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Understanding Adherence to Ankle-foot Orthoses: An Application of the Theory of Planned Behaviour

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Author's Declaration

This thesis is the result of the author's own research. It has been composed by the author and has not been submitted for examination which has led to the award of a degree.

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Publications and Presentations

Some of the work carried out in this thesis has been published in a peer reviewed journal and presented at conferences as detailed below:

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Executive Summary

Ankle-foot orthoses (AFOs) are used to manage mobility disability in a wide range of conditions such as stroke, multiple sclerosis, arthritis, and trauma. However, sub-optimal adherence has been identified as a major concern. Poor adherence to AFOs may result in diminished physical and mental health outcomes, and is also an inefficient use of scarce resource. In addition, little is known about the extent of use of AFOs in the longer term. Therefore, this thesis set out to initially understand the prevalence of adherence to AFOs, and the relationship between adherence to AFOs and health and functioning outcomes. The International Classification of Functioning Disability and Health (ICF, WHO, 2001) was used as a framework to define health outcomes. The first investigation was a cross-sectional survey, conducted with 157 participants from NHS Greater Glasgow and Clyde, who had been prescribed an AFO for a range of conditions. The adherence rate to use of AFOs as recommended was 56%. This study demonstrated that AFO use as recommended was associated with better physical and mental health outcomes. Therefore, an understanding of potentially modifiable factors, which can improve adherence to AFOs, offers an alternative method of optimising outcomes of AFO use.

The Medical Research Council's framework for complex interventions (Craig et al., 2013) identifies the need for theory-driven research to inform interventions. Consequently, this thesis used a theoretical approach to attempt to understand adherence to orthoses. Firstly, the Theory of Planned Behaviour (TPB, Ajzen, 1991) was identified as a potentially appropriate model. Then, a meta-analysis was conducted, which drew on the wider health adherence literature, to review the efficacy of the TPB in understanding health adherence behaviours in conditions, which may give rise to an orthotic intervention. This found that the TPB accounted for 28.3% of the variance in intentions and 14% of the variance in adherence behaviours. Attitudes and Perceived Behavioural Control (PBC) were significant predictors of intention, and intention was a significant predictor of behaviour. In line with the TPB, intention mediated the effects of attitude and PBC on behaviour. This suggested the TPB might offer a useful model to investigate adherence to AFOs.

This thesis then applied the TPB to modelling AFO use in people with stroke. Stroke was selected as the focus of this investigation, as it is the leading cause of acquired adult disability worldwide (McGrath, Canavan, & O'Donnell, 2018), and, in the first study, was identified as

the most common condition for which an AFO is prescribed. In addition, Scotland has a high incidence of stroke, compared to other UK nations, and improving the treatment and care of stroke is a clinical priority (Scottish Government, 2014a). In order to conduct a TPB investigation, firstly, a beliefs elicitation study was conducted with 13 participants who had been prescribed an AFO by NHS Lanarkshire following stroke. This study enabled elicitation of attitudinal, normative and control beliefs, in line with the TPB model.

Participants reported more advantages compared to disadvantages of using AFOs, suggesting that they had a generally positive attitude towards AFO use. The most commonly stated advantages were 'increased mobility' and 'supports the position of the leg or foot'. The most common disadvantage detailed was 'discomfort', followed by 'problems with footwear size' and 'problems with footwear style'. Participants also identified a far greater number of people who would approve of AFO use, compared to people who would disapprove of AFO use suggesting that support for use of AFOs from a wide range of normative groups is high. Family and health professionals were the most frequently elicited supporting normative referents. However, participants identified far fewer enabling factors compared to factors which made AFO use difficult, suggesting that perceived control of AFO use may be low in people with stroke. The main barriers to AFO use highlighted by participants were: obstacles in the environment, needing help to put the AFO on and off, the AFO causing pain or discomfort, and low mood or tiredness.

Then, the efficacy of the TPB model in explaining adherence to use of AFOs in people with stroke was investigated. Attitude, subjective norm and PBC were measured at Time 1 and behaviour was measured one month later, at Time 2, using a prospective questionnaire design in 49 participants from NHS Lanarkshire. In this investigation, 63% of people used their AFO as recommended. The TPB accounted for 57% variance in intentions and 43% variance in use of AFOs as recommended. The significant amount of variance accounted for indicates the TPB is a useful model for understanding adherence to AFOs in people with stroke. Attitude was the only significant predictor of intention, and intention was the only significant predictor of behaviour. These findings were broadly in line with the meta-analysis conducted, albeit, with a greater amount of variance explained. The higher level of variance found in the TPB study could potentially be explained by careful design of the questionnaire, and use of an elicitation investigation using participants with the same inclusion criteria, which ensured compatibility of measures.

The relationship between the underlying beliefs, the direct TPB constructs, and intention and behaviour, were analysed, enabling potential targets of a future intervention to be identified. Attitudinal beliefs, normative beliefs and control beliefs were significantly correlated with the direct constructs, demonstrating that the beliefs measured provided a good understanding of the cognitive foundations of attitude, subjective norms and PBC. Analysis of correlations between belief-based measures, intention, and behaviour enabled the identification of beliefs that could be targeted in a future intervention to increase adherence to AFO use. These were positive attitudinal beliefs that AFOs can increase mobility, improve balance, and help a person to improve during rehabilitation, and also negative beliefs that AFOs may cause pain or discomfort, are heavy, and are effortful to use.

This thesis is the first body of work, which has applied a psychological model of behaviour to understanding AFO use in stroke, and therefore makes a significant contribution to the emerging cross-disciplinary field of psychology and physical rehabilitation for mobility disabilities. In addition, this work provides evidence of the efficacy of the TPB as a theoretical model for investigating other health behaviours, and specifically adherence behaviours in stroke. Finally, this investigation has identified potential beliefs, which could be utilised in a future intervention to increase adherence to use of AFOs, by targeting the significant underlying attitudinal beliefs. More research is required to corroborate these findings, and important areas for future research have also been highlighted: there is the need for a stronger evidence base for recommendations for use of AFOs, and researchers should consider a broader range of outcome measures, which are more reflective of the patient experience of using an AFO in a real-world setting.

Chapter 1 Introduction

1.1 Introduction to Chapter

This chapter provides the background context to this thesis. It describes the role of orthoses in the management of long-term conditions, and details orthotic service provision in the Scottish context. The challenge of adherence to orthoses is outlined. This chapter then introduces the International Classification of Functioning, Disability and Health (WHO, 2001) as a framework by which mobility disabilities can be conceptualised and understood. To provide background to the reader, this chapter explains orthotic terminology and the most common types of ankle-foot orthoses (AFOs) used. The role of AFOs in managing mobility disabilities, is then considered. An overview of the evidence for use of AFOs is provided and the ICF is then used as a framework to review outcomes measured in orthotic intervention. Therefore, this provides the context through which adherence, as a health behaviour can be understood.

1.2 Background

The UK has a growing elderly population, with people living longer and with an increasing complexity of long-term conditions (George & Martin, 2016; Office for National Statistics, 2018a; Scottish Government, 2016). For this population, maintaining function and mobility is essential to active aging, and can enable older adults to be valued contributors to society who can lead full and independent lives (WHO, 2007, 2015). The importance of mobility to health, has also been recognised by the Scottish Government which has made staying physically active, a public health priority (Scottish Government, 2018a). In order to maintain movement in people with mobility disabilities, they often require assistive devices to enable them to walk or enhance the quality of their gait. Examples of assistive technologies for mobility include wheel chairs, walking canes, prostheses and orthoses. Globally it has been estimated that 1.5% of the world population, or in excess of 100 million people, require prosthetic or orthotic management (Khasnabis, 2015). In the UK, with a population of 66.04 million people (Office for National Statistics, 2018b), this equates to approximately 1 million people. The main purpose of such devices and technologies is to improve functioning and independence in order to enable people to participate in society and to enhance their overall well-being (WHO, 2018b).

The role of orthoses in managing mobility disability has, until recently, received scant attention. Much of the focus has been on attractive, high-end technology solutions, such as powered wheelchairs, and improvements in prosthetic limb control, including computerised devices (Cowan et al., 2012). However, there has been a growing recognition of the value of orthotics in the management of long-term conditions, not only for individuals who can maintain independent living, but also in the economic benefits that orthotic intervention might offer for society (Hutton & Hurry, 2009; NHS England, 2015). Orthoses are external devices applied to the whole or part of the limb, spine, or head or neck, to assist the neuro-muscular and skeletal systems (ISO, 2006). The type of orthosis is described in reference to the anatomical joints or body segments that it encompasses (e.g., foot orthosis (FO), ankle-foot orthosis (AFO), and knee-ankle-foot orthosis (KAFO)). Orthoses can be used to manage a wide range of people with mobility disabilities, including: children with conditions such as cerebral palsy, muscular dystrophy and spina bifida, people of any age who have experienced trauma such as fractures and burns, athletes recovering from injury or surgery, or older people with longer term conditions such as stroke, arthritis and diabetes (Neilsen, 2000). Orthotic services can support a wide range of health specialities including diabetic care, neurological services including stroke and multiple sclerosis, orthopaedics and trauma (NHS England, 2015). Orthoses can, therefore, be used for a variety of reasons: to protect a joint, to stabilise a limb in the place of weak muscles, to control motion at a joint, to reduce pain, to prevent further deformity, or to off-load a joint. Orthoses can reduce impairment and improve functioning for a range of mobility disabilities. However, the majority of people requiring orthotic services are over 50 years of age (NHS Purchasing and Supply Agency, 2004), and with a demographic shift resulting in a growing elderly population who require orthotics (Khasnabis, 2015), the demand for orthotic services is likely to rise (NHS England, 2015).

