fitted the AFOs gave appropriate instructions regarding use, and we believe this to be a reasonable assumption. However, this does highlight the need for evidence relating to optimal wearing times for AFOs. Finally it is not possible to comment on the fit or function of the AFOs supplied in this study given the research design. Visual assessment of fit and appropriate function would be necessary to control for these factors in a prospective study.

Conclusion

The ICF has been used as a framework to explore differences in impairment, activity limitation and participation restrictions between participants who used AFOs as recommended, those who did not use as recommended and those who did not know recommendations for use. This study has demonstrated significantly lower impairment, as measured by higher energy levels, and lower anxiety in people who use AFOs as recommended; lower activity limitations as measured by physical functioning, and role limitations due to emotional problems which crosses both activity limitations and participation restrictions. Depending on the individual, an orthosis may be either a barrier or a facilitator to a range of activities. Further investigation is required to understand the relationship between psychological variables and AFO use, with a view to developing orthotic interventions that also consider an individual's psychological status. This may allow increased use of AFOs and other types of orthotic management as recommended and therefore positively impact on functioning, activity levels, participation, and psychological well-being of orthotic users.

Acknowledgements

Thanks to Chris Rowley and Irene Martin who assisted in dissemination of the questionnaire

Declaration of Interest

The Orthotics Education and Training Trust (OETT) provided funding to support this research as part of a PhD programme. The authors report no other declaration of interest

References

[1] International Organisation for Standardisation. ISO 8549-3:prosthetics and orthotics vocabulary Part 3.Terms relating to external orthoses. Geneva International Organisation for Standardisation; 1989. p p.1-5.

[2] Bowers R, Ross K, NHS Quality Improvement Scotland. Best practice statement: use of ankle-foot orthoses following stroke. 2009.

[3] Morris C. A review of the efficacy of lower-limb orthoses used for cerebral palsy. Developmental Medicine & Child Neurology 2002;44:205-11.

[4] Polliack AA, Elliot S, Caves C, McNeal DR, Landsberger SE. Lower Extremity Orthoses for Children with Myelomeningocele: User and Orthotist Perspectives. JPO: Journal of Prosthetics and Orthotics 2001;13:123-9.

[5] Lehmann JF, Condon SM, de Lateur BJ, Price R. Gait abnormalities in peroneal nerve paralysis and their corrections by orthoses: a biomechanical study. Arch Phys Med Rehabil 1986;67:380-6.

[6] Waring WP, Maynard F, Grady W, Grady R, Boyles C. Influence of appropriate lower extremity orthotic management on ambulation, pain, and fatigue in a postpolio population. Arch Phys Med Rehabil 1989;70:371-5.

[7] Thomson JD, Ounpuu S, Davis RB, DeLuca PA. The effects of ankle-foot orthoses on the ankle and knee in persons with myelomeningocele: an evaluation using three-dimensional gait analysis. J Pediatr Orthop 1999;19:27-33.

[8] Ross K, Bowers R, ISPO. A review of the efectiveness of lower limb orthoses used in cerebral palsy. International Society for Prosthetics and Orthotics; 2009.

[9] Leung J, Moseley AM. Impact of ankle-foot orthoses on gait and muscle activity in adults with hemiplegia. Physiotherapy 2003;89:39-60.

[10] Gok H, Kucukdeveci A, Altinkaynak H, Yavuzer G, Ergin S. Effects of ankle-foot orthoses on hemiparetic gait. Clin Rehabil 2003;17:137-9.

[11] Pavlik AJ. The Effect of Long-Term Ankle-Foot Orthosis Use on Gait in the Poststroke Population. JPO: Journal of Prosthetics and Orthotics 2008;20:49-52 10.1097/JPO.0b013e3181695630.

[12] Ramdharry GM, Day BL, Reilly MM, Marsden JF. Foot drop splints improve proximal as well as distal leg control during gait in Charcot-Marie-Tooth Disease. Muscle & Nerve 2012;46:512-9.

[13] Doğğan A, Mengüllüogglu M, Özgirgin N. Evaluation of the effect of ankle-foot orthosis use on balance and mobility in hemiparetic stroke patients. Disability and Rehabilitation 2011;33:1433-9.

[14] Balaban Br, Yasar E, Dal U, Yazi¨ci¨oglu Kl, Mohur H, Kalyon TA. The effect of hinged ankle-foot orthosis on gait and energy expenditure in spastic hemiplegic cerebral palsy. Disability and Rehabilitation 2007;29:139-44.