1.2.1 Orthotic Provision in the Scottish Context

Scotland's unenviable reputation as the sick man of Europe (Whyte & Ajetunmobi, 2012) suggests an even greater need for orthotic services in Scotland. This reputation is due to the high prevalence of risk factors associated with stroke, heart disease and diabetes, such as high blood pressure, poor diet, lack of exercise and smoking (Scottish Government, 2009, 2018b). The number of people using orthotic services in Scotland is not currently known, although it is estimated that 18 patients per 1000 population are treated annually with orthotics in Scotland (Scottish Orthotic Services Review Group, 2005). However, this figure represents a service at full capacity and does not address the continuing rise in unmet need (Scottish

Orthotic Services Review Group, 2005). Since the Scottish Orthotic Services Review in 2005, there has been a major re-organisation of Orthotic Services in Scotland. However, the number of orthotists employed in Scotland (n=81) (ISD Scotland, 2018a) is still significantly lower than the figure recommended (n=167) during the review in 2005, demonstrating a continuing discrepancy in workforce capacity. Given the likely increased need for orthotics in Scotland, orthotic services still appear to be significantly under resourced.

Indeed, management of long-term conditions such as stroke and diabetes are a government priority (Scottish Government, 2010, 2014a). The Scottish Government's vision for 2020 aims to achieve sustainable services in the face of these changing demographics and Scotland's public health challenges (Scottish Government, 2011). This involves transforming primary care and enabling the integration of health and social care, providing improved heath, and better care in a cost effective manner (Scottish Government, 2016). There is a specific focus on returning people to their home or community environment, as soon as appropriate, with a minimal risk of re-admission to hospital (Scottish Government, 2016). Orthotics can, therefore, play an important role in meeting the changing demands of health care provision to address prevention, early intervention and successful self-management of people with mobility disability.

The economic benefit of orthotic services to the NHS has also been demonstrated: Hutton and Hurry (2009) identified that for every £1 spent on orthotic services, £4 is saved by the NHS. Orthoses are a relatively low cost intervention, which as well as offering improved gait for patients who have long-term impairment, may reduce hospital admissions and time spent in hospital, prevent falls, and increase independence and mobility (Hutton & Hurry, 2009). Therefore, orthotic management appears to offer an invaluable contribution to enable independent living for a growing elderly population, and in meeting the specific health challenges facing the Scottish population, whilst also providing cost efficiencies to the NHS in a difficult economic environment. However, orthotic management will only be successful, and provide the benefits described above, if patients engage with orthotic management, and use their orthoses as recommended by their health care provider.

1.3 The Problem of Sub-optimal Adherence to Orthoses

Non-adherence to orthotic devices is increasingly being recognised as a significant problem (Swinnen & Kerckhofs, 2015) and some authors have recently called for more research into factors affecting acceptance of AFOs (Bulley et al., 2014; Tyson & Kent, 2013). Reduced use or rejection of lower limb orthotic devices may result in increased pain and deformity, increased falls and potentially more hospital admissions, as well as reduced independence and mobility. Additionally, sub-optimal adherence has a financial cost to society, as well as wasted effort on the part of the clinician, and, therefore, represents inefficiency in the health system (Swinnen & Kerckhofs, 2015). From a research perspective, poor adherence to an orthotic intervention may also be a potential reason for ambiguous or contradictory results in research investigations. Adherence rates reported in the literature are varied: Vinci and Gargiulo (2008) reported that only 20% of patients adhered to AFOs in people with Charcot-Marie-Tooth disease[1]. However others have reported higher adherence levels (Nakipoğlu-Yüzer, Koyuncu, Çam, & Özgirgin, 2018; Swinnen & Kerckhofs, 2015). Chapter 2 provides an in-depth look at studies investigating adherence to orthotic interventions.

A few investigations have considered reasons for non-adherence to lower limb orthotic devices from the user perspective (Phillips, Radford, & Wills, 2011; van Netten, Jannink, Hijmans, Geertzen, & Postema, 2010b). Whilst such investigations offer important insights about adherence to orthotic devices, it is not known if higher levels of adherence to orthoses can improve health and functioning outcomes. If it can be shown that higher levels of adherence to orthoses will increase functioning, this offers an opportunity to increase function, by improving adherence to orthoses. Therefore, given the potential for improved outcomes for patients, and cost savings to the NHS, if people adhere to use of orthoses as recommended, it is timely and highly relevant to investigate factors affecting adherence to orthoses with a view to developing future interventions to increase adherence in this patient group and potentially others.

Before adherence to an orthotic intervention to manage mobility disability, can be fully understood, it is necessary to provide some context. Therefore, this introductory chapter considers the way that disability is conceptualised and explains the International Classification of Functioning, Disability and Health (ICF, WHO, 2001), as a conceptual

[1] Charcot- Marie-Tooth disease is a group of hereditary conditions which result in damage to the peripheral nerves. It causes a sensory and motor neuropathy resulting in muscle weakness, and difficulty in walking.

framework for understanding mobility disability and functioning. It then outlines the terminology around use of orthoses; explains the rationale for focusing specifically on ankle-foot orthoses (AFOs); and details different AFO designs and specifications to enable the reader to understand variations of an AFO. The way in which orthoses can improve functioning and activity is outlined. Additionally, an overview of the evidence base for use of ankle-foot orthoses is provided, and then the ICF is used as a framework to understand the outcomes used to measure improvements in body function and structure; and activities and participation, when using an AFO. Therefore, this information will provide the reader with information about the context within which adherence behaviour occurs.

1.4 Conceptualisation of Disability

The way in which a phenomenon such as disability, and the efficacy of an intervention to treat the disability is understood and measured, is a function of how it is conceptualised. Disability has previously been conceptualised as the result of a medical problem or disease process, which requires medical care, and this has been referred to as the medical model (WHO, 1980). For example, difficulties experienced in walking (disability) may be seen following a stroke (the medical problem). There were several criticisms of the medical model, which the social model of disability attempted to address. In the social model, disability was conceptualised as a socially constructed problem, in which an inaccessible environment and the negative attitudes of others towards the disabled person created the disability (Johnston, 1996). Therefore, using the above example, the social model would suggest that difficulties experienced in walking, are caused by challenging environments which do not enable the person to mobilise easily, or by perceptions of others, which may make the person feel uncomfortable when attempting to walk or mobilise. The experience of disability cannot fully be explained by either of these models on their own: disability occurs for the individual in the body, but is also a complex social phenomenon (WHO, 2002). This led to the development of a biopsychosocial model referred to as the International Classification of Functioning, Disability and Health (ICF,WHO, 2001). The ICF as a model aims to radically shift ones' thinking and understanding of disability, and focus on the functioning of the individual (WHO, 2002). It therefore can enable a better understanding of the experience of health and functioning of a person with mobility disability.

The ICF, seen in Figure 1.1 below, provides a conceptual framework for understanding the impact of a health condition on body functions and structures, activities and participation, as well as environmental and personal factors that may impact on disability and rehabilitation. The ICF was developed in response to criticisms of the previous International Classification of Impairments, Disabilities and Handicaps (ICIDH, WHO, 1980). The ICIDH reflected the medical model of disability, and focused on the consequences of the disease on the individual. It therefore did not provide a holistic understanding of other contextual factors which might impact on disability such as environmental barriers (Kostanjsek, 2011). The ICF 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. The interactions between the components work in both directions, as seen in Figure 1.1 below. Personal factors include characteristics of the individual which are not part of the health condition and incorporate a range of constructs such as gender, age, social background, education, habit, past and current experience, behaviour pattern, psychological assets, such as coping mechanisms, and other factors which might influence the experience of disability (WHO, 2001). Personal factors are not specifically classified in the ICF because they are associated with significant social and cultural variances (WHO, 2013). Environmental factors refer to the physical, social and attitudinal environment within which one resides, which may act either as a barrier or facilitator to the way in which individuals live their lives (WHO, 2002).

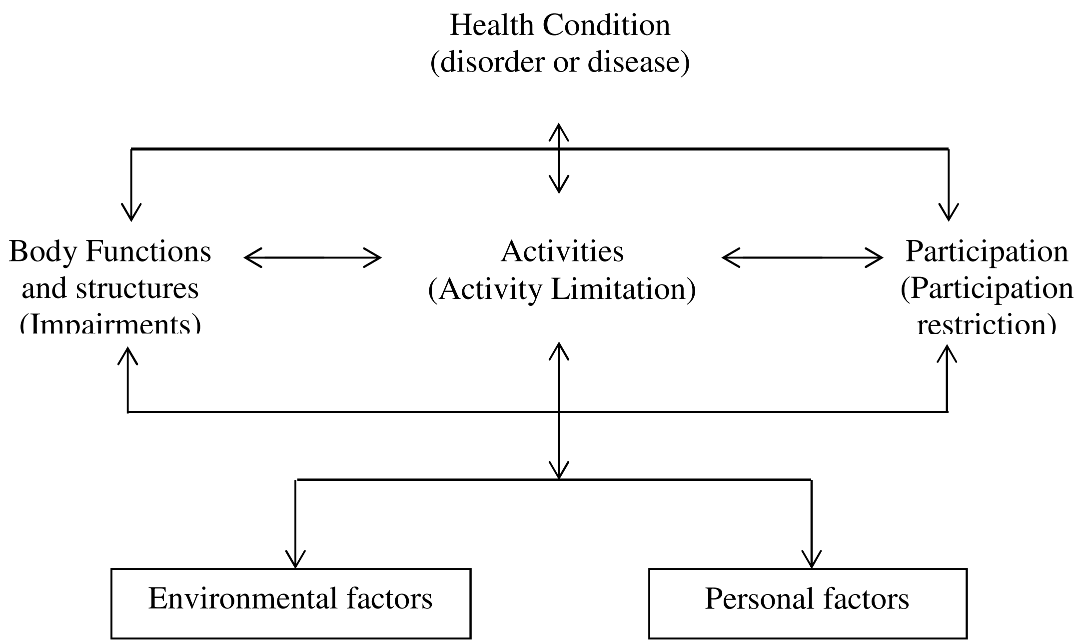

Figure 1-1: The International Classification of Functioning, Disability and Health

Each component consists of several domains (e.g., neuro-musculoskeletal and movement related functions), and each domain contains categories (e.g., function of joints and bones). Functioning and disability of an individual can be described by the categories within these domains, using qualifiers to describe the presence and severity of a problem in functioning (WHO, 2013). For the body function and structures component, a qualifier can be used firstly to denote the presence of an impairment, and then the severity of the impairment, on a five-point scale. For the activity and participation domains, two qualifiers are used: the performance qualifier which details what the participant can do in their own environment; and the capacity qualifier details an individual's ability to perform a task or action, and therefore the highest probable level of functioning in a specific domain. Information about both performance and capacity qualifiers, allows the gap between capacity and performance to be identified (WHO, 2002).

The ICF offers a comprehensive approach to understanding health and disability, compared to its predecessor, the ICIDH (WHO, 2001). It recognises that the level of disability is not simply explained by the impairment, and recognises the reciprocal relationships between body function and structure (or impairment), activity (or activity limitations) and participation (or participation restrictions) (Dixon, Johnston, Rowley, & Pollard, 2008). The ICF also provides a common language for describing health and disabilities, and, therefore, offers opportunities for improved communication between different stakeholders: clinicians, people with disabilities, researchers, and policy-makers (WHO, 2002). The ICF can also be used as a framework to understand and evaluate outcomes for an intervention (WHO, 2013), such as an orthosis. However, before outcomes of orthotic intervention can be evaluated, it is essential to understand orthotic terminology and variations in orthotic design.

1.5 Orthotic Terminology

International Organisation for Standardisation (ISO) terminology provides a systematic and an unambiguous method of describing the device, treatment objectives and functional characteristics of an orthosis (Condie, 2008), and will be used throughout this thesis. An AFO is an externally applied device encompassing the foot and ankle joints, used to modify the structure and function of the neuromuscular and skeletal systems (ISO, 1989, 2006). The term orthosis is derived from the Greek word 'ortho' which means to straighten or align (Seymour, 2002). In general, orthoses are named after the joints that they encompass, so for example, a knee-ankle-foot orthosis (KAFO) also encloses the knee joint and a foot orthosis (FO) encloses the joints of the foot, but does not extend more proximally above the ankle joint. Alternative names sometimes used to describe an AFO include: splint, brace, below knee brace or foot-drop brace. The term 'orthotic' is often erroneously used to refer to an orthosis. However, 'orthotic' is an adjective used to describe a noun (e.g., orthotic device, orthotic clinic). An Orthotist is an allied health professional who provides gait analysis and then engineers solutions for patients with a range of neuro, muscular and skeletal problems (BAPO, 2018). They design, fit, provide and monitor orthoses for this population. In the UK, the title of 'orthotist' is a protected title by law and can only be used by those who have registered with the regulatory body (HCPC, 2017).

Ankle-foot orthoses (AFOs) are the most commonly used orthoses for mobility disability (Whiteside, 2015). AFOs are used routinely to manage functional difficulties seen in a wide range of conditions affecting mobility such as stroke (Condie & Bowers, 2008; Pavlik, 2008), poliomyelitis and post-polio syndrome (Jubelt, 2004), traumatic nerve injury (de Bruijn, Geertzen, & Dijkstra, 2007), cerebral palsy (Morris, 2002), myelomeningocele[2] (Thomson, Ounpuu, Davis, & DeLuca, 1999), and osteoarthritis (Huang et al., 2006). Therefore, this thesis will focus on AFOs. To assist the reader, a brief overview of AFO prescription options is provided, as these designs are referred to elsewhere in this thesis.

1.6 Ankle-Foot Orthosis Design and Specification

Orthoses are prescribed, designed and fitted in order to address the specific functional deficit affecting the individual rather than the diagnosis or health condition (O'Connor et al., 2016). The functional deficit can be determined, based on the findings of physical examination and observation of gait. There are a range of different AFO designs including rigid (or solid), which blocks ankle motion; jointed, which allows motion within a specific range; flexible, also known as posterior leaf spring which offers some resistance to motion; and ground reaction AFO (GRAFO), which is designed to reduce knee flexion in the stance phase of gait[3] (Lin, 2000). These designs can be seen in Figure 1.2 below.

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[2] Myelomeningocele is a type of Spina Bifida where the spinal cord and meninges protrude from the spinal column due to a lack of fusion of the vertebrae of the spine.

[3] A gait cycle involves a period of weight bearing (referred to as stance phase) and a period of non-weight bearing forward motion (referred to as swing phase). One gait cycle lasts from the moment the foot contacts the ground, until the same foot makes the next contact. A gait cycle consists of a stance phase and a swing phase. Stance phase can be further broken down into the following phases: initial contact, loading response, mid stance, terminal stance and pre-swing. The separate stages of swing phase are termed: initial swing, mid swing and terminal swing (Perry, 2008).

	Rigid (Solid) AFO		Flexible (Posterior Leaf Spring) (PLS) AFO
	Jointed AFO with plantarflexion stop		Ground (Floor) Reaction AFO

Figure 1.2: Different AFO Designs made of Polypropylene

(Images courtesy of National Centre for Prosthetics and Orthotics, Department of Biomedical Engineering at the University of Strathclyde)

There are a range of other specifications that can influence the design and fit of the AFO, such as material choice, customisation, and footwear. As these factors have previously been suggested to influence adherence to use of AFOs (Bulley, Shiels, Wilkie, & Salisbury, 2011; Malas, 2011; Swinnen et al., 2017a) they are detailed further below.

1.6.1 Material Choice

An AFO, as seen in Figure 1.2, is most commonly made of polypropylene, a thermoplastic material, which is heat moulded onto a model of an individual's leg. However, AFOs may also be made of other materials, such as carbon fibre, silicone or metal and leather. These materials have their own advantages and disadvantages. Polypropylene is low cost, is easy to manufacture as a customised device, and is available in a range of different colours (Showers & Strunk, 1984), although it is sometimes considered to be bulky. Carbon-fibre is increasingly being utilised, and is thinner, and lighter in weight compared to thermoplastic materials (Brehm, Beelen, Doorenbosch, Harlaar, & Nollet, 2007). However, carbon fibre is more expensive, difficult to adjust after manufacture, and may be prone to sudden failure if it is not manufactured under the correct conditions. Silicone can also be used to make a more flexible type of orthosis, and whilst it provides a good cosmetic result, it can be heavier in weight than other options, and may increase perspiration for the user (Del Bianco & Fatone, 2008). Material selection is an important factor to consider when prescribing an AFO because issues such as weight and cosmesis, which are directly influenced by material choice, have been identified as possible contributing factors to non-adherence to orthoses (Swinnen & Kerckhofs, 2015; Vinci & Gargiulo, 2008). Generally, it is the orthotist who decides on the material being used in the orthotic prescription. However, in NHS settings, use of more expensive materials such as carbon-fibre or silicone, may require an application to an NHS board by the orthotist in order to provide additional funding (O'Connor et al., 2016).

1.6.2 Customisation

Plastic AFOs may either be custom-made, that is made for a specific individual, or prefabricated, which is pre-made to a standard size and then fitted to the patient. A custom-made AFO provides maximal control of the joints of the patient's foot and ankle, due to its close anatomical fit with the patient's lower limb (Bowers, Ross, & NHS Quality Improvement Scotland, 2009b). Pre-fabricated devices may not be able to give an exact fit to match the client, and, therefore, may not be able to control movement of the patient's joints within the device to the same extent. Plastic AFOs offer a relatively low cost intervention, costing anywhere between £20 for a pre-fabricated AFO purchased online (Amazon, 2019) to £487 for a custom-made and fitted AFO provided by a private service (London Orthotic Consultancy, 2019). Before an orthotist fits an AFO, they should assess the patient for the most appropriate orthotic design and if required, provide a customised orthosis to meet the functional deficit (Condie & Bowers, 2008). An orthosis that does not address the functional deficits, or does not fit well, may be uncomfortable and offer little functional benefit, and consequently is more likely to be discarded (Malas, 2011; Vinci & Gargiulo, 2008).

1.6.3 Footwear

Plastic AFOs are designed to fit in regular footwear and the footwear is considered to be an integral part of the orthotic management (Bowers et al., 2009b). The ideal footwear needs to be of an appropriate heel height (Lunnen & Loftspring, 2018), supportive, wide and deep enough able to accommodate the additional space that an AFO takes up inside the footwear. Therefore, the AFO and footwear should be considered in combination. It is the amalgamation of these elements together that determines the biomechanical effect of the orthosis on gait and this is termed the AFO-footwear combination (Owen, 2004). Consequently, if the patient does not use the recommended footwear with the AFO, they may have less than optimal results. Footwear is an important consideration in orthotic use because footwear style has previously been identified a factor in non-adherence to orthotic devices (Phillips et al., 2011; Swinnen et al., 2017a).

1.7 Objectives of AFOs in Management of Mobility Disability

The overall aim of an AFO is to improve function and enable participation in daily activities (Yamane, 2018). The more specific objectives of an AFO will differ depending on the patient's individual functional loss, although AFOs use a biomechanical approach to relieve pain, immobilise musculoskeletal segments by limiting or directing joint motion, prevent or correct deformity, and improve function (Esquenazi, 2008). The objectives of the AFO will be decided during patient assessment, and will aim to address the functional problems identified by the clinical team. This in turn will determine the design and specification of the AFO. In order to provide the reader with an example of how AFOs can be used to address functional gait difficulties, a common gait deviation, hemiplegic gait is described and the effects of the AFO on this gait pattern are detailed.