[15] Noël PH, Williams JW, Unützer J, Worchel J, Lee S, Cornell J, Katon W, Harpole LH, Hunkeler E. Depression and Comorbid Illness in Elderly Primary Care Patients: Impact on Multiple Domains of Health Status and Well-being. The Annals of Family Medicine 2004;2:555-62.
[16] Wells KB, Stewart A, Hays RD, et al. The functioning and well-being of depressed patients: Results from the medical outcomes study. JAMA 1989;262:914-9.
[17] Ramdharry GM, Pollard AJ, Marsden JF, Reilly MM. Comparing Gait Performance of People with Charcot-Marie-Tooth Disease Who Do and Do Not Wear Ankle Foot Orthoses. Physiotherapy Research International 2012;17:191-9.
[18] Teasell RW, McRae MP, Foley N, Bhardwaj A. Physical and functional correlations of ankle-foot orthosis use in the rehabilitation of stroke patients. Archives of Physical Medicine and Rehabilitation 2001;82:1047-9.
[19] Felton. The Use of Adherence Monitors with Orthoses. Journal of Prosthetics and Orthotics 1999;11:98-100.
[20] Aubert EK. Adaptive Equipment for Physically Challenged Children. In: Techlin JS, editor. Paediatric Physical Therapy 3rd ed. Philadelphia: Lippincott, Williams & Wilkins 1999.
[21] Vinci P, Gargiulo P. Poor compliance with ankle-foot-orthoses in Charcot-Marie-Tooth disease. Eur J Phys Rehabil Med 2008;44:27-31.
[22] Lannin N, Morris C, Bowers R, Ross K, Stevens P, Phillips D. Orthotic management of cerebral palsy: Recommendations from a consensus conference. NeuroRehabilitation 2011;28:37-46.
[23] Burton F. Adults with Diabetes and thier expereinces of wearing prescribed orthotic devices Wounds UK 2007;3:14-27.
[24] Bakker JPJ, de Groot IJM, De Jong BA, van Tol-de Jager MA, Lankhorst GJ. Prescription pattern for orthoses in The Netherlands: Use and experience in the ambulatory phase of Duchenne muscular dystrophy. Disability and Rehabilitation 1997;19:318-25.
[25] Medical Research Council. Developing and Evaluating Complex Interventions: New Guidance 2008. 39
[26] WHO. International classification of Functioning, Disability and Health: ICF Geneva 2001.
[27] Ayis S, Arden N, Doherty M, Pollard B, Johnson M, Dieppe P. Applying the Impairment, Activity Limitation, and Participation Restriction Constructs of the ICF Model to Osteoarthritis and Low Back Pain Trials: A Reanalysis. The Journal of Rheumatology 2010;37:1923-31.
[28] Fleming J, Kuipers P, Foster M, Smith S. Evaluation of an outpatient, peer group intervention for people with acquired brain injury based on the ICF 'Environment' dimension. Disability and Rehabilitation 2009;31:1666-75.
[29] Pollard B, Johnston M, Dieppe P. Exploring the relationships between International Classification of Functioning, Disability and Health (ICF) constructs of Impairment, Activity Limitation and Participation Restriction in people with osteoarthritis prior to joint replacement. BMC Musculoskeletal Disorders 2011;12:97.
[30] Johnston M, Dixon D, Hart J, Glidewell L, Schroder C, Pollard B. Discriminant content validity: a quantitative methodology for assessing content of theory-based measures, with illustrative applications. Br J Health Psychol 2014;19:240-57.
[31] Brehm M, Bus SA, Harlaar J, Nollet F. A candidate core set of outcome measures based on the International Classification of Functioning, Disability and Health for clinical studies on lower limb orthoses. Prosthet Orthot Int 2011;35:269-77.
[32] Bickenbach J CA, Rauch A, Stucki G, (eds). ICF Core Sets Manual for Clinical Practice 2012.
[33] Johnston M, Morrison V, Macwalter R, Partridge C. Perceived control, coping and recovery from disability following stroke. Psychology & Health 1999;14:181-92.
[34] Schröder C, Johnston M, Morrison V, Teunissen L, Notermans N, van Meeteren N. Health condition, impairment, activity limitations: Relationships with emotions and control cognitions in people with disabling conditions. Rehabilitation Psychology 2007;52:280-9.