1.7.1 Hemiplegic Gait and the Role of AFOs in its Management

Hemiplegia is a common gait problem for which an AFO is prescribed (Bowers et al., 2009b; Gok, Kucukdeveci, Altinkaynak, Yavuzer, & Ergin, 2003; Leung & Moseley, 2003; Tyson & Thornton, 2001). Hemiplegia refers to a paralysis of one side of the body, whereas hemiparesis refers to a slight paralysis or weakness of one side of the body (Headway, 2013). Hemiplegia and hemiparesis and can be seen in several conditions, including stroke, cerebral palsy, and traumatic brain injury (Balaban & Tok, 2014; Esquenazi, 2008; Morris, 2002).

Hemiplegic gait[4] will be described in more detail below to assist the reader in understanding how an AFO addresses the functional problems seen in pathological gait.

Any disease or injury causing damage to the central nervous system can cause hemiplegia or hemiparesis. Therefore, hemiplegia or hemiparesis is only one aspect of the functional deficit; increased muscle tone[5], lack of co-ordination, problems with balance and perceptual disorders may also contribute to challenges in walking (Davies, 2000). Hemiplegic gait is often described as slow and stiff, with reduced step and stride length, reduced speed, an increased amount of time spent in double support[6], and with asymmetrical motion of the legs (Perry, 2008). The foot is often in a plantarflexed position, with the toe pointing downwards. This is most commonly described as a 'drop foot', and is seen during the swing phase[7] of gait, and can be a tripping hazard (Bowers et al., 2009b). However, as well as affecting the swing phase of gait, a plantarflexed foot has a negative effect on the stance phase. Initial contact with the floor may be made with the forefoot rather than the heel, and the foot may remain plantarflexed throughout the stance phase with the heel not contacting the floor. This alters the normal biomechanics of walking, and impacts on the position of the more proximal joints of the limb: the knee tends to remain in extension during stance phase, and the hip tends to remain in flexion because of abnormal forces acting at the foot and knee (Bowers et al., 2009b).

AFOs can help to maintain the foot in an optimally aligned position which provides stability in stance phase, and can help to improve balance, as well as allowing clearance of the foot during swing phase and reducing the potential for trips and falls (Bowers et al., 2009b). In turn, when orthoses are appropriately aligned, they can positively influence the position of the more proximal joints in walking (Carse, Bowers, Meadows, & Rowe, 2014; Jagadamma et al., 2010). The final part of Chapter 1 will provide an overview of the evidence for use of AFOs, and then use the framework of the ICF to consider the evidence in relation to the ICF outcomes. Whilst the focus is on use of AFOs in hemiplegic gait, the evidence also draws on other functional gait problems where appropriate.

[4] Hemiplegic gait and hemiparetic gait are similar, although the problems experienced with hemiplegic gait are more pronounced.
[5] Muscle tone is the normal resting tension in a muscle. In a disorder affecting the brain or the spinal cord this resting tension or muscle tone may be increased causing stiffness and difficulty in initiating movement.
[6] Double support refers to the time during gait when both feet are on the ground at the same time.
[7] The swing phase is when the leg is when the foot is swinging though and not in contact with the ground.

1.8 Overview of Evidence for Use of AFOs

Most of the higher quality evidence for use of AFOs has been conducted in patients with stroke, who present with hemiplegia, possibly because this condition represents the largest relatively homogenous group of patients, who require orthotic intervention. A range of systematic reviews and meta-analyses have been conducted which provide evidence for use of AFOs following stroke (Bowers et al., 2009b; Ferreira et al., 2013; ISPO, 2004; Tyson & Kent, 2013; Tyson, Sadeghi-Demneh, & Nester, 2013), although there is some controversy regarding the AFO design which may be optimal to manage the mobility problems seen in stroke. Some authors favour the use of articulated AFOs which allow some movement in the ankle (Ramstrand & Ramstrand, 2010; Tyson & Thornton, 2001), whereas others recommend a rigid AFO, which blocks ankle motion, and, as a result, encourages a more normalised gait pattern of hip and knee extension in terminal stance (Bowers et al., 2009b). A recent review found that both orthoses can provide support for the foot in stance and swing phase (Daryabor, Arazpour, & Aminian, 2018). Regardless of this area of uncertainty, there is a wealth of evidence supporting the use of AFOs to manage mobility disability in stroke (see above), and in addition, National Clinical Guidelines (Royal College of Physicians, 2016; Scottish Intercollegiate Guidelines Network, 2010) which recommend their use.

Other conditions for which high level evidence exists to support use of AFOs includes cerebral palsy (Bowers, Ross, & ISPO, 2009a; Morris, 2002), although the majority of investigations reported in the literature focus on use of orthoses in children. In addition, some reviews have focused on the effect of AFOs on specific aspects of mobility disability such as knee instability (McDaid et al., 2017), muscle weakness (van der Wilk, Dijkstra, Postema, Verkerke, & Hijmans, 2015), or balance (Ramstrand & Ramstrand, 2010). These reviews encompass multiple conditions such as stroke, poliomyelitis, and multiple sclerosis. Consequently, these reviews provide effective evidence for use of AFOs to manage mobility disability in general, but do not detail the effect of AFOs on outcomes for individual health conditions. However, this is perhaps of less concern when it is considered that orthoses are designed to manage the functional impairment caused as a result of the condition rather than the condition per se (Yamane, 2018).

1.9 Application of the ICF to Understanding Evidence for Orthoses

Use of the ICF to understand the efficacy of an orthotic intervention does not appear to be problematic. Indeed, there are many aspects of orthotic intervention, which appear particularly relevant when considering the context of the ICF. Firstly, the definition of an orthosis (See Section 1.5) refers to modification of the structure and function of the neuromuscular and skeletal systems (ISO, 2006). Also, AFOs are used to reduce impairment (Bowers et al., 2009b; Chisholm & Perry, 2012; Daryabor et al., 2018). Thus, the language used in describing orthoses and their functions is similarly reflected in the language of the ICF. Secondly, patients are prescribed their AFO based on the functional deficit, which is assessed by physical examination and analysis of gait, i.e. the orthotic design or prescription is based upon the level of functioning as opposed to the diagnosis or clinical condition (O'Connor et al., 2016). In the same way, the ICF focuses on level of functioning and is considered to be 'aetiology-neutral' (i.e., it can be applied across multiple conditions) (WHO, 2013, p.5). This enables comparison across different health conditions. Thirdly, it is recognised that the contextual factors (i.e., personal and environmental factors), which influence health and functioning, should be considered in order to obtain the optimal orthotic prescription (Yamane, 2018). Therefore, it appears a logical step to then consider the impact of such a reduction in impairment on a person's activity and participation, to gain a more complete understanding of the value of the orthotic intervention. Therefore, the ICF would appear to be a highly relevant framework for understanding functional losses seen and comprehending the impact of orthotic intervention on functioning.

However, in general, the evidence for AFO use has not been considered in the context of the ICF. Understanding the evidence for use of AFOs through the prism of the ICF, is valuable because it offers an overview of the effects of an AFO on different aspects of health and disability, and can guide choice of appropriate outcome measures in orthotic investigations. Additionally, it can highlight gaps in evidence, which have not previously been considered. Brehm, Bus, Harlaar, and Nollet (2011) have contributed to the debate by suggesting a candidate set of outcome measures, based on the ICF, which might be used in orthotic investigations. For example, the body function and structure component of the ICF could be investigated by measuring gait pattern functions (e.g., quantifying the effect of the AFO on gait kinetics and kinematics), pain (e.g., by use of validated pain scales), or exercise tolerance functions (e.g., energy cost of walking). Whilst they acknowledged that motivational factors would play a significant role in obtaining success in an orthotic intervention, the absence of mental-health or well-being outcomes in their suggested core outcome measures for orthotic intervention was surprising.

One investigation, which has aimed to identify the feasibility of using the ICF in a prosthetics/ orthotic outpatient clinic (Burger, 2011), used ICF codes to describe functioning in 100 participants, and aimed to demonstrate the effect of a prosthesis or orthosis on a person's functioning. The most frequently used category for body functions was mobility of joint functions, and the most frequently used category for body structures was structure of the skin. For activities and participation, the most common category was walking, followed closely by moving around. She found that the qualifiers of capacity and performance were required to demonstrate the influence of prosthetic and orthotic devices on a person's function. Whilst general background data such as age and gender were collected, personal factors were not specifically addressed, and measures of psychological assets, behaviour patterns, or well-being outcomes were not included. Whilst this study demonstrates the feasibility of using the ICF routinely in a clinical setting, the absence of psychological well-being outcomes highlights that this important aspect of health and functioning is not being considered in orthotic clinics.

In identifying the outcomes which are frequently used in orthotic investigations, the majority of investigations evaluate aspects of body function and structure (e.g., gait pattern functions such as the angulation of a joint at a particular point of the gait cycle) or activities related to distinct aspects of walking (e.g., walking speed or distance) (Brehm et al., 2011). These outcomes are quite specific, and do not reflect the potential impact that AFOs could have in a person's everyday life. As AFOs are designed to modify body function and structure (ISO, 1989), they might be expected to reduce activity limitations, and increase participation in activities and society. As such, it would be expected that AFO use would be associated with patients' psychological and social well-being. Therefore, whilst AFOs are expected to positively impact on body function and structure, activity, and participation, the evidence for effects of AFOs on psychological well-being should also be considered. Therefore, Sections 1.9.1- 1.9.3 will use the ICF as a framework to provide an overview of the evidence for efficacy of AFOs in reducing impairment, activity limitation, participation restriction and psychological distress, highlighting the outcome measures which are used. This, therefore, will assist in identification of gaps in the evidence base for AFOs.

1.9.1 Effects of AFO on Impairment

Body functions/structures and their associated impairments refer to the physiological functions of the body (including psychological functions), whereas impairments refer to limitations to body function or structure, resulting in a significant deviation or loss (WHO, 2002). Body functions and structures include mental functions, sensory functions (and pain), functions of the cardiovascular and respiratory system, and neuro-musculoskeletal and movement related functions. Brehm et al. (2011) proposed that for the ICF component of body function and structure, the functions of joints, muscles and bones, gait pattern functions or pain, or exercise tolerance functions could be measured.