[35] Davidson AC, Auyeung V, Luff R, Holland M, Hodgkiss A, Weinman J. Prolonged benefit in post-polio syndrome from comprehensive rehabilitation: A pilot study. Disability and Rehabilitation 2009;31:309-17.
[36] Bonetti D, Johnston M. Perceived control predicting the recovery of individual-specific walking behaviours following stroke: Testing psychological models and constructs. British Journal of Health Psychology 2008;13:463-78.
[37] Guest RS, Klose KJ, Needham-Shropshire BM, Jacobs PL. Evaluation of a training program for persons with SCI paraplegia using the Parastep 1 ambulation system: part 4. Effect on physical self-concept and depression. Arch Phys Med Rehabil 1997;78:804-7.
[38] Gontkovsky ST, Russum P, Stokic DS. Perceived information needs of community-dwelling persons with chronic spinal cord injury: Findings of a survey and impact of race. Disability and Rehabilitation 2007;29:1305-12.
[39] Hatcher MB, Whitaker C, Karl A. What predicts post-traumatic stress following spinal cord injury. British Journal of Health Psychology 2009;14:541-61.
[40] McLoone P. Carstairs scores for Scottish postcode sectors from the 2001 Census. Glasgow2004.
[41] Hampson SE, Glasgow RE, Strycker LA. Beliefs versus feelings: A comparison of personal models and depression for predicting multiple outcomes in diabetes. British Journal of Health Psychology 2000;5:27-40.
[42] Janssens ACJW, van Doorn PA, de Boer JB, van der Meché FGA, Passchier J, Hintzen RQ. Perception of prognostic risk in patients with multiple sclerosis: the relationship with anxiety, depression, and disease-related distress. Journal of Clinical Epidemiology 2004;57:180-6.
[43] Hayes RD, Morales LS. The RAND-36 Measure of health-related quality of life Annals of Medicine 2001;33:350-7.
[44] Pollard B, Dixon D, Dieppe P, Johnston M. Measuring the ICF components of impairment, activity limitation and participation restriction: an item analysis using classical test theory and item response theory. Health And Quality Of Life Outcomes 2009;7:41-.
[45] Zigmond AS, Snaith RP. The hospital anxiety and depression scale. Acta Psychiatr Scand 1983;67:361-70.
[46] Cohen J. Statistical Power Analysis for the Behavioural Sciences. New York Academic Press 1988.
[47] Francheschini M, Massucci M, Ferrari L, Agosti M, Paroli C. Effects on an ankle- foot orthosis on spatio-temporal parameters and energy cost in hemiparetic gait. . Clinical Rehabilitation 2003;17:368-72.
[48] Corcoran PJ, Jebsen RH, Brengelmann GL, Simons BC. Effects of plastic and metal leg braces on speed and energy cost of hemiparetic ambulation. Arch Phys Med Rehabil 1970;51:69-77.
[49] Jagadamma KC, Owen E, Coutts FJ, Herman J, Yirrell J, Mercer TH, Van Der Linden ML. The Effects of Tuning an Ankle-Foot Orthosis Footwear Combination on Kinematics and Kinetics of the Knee Joint of an Adult with Hemiplegia. Prosthetics and Orthotics International 2010;34:270-6.
[50] Johnson MD, Alvarez RG. Nonoperative management of retrocalcaneal pain with AFO and stretching regimen. Foot Ankle Int 2012;33:571-81.
[51] Attard J, Singh D. A comparison of two night ankle-foot orthoses used in the treatment of inferior heel pain: a preliminary investigation. Foot Ankle Surg 2012;18:108-10.
[52] Tyson SF, Kent RM. Effects of an ankle-foot orthosis on balance and walking after stroke: a systematic review and pooled meta-analysis. Arch Phys Med Rehabil 2013;94:1377-85.
[53] de Bruijn IL, Geertzen JH, Dijkstra PU. Functional outcome after peroneal nerve injury. Int J Rehabil Res 2007;30:333-7.
[54] Pollard B, Dixon D, Johnston M. Are the mental representations of people with osteoarthritis consistent with the International Classification of Functioning Disability and Health? Disabil Rehabil 2013;35:1460-5.
[55] Dixon D, Johnston M, Rowley D, Pollard B. Using the ICF and Psychological Models of behaviour to predict mobility limitation. Rehabilitation Psychology 2008;53:191-200

[56] Dixon D, Johnston M, Elliott A, Hannaford P. Testing integrated behavioural and biomedical models of activity and activity limitations in a population-based sample. Disability and Rehabilitation 2012;34:1157-66.
[57] Hanger H, Mulley G. A survey of lower leg braces worn by the over-60s. Clinical Rehabilitation 1991;5:95-101.
[58] Tyson SF, Thornton HA. The effect of a hinged ankle foot orthosis on hemiplegic gait: objective measures and users' opinions. Clin Rehabil 2001;15:53-8.