Given that AFOs are designed to alter the biomechanics of walking (Tyson et al., 2013), it is not surprising that the majority of studies, which investigate the efficacy of AFOs, tend to focus on effects of AFOs on gait. Assessment of the effects of AFOs on gait pattern are typically carried out by observation in the orthotic clinic, although these effects can be more accurately measured using 3-D instrumented gait analysis systems. The most commonly measured outcomes in lower limb orthotic intervention relate to temporal-spatial parameters of gait, and kinematics and kinetics of gait. Temporal-spatial parameters of gait are outcomes related to time and distance, such as velocity and cadence[8] (Levine, Richards, & W Whittle, 2012). Kinematics of gait refers to the study of motion of joints or body segments during walking, whereas kinetics of gait refers to the study of forces acting on the body during gait (Levine et al., 2012). Evidence relating to these outcomes is considered below.

Researchers have highlighted increased cadence in gait (Mojica et al., 1988; Nikamp et al., 2017; Tyson & Thornton, 2001); increased walking speed (Ferreira et al., 2013; Franceschini, Massucci, Ferrari, Agosti, & Paroli, 2003; Gok et al., 2003); and step and stride length (Leung & Moseley, 2003; Pavlik, 2008; Wang et al., 2005) in patients with hemiplegia, or hemiparesis, when walking with an AFO. These findings mean that people can walk faster, and walk a greater distance over the same time period, when walking with an AFO compared to walking without an AFO.

AFOs have been shown to have a positive effect on kinematics and kinetics of gait. Tyson et al. (2013), in a meta-analysis of 20 trials on the biomechanical effects of AFOs on stroke patients found that AFOs had a positive effect on ankle kinematics ($p< 0.00001–0.0002$); knee kinematics in stance phase ($p < 0.0001–0.01$); and kinetics ($p = 0.0001$), although they did not find a difference in knee kinematics in swing phase or hip kinematics. Tyson et al. did not consider the effects of different AFO designs as a moderator in this investigation. A few investigations have supported the use of rigid AFOs, which were appropriately tuned (Carse et al., 2014; Jagadamma et al., 2010) in positively influencing joint kinematics. However, a

[8] Cadence refers to the number of steps taken per unit of time (usually per minute).

more recent systematic review by Daryabor et al. (2018) investigated the effect of different AFO designs on kinetics and kinematics and found that all AFO designs had positive effects on ankle kinematics in early stance phase and swing phase, but not on knee kinematics in swing phase or hip kinematics. These findings, taken together, suggest that a range of different AFO designs can positively impact on ankle motion during gait, although the evidence for improvement (i.e. normalisation) in proximal joint motion is currently limited.

Pain is another outcome, related to the body function/ structure component of the ICF. Pain may be caused by overuse or increased loading though joints, and AFOs are often prescribed to reduce pain by blocking abnormal or painful motions (Shine & Bongiovanni, 2009). There is some evidence that AFOs can reduce or prevent pain (Bek, Öznur, Kavlak, & Uygur, 2003; O'Connor et al., 2016; Oleson et al., 2017; Presuto, Stickley, Perlsweig, Kimura, & Antoine, 2013) across a range of conditions including posterior tibial tendon dysfunction, neuromuscular conditions, haemophilia, and nerve injury. However, this evidence is considered low level, with only non-controlled studies, qualitative analyses and case studies documenting this effect.

Exercise tolerance functions are also suggested by Brehm et al. (2011), as useful outcomes which might be measured under the body function/ structure component of the ICF. Exercise tolerance functions include walking efficiency and energy cost of walking. Corcoran, Jebsen, Brengelmann, and Simons (1970) found a significant reduction in oxygen consumption, when using both plastic and metal AFOs, compared to not using an AFO in people with stroke. Balaban et al. (2007) also found a significant reduction in oxygen consumption in children with hemiplegic cerebral palsy when using hinged AFOs. A few other studies have measured the effect of AFOs on energy expenditure, and have found a decrease in energy cost related to AFO use in adults with stroke and multiple sclerosis (Bregman, Harlaar, Meskers, & de Groot, 2012; Danielsson & Sunnerhagen, 2004; Franceschini et al., 2003; Tyson et al., 2013). Whilst all the outcome measures highlighted above, provide useful evidence of the efficacy of AFOs, they do not inform clinicians and researchers if these benefits are translated to the AFO user. Therefore, use of outcomes linked to activity and participation are essential to understand the effects of reduced impairment on mobility and function.

1.9.2 Effects of AFOs on Activity Limitations and Participation Restrictions

In the ICF, activity is defined as the execution of a task or action by an individual, and activity limitation is defined as difficulties an individual may have in executing activities.

Participation is defined as involvement in a life situation and participation restrictions are defined as problems an individual may experience in life situations (WHO, 2002). Activities and participation include a range of different domains such as mobility, self-care, communication and domestic life. These domains can be broken down into different categories, so, for example, mobility may comprise of: maintaining a body position, changing a body position and transferring oneself, walking; moving around, and moving around in different locations.

In orthotic investigations, outcomes, which have been measured in relation to activities, have measured mobility (e.g., the effect of the AFO on moving around the environment) and function (e.g., on balance). For example, Tyson and Kent (2013), in a meta-analytic review, investigated the effects of AFOs on balance and mobility in people with stroke, and found a significant and beneficial effect of AFO on mobility[9] ($p<0.001$) and balance ($p=0.003$). Nolan, Savalia, Lequerica, and Elovic (2009) and Hung, Chen, Yu, and Hsieh (2011) both used the 6-Minute Walk Test (6MWT) to measure functional ambulation in patients with hemiplegic stroke and found significant improvements ($p=0.002$, and $p<0.01$ respectively) when using an AFO. The 6MWT is a more reflective measure of functional ambulation, as it corresponds more closely to activities conducted in daily life (Guyatt et al., 1985). Both authors reported benefits were greater for individuals with reduced speed of walking. This suggests that users with more severe levels of functional loss following stroke, may gain more advantage (in walking speed) from orthotic intervention than those with less severe functional impairment.

No investigations into AFOs have specifically measured the effects of AFOs on participation or participation restrictions. However, a number of studies have looked at the effect of AFOs on quality of life. Quality of life is defined as an individual's perception of their position in life, in the context of the culture and value systems within which they live, and in relation to their goals, expectations, standards, and concerns (WHO, 1997). Consequently, quality of life measures consist of a number of scales which identify different aspects of body function and structure, activity and participation. These scales are then combined together to obtain on

[9] Mobility was measured using Functional Ambulation Category (Mehrholz, Wagner, Rutte, Meissner, & Pohl, 2007). This is a functional test which assesses ambulation status by considering the amount of support that is required from another human when walking. It therefore provides an indication of the patient's ability to walk independently.

overall measure of quality of life (QoL). For example, the 36 item Short Form Survey (SF-36, Ware & Sherbourne, 1992) contains eight scales which measure vitality, physical functioning, pain, general health perceptions, role functioning-physical, role-functioning-emotional, social functioning, and mental health. Physical and mental health summary scores can be calculated from these eight scales. Therefore, in relation to the ICF framework, impairment could be measured by pain, general health, and vitality scales in the SF-36, activity limitations could be measured physical functioning, and participation restrictions could be measured by social functioning (Pollard, Dixon, Dieppe, & Johnston, 2009; Stucki & Cieza, 2004).

A few studies have investigated the relationship between AFO use and QoL, using different QoL tools. de Bruijn et al. (2007) measured quality of life of patients in the Netherlands after peroneal nerve injury using the RAND-36 health survey. However, only 11% of patients used AFO at follow-up and no comparison of QoL between users and non-users was made. Aprile et al. (2013) investigated the effect of custom lower limb orthoses on 15 patients with fascio-scapulohumeral (FSH) muscular dystrophy. Using the SF-36 questionnaire, they demonstrated a statistically significant improvement in physical function, general health, social function sub scores and the physical health composite score of the SF36, when using customised orthoses. However, this study investigated both foot orthoses and AFOs, and it was not possible to isolate the effect of AFOs on the QOL scores. Shearin, Smith, Querry, and McCain (2015) conducted a case series study involving three patients with Parkinson's disease fitted with a hinged AFO. They used the Parkinson's Disease Questionnaire (PDQ-8) to measure QoL and demonstrated improvements in walking speed, endurance, dynamic balance and QoL. However, whilst QoL measures offer a holistic approach to understanding the impact of health status on quality of life, categorisation of the different QoL scales into the ICF components of body function and structure, activity and participation is not straightforward (Meirte et al., 2014; Pollard, Johnston, & Dieppe, 2006; Stucki & Cieza, 2004), and requires careful consideration of the constructs which need to be measured. Indeed, no previous orthotic investigations, which have investigated QoL have previously considered the relationship between QoL sub-scales and the ICF components, and specifically isolated the effects of AFOs on participation.

1.9.3 Effect of AFOs on Psychological Well-being/ Distress

Another outcome measure which holds similar challenges in its compatibility with the ICF components is psychological well-being /distress. Measurement of psychological well-being/

distress is necessary in order to capture the psychological benefits of increased mobility which orthoses can provide for everyday life, and to understand, from the user's perspective, the psychosocial effects of assistive technologies on the individual and society. Additionally, there is a need to understand the complex relationship between psychological well-being, physical health outcomes, and orthotic interventions. Psychological well-being can be defined as a person's perception of engagement with existential challenges of life, which includes dimensions of self-acceptance, mastery of the environment, purpose in life, and personal growth (Keyes, Shmotkin, & Ryff, 2002). However, many authors have reported challenges in defining and measuring well-being (Dodge, P. Daly, Huyton, & Sanders, 2012; Ryff & Singer, 1996; Winefield, Gill, Taylor, & Pilkington, 2012), given its multifaceted and subjective nature. Indeed, many investigations, examining the relationship between physical disability and mental health have used measures of psychological distress such as anxiety and depression to quantify psychological health (Lenze et al., 2001; Sagen et al., 2010; Siegert & Abernethy, 2005).

In the ICF framework, mental functions are categorised under body function and structure (WHO, 2001). However, a number of authors from the psychology field (Dekker & de Groot, 2018; Dixon et al., 2008; Grotkamp et al., 2012) have argued that this conceptualisation is unclear, and psychological factors may be better conceptualised under personal factors. The ICF component of personal factors does not provide a taxonomy or classification of personal factors (Simeonsson et al., 2014), although, it includes psychological resources such as coping mechanisms and self-esteem. Muller and Geyh (2015) note that personal factors are not clearly conceptualised, and there is the potential for overlap between personal factors and the other ICF components. However, despite the lack of clarity around the categorisation of psychological factors in the ICF, some authors have called for greater recognition of the importance of utilising psychological measures in orthotic management (Bulley et al., 2011; Desmond & MacLachlan, 2002). There is currently limited evidence of the effect of AFOs on psychological well-being/ distress, and only a few studies have investigated this relationship, mostly using qualitative approaches, and mostly using measures of distress. The broader literature relating to different orthotic interventions demonstrates that a positive relationship between psychosocial well-being and different orthotic interventions exists, and, therefore, suggests a possible relationship between AFO use and psychological well-being/ distress. This literature, described below, also gives insight into the range of outcomes used to measure psychological well-being/ distress.

Studies investigating the relationship between lower limb orthotic use and psychosocial well-being in adults have mostly focused on psychosocial effects of more complex orthoses for spinal cord injury (SCI) or multidisciplinary interventions. Guest, Klose, Needham-Shropshire, and Jacobs (1997) evaluated a physiotherapy training programme which included an orthotic ambulation system[10] for people with SCI. They found statistically significant improvements in physical self-concept and depression levels using the Beck Depression Inventory (BDI). Similar results were found by Davidson et al. (2009), with a significant decrease in depression scores using the Hospital Anxiety and Depression Scale (HADS), after completion of a multidisciplinary rehabilitation programme, for patients with post-polio syndrome. They demonstrated increased exercise endurance, decreased perceived exertion, and a decrease in depression levels, which were all maintained for 6 months. There are also a number of other studies reporting on the psychosocial benefits of exoskeletal devices using qualitative methodologies (Esquenazi, Talaty, Packel, & Saulino, 2012; Wolff, Parker, Borisoff, Mortenson, & Mattie, 2014).

Studies which have specifically investigated AFO use and psychosocial outcomes are detailed below. Zissimopoulos, Fatone, and Gard (2013) investigated the effect of AFOs on falls-related self-efficacy in 15 people with chronic[11] stroke, using an Activities Specific Balance Confidence Scale, and found that participants, in a repeated measures study comparing walking with and without the AFO, reported significantly higher balance confidence with AFO use. Despite the small number of participants, as the only quantitative study investigating AFO use and an aspect of psychosocial well-being, this study inevitably gains more importance than others. However, its focus on such a narrow aspect of psychosocial well-being, provides no information about the relationship between use of AFOs and general well-being.

Other studies investigating the relationship between AFO use and psychological well-being/distress have been qualitative, descriptive investigations. The Best Practice Statement on use of AFOs in stroke (Bowers et al., 2009b), reported a descriptive survey which

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[10] The orthotic intervention in this study was a Parastep I™ system which is a microcomputer functional neuromuscular stimulation system designed to allow standing and walking for people with Spinal Cord injury.

[11] Chronic stroke is not always well defined, and indeed, the timeframe was not specifically defined in the paper referred to above. However a consensus document relating to agreed definitions in stroke has described ‘chronic’ as referring to the timeframe >6 months after stroke (Bernhardt et al., 2017).

investigated the impact of using an AFO following a stroke: of the 38 respondents, 58% reported an AFO takes away their distress, 68% reported an AFO takes away fear of falling, 82% reported that the AFO improved their confidence, and 64% reported that the AFO made them feel better about themselves. However, this study was not peer reviewed or published, with minimal detail reported within the Best Practice Statement. Bulley et al. (2014) used a constructivist phenomenological approach to compare a Functional Electrical Stimulation (FES)[12] device (n=6) and AFOs (n=4) for patients with multiple sclerosis, and found that AFOs improved confidence and self-esteem, and reduced stress, mental effort, and fear of tripping. In a qualitative survey reporting on orthotic devices for knee instability in people with neuromuscular and central nervous system disorders, O'Connor et al. (2016) noted that patients with orthoses associated the ability to mobilise confidently with increased self-esteem, employment opportunities and financial benefits, and enjoyment of family and social life.

An overview of the literature relating to lower limb orthotic use in other groups is useful because it highlights some quantitative research using validated measurement tools, which have demonstrated statistically significant decreases in psychological distress related to orthotic use. The limited number of investigations, which have investigated the relationship between orthotic use and psychological well-being/ distress, demonstrates a major gap in the literature, especially given the established relationship between well-being and functional outcome (Hernandez et al., 2017; Schröder et al., 2007). Consequently, this highlights the need for quantitative investigations, which examine the relationship between AFO use and psychological well-being/ distress, using validated outcome measures. In addition, use of the ICF framework to identify outcomes, reinforces the importance of including psychological well-being/distress measures in future investigations of orthotic use, because it recognises the interaction of psychological health with impairment, activity limitation and participation restriction.

[12] Functional Electrical Stimulation is a treatment that applies electrical stimulation to muscles in people with paralysis due to damage to the central nervous system. It can be used for the treatment of dropped foot by stimulating the common peroneal muscle (on the lateral aspect of the calf), and therefore lifts the foot up to enable clearance in swing phase (Burridge, Taylor, Hagan, Wood, & Swain, 1997). FES does not address stance phase problems in gait.

1.9.4 Understanding Adherence in the Context of the ICF

The ICF, as a biopsychosocial model, enables a person-centred approach to rehabilitation of the individual, because it recognises the complex interplay between individual health and functioning and the contextual factors which can effect outcomes (WHO, 2001). Inclusion of personal factors in the ICF enables the individual's perspective about their own health and functioning to be strengthened (Geyh et al., 2011). Whilst many personal factors, such as age and gender are routinely measured and documented in clinical investigations, less attention has been paid to personal factors identified by WHO (2001), which recognise an individual's perspective, including: past and current experience, coping styles, behavioural pattern and individual psychological assets. Recognition of an individual's evaluation of their health and well-being, and their view of different treatment options is at the heart of understanding health adherence behaviours in physical rehabilitation. Whilst it is recognised that motivational factors can influence adherence to rehabilitation (Brewer et al., 2000; Zinn, 2006), and specifically adherence to an orthotic intervention (Burton, 2007; Swinnen et al., 2017b; Veehof, Taal, Willems, & van de Laar, 2008), no previous research into orthoses has investigated adherence to orthoses within the context of the ICF. Additionally, the effects of adherence on orthotic outcomes have not been definitively demonstrated. Therefore, it is important to determine if people who adhere to orthoses have better outcomes for the ICF constructs of body function and structure, and activities and participation, compared to people who do not adhere optimally.

1.9.5 Summary of Evidence for Efficacy of AFOs in relation to the ICF Framework

In summary, there is good evidence that AFOs can positively influence impairment seen in a range of different conditions, by improving or normalising the temporal spatial parameters of gait, certain kinetic and kinematic aspects of gait. There is also some evidence that AFOs can reduce activity limitations, by having positive effects on mobility, balance and function. However, no previous investigations have specifically measured the effects of AFOs on increasing participation. The majority of investigations focus on stroke and/or hemiplegia, and whilst similar functional problems in gait are seen with other conditions, there is limited evidence for use of orthoses in other less common pathologies, due to the small number of studies that have investigated orthotic use in these conditions. In critically appraising the literature, most studies have been conducted on small numbers of participants, resulting in studies, which are often underpowered, potentially introducing bias into the findings. In most orthotic studies it is impossible to blind users to the intervention, and, therefore, in reviews many investigations are scored lower in the critical appraisal process. The vast majority of the evidence focuses on the short term effects of AFO use (e.g., using a randomised cross-over design to compare AFOs with no AFOs in the gait laboratory), and measures temporal-spatial parameters, walking speed, balance and mobility levels. These tests are conducted in controlled conditions in a gait laboratory, and therefore whilst this evidence may be considered as robust, they do not provide information about use of AFOs in everyday settings, or the effect of AFOs on a patient's day-to-day life.

Therefore, when identifying outcome measures in orthotic investigations, if the objective of the researcher is to gain insight into longer-term use of orthoses and their benefits to users, it is necessary to consider outcomes, which are more reflective of the broader experience of disability and the value of an AFO intervention in day-to-day life. Use of the ICF to guide the selection of outcomes will enable different aspects of disability and functioning to be captured, including impairment, activity limitation and participation restriction. Additionally, despite the lack of clarity over the classification of psychological factors within the ICF structure, there is a need to ensure that the importance of measuring psychological outcomes in orthotic management is recognised, as psychological factors also impact on functional outcomes.

An important consideration when measuring the outcomes of any intervention, is the extent of adherence to the intervention. Orthotic management will only be successful, and provide the benefits described above, if patients engage with orthotic management and use their orthoses as recommended by their health care provider. As highlighted above the majority of outcomes in AFO studies consider the effects of AFOs in gait and are conducted in a laboratory based setting. Therefore, they do not provide information about the extent of AFO use in everyday life. The phenomenon of adherence to orthoses, is an important area of investigation in its own right, and increased adherence to AFOs may offer improvements in functional outcome. Efforts to pursue improvements in orthotic intervention need to move beyond the design and construction of the technology, and focus on the perceptions of the end-user. Therefore, Chapter 2 will provide an in-depth overview of the current knowledge about adherence to orthoses.