Tables with Captions

	Full Sample (n=157)	AFO used as recommended (n=64)	AFO not used as recommended (n=51)	Did not know recommendations for use (n=42)	χ^2/F	p
Gender:						
Male (n (%))	72 (45.9%)	35 (64.8%)	19 (35.2%)	18 (42.9%)	3.68	0.16
Female (n (%))	85 (54.1%)	29 (43.9%)	32 (56.1%)	24 (57.1%)		
Age	59.0 (SD 16.3)	59.6 (SD 16.5)	58.5 (SD 16.5)	58.8 (SD 16.3)	0.06	0.94
Deprivation score	4.4 (SD 1.9)	4.4 (SD 1.9)	4.3 (SD 2.0)	4.26 (SD 1.9)	0.09	0.91
Condition:						
Condition caused by damage to brain (n (%))	82 (53.6%)	31 (20.3%)	27 (17.6%)	24 (15.7%)	0.94	0.63
Condition caused by damage to other parts of the body (n (%))	71 (46.4%)	32 (20.9%)	22 (14.4%)	17 (11.1%)		
Self -reported seriousness of condition	2.25 (SD 0.61)	2.30 (SD 0.59)	2.29 (SD 0.61)	2.12 (SD 0.63)	1.34	0.26
Number of co-morbidities	1.56 (SD 1.39)	1.52 (SD 1.47)	1.70 (SD 1.30)	1.46 (SD 1.40)	0.38	0.69
Self- reported seriousness of co-morbidities	1.87 (SD 0.68)	1.93 (SD 0.76)	1.85 (SD 0.70)	1.82 (SD 0.55)	0.21	0.81

Table 1: Comparison of Demographic and Clinical Variables between participants using AFOs as recommended, participants not using AFOs as recommended, and participants who did not know recommendations for use

Construct	Measure	Mean (SD)				*F*	*p*	Cohen's *f*
		Full Sample	AFO used as recommended	AFO not used as recommended	Did not know recommendations for use			
I	General Health	44.4 (24.9)	47.4 (25.6)	41.9 (24.8)	42.9 (24.0)	0.74	0.48	0.10
	Pain	51.6 (30.9)	53.9 (30.8)	48.8 (30.4)	51.6 (32.1)	0.38	0.69	0.07
	Energy/ Fatigue	39.4 (20.9)	43.4 (21.3)	33.2 (21.1)	40.8 (19.0)	3.45	0.03*	0.22
	Emotional Well being	66.3 (21.9)	68.9 (20.1)	61.3 (22.3)	68.4 (23.5)	1.83	0.16	0.16
A	Physical Functioning	45.4 (33.8)	50.9 (34.8)	34.4 (29.6)	50.4 (34.7)	3.95	0.02*	0.23
P	Social Functioning	56.5 (32.1)	60.5 (32.7)	51.2 (31.7)	56.9 (32.1)	1.17	0.31	0.12
A & P	Role Limitations due to Physical Problems	29.6 (37.8)	36.9 (42.5)	25.0 (32.7)	25.4 (36.4)	1.47	0.23	0.15
	Role Limitations due to Emotional Problems	58.1 (44.1)	73.8(40.5)	45.9 (41.6)	52.8 (46.7)	5.27	<0.01**	0.29
Psychol. Distress	Anxiety	7.3 (5.4)	6.1 (4.80)	8.8 (5.4)	7.1 (5.9)	3.70	0.03*	0.22
	Depression	6.89 (4.62)	5.9 (4.1)	7.8 (5.0)	7.2 (4.7)	2.31	0.10	0.18

Table 2[1]: Between group ANOVAs testing differences between participants using AFOs as recommended, participants not using AFOs as recommended, and participants who did not know recommendations for use in measures of body functions and structure, activity and participation

* $p < 0.05$ ** $p < 0.01$

[1] RAND 36 was used to measure impairment (I), activity limitations (A), participation restrictions (P) and combined measure of activity limitations and participation restrictions (A&P). HADS was used to measure psychological Distress: Anxiety and Depression.

Figures with Captions

Figure 1: The International Classification of Functioning, Disability and Health