Key Points from Chapter 1

1. AFOs are used as a standard non-surgical treatment for foot and ankle dysfunction arising from a wide range of conditions including stroke, arthritis and trauma. Orthotics has an important role to play in meeting the changing demands of health care provision in the Scottish and UK context, to address prevention of injury, early intervention and successful self-management of people with mobility disability.
2. Non-adherence in orthotic intervention is recognised as a significant problem. There is a need to investigate factors affecting adherence, with the aim of identifying modifiable factors which might increase adherence to AFOs.
3. The objectives of AFOs are to: relieve pain, immobilise musculoskeletal segments by limiting or directing joint motion, prevent or correct deformity, and improve function. Given that AFOs are designed to influence body structure and function, the ICF offers a valuable framework for understanding the effect of AFO interventions.
4. No authors have previously used the ICF as a framework to specifically investigate the efficacy of orthotic interventions. Nevertheless, in reviewing investigations into AFOs, studies have demonstrated reduced levels of impairment and activity limitation. However, no studies have specifically investigated the participation component of the ICF. The outcomes of such investigations demonstrate the short term effects of the orthosis (in a gait laboratory) and do not consider the effect of AFOs on a person's day-to-day life.
5. The ICF offers a holistic framework to identify appropriate outcomes relating to AFO use. However, in order for people with mobility disability to gain optimal benefits from AFOs, the importance of adherence to AFOs must be recognized, understood and measured.

Next Steps

Chapter 2 will focus on adherence: the concept of adherence will be considered; current knowledge about adherence rates to orthoses will be described; ways of measuring adherence will be detailed; alongside their advantages and disadvantages; and the current knowledge regarding patient's beliefs and opinions regarding AFO use will be outlined. Then the value of a theory-based approach to understanding adherence as a health behaviour is highlighted.

Chapter 2 will also detail the aims of the thesis, present the key research questions, and provide an outline of the remaining chapters.

In order to identify if people who adhere to using AFO have better outcomes, it is necessary to identify if use of AFOs as recommended is associated with reduced levels of impairment, activity limitation and participation restriction. This is seen in Chapter 3. If use of AFOs as recommended is associated with these outcomes, increasing knowledge of factors affecting adherence to AFOs will provide valuable knowledge to enable design of interventions, which could potentially increase adherence to orthoses. This, in turn, could improve health outcomes.

Chapter 2 Adherence to Orthoses

2.1 Introduction to Chapter

The previous chapter provided the background context for this thesis. The ICF as a framework for conceptualizing disability was introduced and the evidence base for use of orthoses in relation to the ICF outcomes of impairment, activity limitation and participation restriction was outlined. This highlighted that the majority of evidence is based on gait laboratory studies, which do not indicate the extent to which AFOs are actually used in day-to-day life. Furthermore, if people choose not to adhere to using AFOs, evidence from these investigations does not necessarily translate into benefits for people who have been prescribed AFOs. Efforts to optimise adherence are therefore warranted for people who have been prescribed AFOs in order to obtain the best outcomes. Therefore, this chapter will outline the current knowledge relating to adherence to use of orthoses. The definition of adherence will be considered, the literature relating to adherence rates for orthotic interventions, measurement of adherence, and potential determinants of adherence will be detailed. This chapter then argues for the need for a theory-based approach to understand adherence to AFOs. The chapter concludes by outlining the research questions which this thesis aims to answer.

2.2 Terminology

The WHO (Sabaté, 2003, p.3) defines adherence as *"the extent to which a person's behaviour -taking medication, following a diet, and/or executing lifestyle changes, corresponds with agreed recommendations from a health care provider"*. Adherence is seen as being a more neutral term than compliance (Munro, Lewin, Swart, & Volmink, 2007), which is defined as "*the extent to which the patient's behaviour matches the prescribers recommendations"* (Haynes, 1979, p.1). The term compliance reflects a traditional bio-medical approach where the doctor or health professional is viewed as an expert and the person receiving treatment as a passive recipient. However, a patient-centred approach, seeks to ensure that the patient is fully informed, consents to treatment, has a positive interest in maintaining their health, and will actively engage in their treatment plan. Dickinson, Wilkie, and Harris (1999) argue that concordance may be a more appropriate term which is reflective of a patient-centred approach. Concordance implies that the prescriber and patient will come to an agreement about the treatment regimen, and that patients should take greater responsibility for management of their own condition (Aronson, 2007). However, some patients may prefer to be told what to do by their medical professional, or do not wish to make decisions regarding their own health, and also may not be able to give full consent to treatment. In such instances the term concordance may not be appropriate. Adherence is the term utilised by a wide number of organisations who influence decision making in health care such as, the World Health Organisation (Sabaté, 2003), the Cochrane Collaboration (Haynes, Ackloo, Sahota, McDonald, & Yao, 2008), and NHS Education for Scotland (Carney, 2011). Therefore, 'adherence' is considered to be the most appropriate word in the context of this thesis and will be used throughout. However, the term 'compliance' may be used in discussing the literature, if this is the preferred terminology of a particular author.

2.3 Effects of Low Adherence

In developed countries it is estimated that only 50% of patients who have chronic disease will adhere to treatment recommendations (Sabaté, 2003). Across the health care system, poor adherence will not only reduce treatment effectiveness and potentially have adverse health outcomes for the individual patient, but will also result in increased health care costs. The cost of non-adherence to medicine in the UK is estimated to be more than £500 million per year (Langley & Bush, 2014).

Poor adherence is the main cause of inferior clinical outcomes; It produces medical and psychosocial complications, a decreased quality of life for patients, and is an inefficient use of health care resource (Sabaté, 2003). Adherence is a complex phenomenon in health care, and despite a wealth of research into adherence (Christensen, 2004; Haynes et al., 2008; Martin, Haskard-Zolnierek, & DiMatteo, 2010; Nieuwlaat et al., 2014), there has been little change in adherence rates in the last 50 years. Furthermore "*without a system that addresses the determinants of adherence, advances in biomedical technology will fail to realize their potential to reduce the burden of chronic illness*" (Sabaté, 2003,p.23). AFOs offer a low cost technology which, if utilised properly, can reduce falls, improve gait, and also has potential to increase activity levels and societal participation. Despite this, there has been, until recently (Swinnen & Kerckhofs, 2015), limited interest in adherence in the orthotic literature. The current knowledge base concerning adherence rates, measurement of adherence, and determinants of adherence to orthotic devices is outlined below.

2.4 Adherence Rates to Lower Limb Orthoses

A systematic review of compliance to orthotic devices for the lower limb and orthopaedic footwear reported a wide variation in rates of non-compliance of between six and 80% (Swinnen & Kerckhofs, 2015). Their review included six studies of orthopaedic footwear, two studies of FES, one study of AFOs, and one study, which investigated adherence to a range of devices. The review reported on a range of conditions including rheumatoid arthritis, stroke, trauma, diabetes and Charcot-Marie-Tooth (CMT) disease. The highest adherence rate was 94% (van Netten et al., 2010b), in a study investigating use of orthopaedic footwear, and the lowest adherence rate reported was 20% (Vinci & Gargiulo, 2008), in a study researching use of AFOs in CMT Disease. In the latter study, interviews were conducted with eight females and 17 males, with a mean age of 41.6 years, presenting with severe dropped foot. Twelve out of 25 participants did not even attend the clinic to obtain the device, which is reflected in the high rate of rejection. However, across the different investigations included in the review, diverse methods of categorising adherence were used, meaning that adherence rates were not directly comparable. For example, in some studies participants were categorised as users or non-users (Philipsen, Ellitsgaard, Krogsgaard, & Sonne-Holm, 1999) and other studies reported the duration of wear e.g. hours/day or days/week. No studies in the review commented on the appropriate or recommended wearing time.

An important omission from the review of Swinnen and Kerckhofs (2015) is a study by Bakker, de Groot, De Jong, van Tol-de Jager, and Lankhorst (1997) who reported a discrepancy between recommended use and actual use of orthoses in patients with Duchene Muscular Dystrophy. They found that 18 out of 25 patients did not use their AFOs for the recommended amount of time, with all of these participants using the AFO less than recommended. The authors speculated that this might be due to pain and patient reluctance to wear the orthotic devices; however, reasons for their reluctance to use devices were not formally investigated. This study is important in the context of investigating adherence because it captures differences between recommended and actual usage times for an AFO, and, therefore, perhaps offers a more accurate method of capturing a percentage adherence rate.

Sangiorgio, Ho, Morgan, Ebramzadeh, and Zionts (2016) also investigated differences between recommended and actual use of an orthotic intervention. They used temperature sensors to measure adherence to a brace for the treatment of idiopathic club foot in children across 4 different age groups: 6-12 months; 1-2 years, 2-3 years, and 3-4 years. They compared the number of hours of use as recorded by the temperature monitors with recommended use and parent-reported use. Statistically significant differences in the physician recommended use and actual use ($p \leq 0.002$), and also in parent-reported use and actual use ($p \leq 0.013$) were found in the 3 younger age groups, with actual use being lower than recommended or parent-reported use. Additionally, they found that the children who relapsed (i.e. their foot deformity increased) were less adherent, and wore their orthoses for a significantly fewer number of hours than children who did not relapse. This investigation is of interest because it also focuses on the discrepancy between recommended and reported use. However, whilst both Bakker et al. (1997) and Sangiorgio et al. (2016) offer important insights into use of orthoses as recommended, it could be argued that investigations involving children do not measure patient adherence, because in such investigations, parents have the ultimate responsibility for their children using the orthoses.

A further omission by Swinnen and Kerckhofs (2015) was the lack of inclusion of orthoses, which might be required to support more proximal joints such as the knee and hip. Although their focus was on orthoses for the lower extremity, they did not consider orthoses which might be fitted at a level more proximal to the foot and ankle (e.g., KAFOs or HKAFOs). For example, orthoses such as exoskeletons for Spinal Cord Injury were not considered. For such devices, the user would only be expected to use the device for a maximum of a few hours per day, as the aim of this device is to allow limited standing and walking as a means of exercise for those who would not otherwise be able to stand upright. Such orthoses have a high level of physiological demand, are challenging to don and doff, and, due to their complexity, are more liable to mechanical failure (Chafetz, Johnston, & Calhoun, 2008); therefore, this may have a negative impact on adherence rates, and it is possible that Swinnen and Kerckhofs (2015) deliberately excluded these devices for this reason. No rationale was provided for their exclusion, and as a result, the unique insights these studies might provide on the adherence issue were not considered. However, an overview of these key studies is provided below.

Jaspers, Peeraer, Van Petegem, and Van der Perre (1997) describe an interview study of 14 people with paraplegia and reported that 85% were still wearing the device regularly at one year follow-up. This appears to contrast with Scivoletto et al. (2000) who reported that 46 % of 24 patients with traumatic spinal cord injury no longer used their reciprocating gait orthoses[13] (RGOs) at 1 year follow-up. The definition of frequent use by Jaspers et al. (1997) was vague, with one participant using the orthosis for one or two hours twice per month, being classed as a regular user. A study with a longer follow-up (mean of 5.4 years) of 35 patients using an RGO, reported that 29% of people were still using their devices (Sykes, Edwards, Powell, & Ross, 1995), perhaps suggesting that adherence may reduce further over the longer term. This type of orthotic intervention has different advantages and disadvantages compared to an AFO, and, therefore, may have potentially different motivations for the patient to use. However, these studies do highlight differences in the way that adherence is measured and recorded, that need to be considered, if investigating adherence to orthotic devices.

Only one published study has reported adherence to use of AFOs, specifically in people with stroke (Nakipoğlu-Yüzer et al., 2018). This recent study investigated the regularity of orthotic use in 64 participants, who were between 3-6 months' post-stroke in Turkey. They used a questionnaire design to ask patients about use of their orthoses, including both AFOs and KAFOs, and found that 59.4% of participants used their orthosis every day. However, they did not consider the extent to which participants used their orthoses each day, or if use of the orthosis, matched recommendations from the clinician.

In summary, adherence rates appear to be varied across different health conditions and also may depend on the type of device being prescribed. Additionally, very few investigations have used objective measures of adherence, and where subjective measures have been used, there have been challenges in defining adherence to ensure that it is a relevant measure, which is comparable with other studies. Therefore, the definition and measurement of adherence are critical to obtaining a valid measure of adherence. These are considered in Section 2.5 and 2.6 below.

2.5 Definition of Adherence

In this thesis adherence is defined as "use of the AFO as recommended". A patient who is prescribed an AFO should be provided with instructions by the orthotist, either written or verbal, relating to the recommended use of the orthosis (Felton, 1999). It is recognised that

[13] A reciprocating gait orthosis is a type of orthosis, fitted to people with paraplegia due to conditions such as Spinal Cord Injury or Spina Bifida, and allows limited standing and walking. It comprises of full leg orthoses (Knee Ankle Foot Orthoses) on each leg which are linked together proximally by a pelvic section to allow reciprocal gait (i.e. as one leg bears weight, the other is able to swing through). Traditionally hip joints are linked to prevent bilateral hip flexion, thereby creating mechanical stability on one leg.

people may be provided with different recommendations for use of AFOs, dependent on the functional loss and orthotic aims. For example, foot abduction orthoses for congenital talipes equinovarus (club foot) should be used 23 hours/day, for the first 3 months, to maintain a stretch on the medial structures of the foot (Desai, Oprescu, DiMeo, & Morcuende, 2010); AFOs may be recommended for night-time use to manage contractures in neuromuscular disease (Skalsky & McDonald, 2012); and recommendations may be made for day-time use of AFOs (e.g. 6-12 hours) to improve gait kinetics and kinematics in neurological conditions (Buckon et al., 2004; Das, Mohapatra, & Lenka, 2018). The recommendations which are made for AFO use may also depend on the individual's diagnosis or prognosis, as well as other functional challenges that they may have. In addition, the individual goals of the patient should also be considered when the orthotist makes recommendations for use of the AFO. This is considered in further detail in 2.5.1.

The recommendations made to patients about use of AFOs include: the recommended wearing times and a wearing-in schedule; donning the orthosis correctly to ensure the heel is located in the appropriate position; use of an appropriate interface donned without wrinkles; tightening of the straps to provide the correct tension and maintain the position of the AFO on the leg; using footwear which fits well, and is appropriate to accommodate and support the orthosis and leg; and footwear which has the correct heel-height for which the orthosis was designed (Bowers, Ross, & NHS Quality Improvement Scotland, 2009; Kogler, 2012; Royal Berkshire NHS Trust, 2013; Sheffield Teaching Hospitals NHS Trust, 2014). In addition, the activities for which the orthoses are used, the care and maintenance of the orthosis and attendance at follow-up appointments, all contribute to adherence to use of the AFO as recommended (Coppard & Lohman, 2015). Therefore, the definition of adherence used in this thesis, "use of the AFO as recommended", encompasses several different elements of adherence: not only the length of time over which orthosis is worn, but also incorporates correct donning of the orthosis, use of the orthosis for appropriate activities, appropriate footwear choice, and other aspects of follow-up care. These recommendations should be made only following discussion and agreement with the patient, and should reflect the patient's goals.

2.5.1 Goal Setting and Recommended Use of Orthoses

Goal setting refers to process by which the rehabilitation professional or a multidisciplinary team, together with the patient and/or their family, discuss and negotiate goals of treatment or rehabilitation (Wade, 2009). Identification of patients' goals and agreement of these goals with patients, is a core component of the rehabilitation process. The purpose of setting such goals is to motivate the patient; allow changes in patient outcomes to be monitored; and to facilitate multidisciplinary team members to work towards the same goals (Wade, 2009). Goal setting for adults receiving rehabilitation following an acquired disability can improve psychosocial outcomes, such as health-related quality of life, emotional well-being and self-efficacy (Levack et al., 2015). Given that the overall aims of an orthosis are to improve function and increase activity and participation (Yamane, 2018), use of orthoses are usually concordant with the goals of the patient. Despite this, there is limited knowledge about goal setting in the orthotic context, and specifically the relationship between recommended use of orthoses and goal setting. However, the literature provides some guidance in relation to how decisions about recommended use might be made.

For some patients, their goals may not be entirely compatible with orthotic use. For example, if a patient is unrealistic about their recovery following rehabilitation, it is doubtful whether they will adhere to an orthotic programme of care (Edelstein & Brookner, 2002). Also, some patients may choose to discard their devices because they are concerned about appearing disabled (Vinci & Gargiulo, 2008). Also, cosmetic concerns with orthoses have been identified as negatively impacting on adherence (Phillips, Radford, & Wills, 2011; Swinnen & Kerckhofs, 2015). In order to identify and address these concerns, it is important that the orthotist builds a relationship with the patient in which the patient feels heard and understood (van Netten et al., 2016). The orthotist may then be able to understand challenges to adhering to the orthosis from the patient's perspective, and advise the patient appropriately. For example, a patient may wish to wear specific shoes or an outfit when attending a wedding, which are not compatible with the prescribed orthosis. The orthotist can give advice regarding use of the orthosis, to highlight the risks of not using the device (e.g. falling) and provide guidance in the steps which might be taken to minimise these risks, whilst not using the orthosis. The patient is thus provided with important information to enable informed decision making about use of the device for a specific occasion, and can discuss and negotiate with the orthotist to agree their orthotic use.

This shared decision-making process ensures that the provider and patient are working together to agree an optimal treatment choice which is evidence based, and also acknowledges the patient's values, preferences and individual circumstances (Hoffmann, Montori, & Del Mar, 2014). Therefore, in this way, recommendations for orthotic use can be agreed between the patient and orthotic provider. Indeed, this highlights the important difference between compliance, in which the patient is expected to do what has been recommended by the health professional (Haynes, 1979); and adherence, in which the patient's behaviour corresponds with the *agreed* recommendations between the health care provider and the patient (Sabaté, 2003). Thus, although much of the advice is given to all patients is similar, recommendations about use of the orthosis are individualised to each patient, and should enable their views and opinions to be heard.

2.6 Measurement of Adherence

Measurement of adherence is usually described as being objective or self-reported. Examples of an objective measure of adherence to a health behaviour may be: measurement of blood glucose levels to measure adherence to an insulin regime for diabetes (Gucciardi, Demelo, Lee, & Grace, 2007), attendance at appointments (Orbell, Hagger, Brown, & Tidy, 2006), or weight loss maintenance (McConnon et al., 2012). Examples of self-reported measures include questionnaires which may ask the patient to rate their participation in particular activities such as exercise (Courneya et al., 2004) or self-care (Shankar, Conner, & Bodansky, 2007), filling in a diary to report on exercise activity (Niven, Nevill, Sayers, & Cullen, 2012) or maintaining a food diary (Cooper et al., 2012). However, some authors have also used estimates of adherence from health professionals (Bains, Powell, & Lorenc, 2007; Conner, Black, & Stratton, 1998), which have attempted to reduce the type of self-report bias seen in patients, and provide an independent account of someone's behaviour. The advantages of self-report measures are ease of administration and low cost, while objective measures are likely to be more expensive due to human resource or technology required to measure adherence. When compared with objective measures, self-reported measures of adherence are considered to estimate higher levels of adherence due to desirability bias, and may therefore be less accurate (National Collaborating Centre for Primary Care, 2009). However, there are ways of trying to counter this effect e.g. anonymity of questionnaires rather than face to face interviews, encouraging participants to be honest, and avoiding use of staff, who are directly involved in service delivery, in data collection.

There are no definitive guidelines for optimal levels of adherence for AFOs. However, the risks of not using an orthosis when standing or walking include an increased risk of falling or tripping without an AFO (Cakar, Durmus, Tekin, Dincer, & Kiralp, 2010). Therefore, non-adherence in AFO use may be of greater consequence than e.g. missing an appointment or not exercising one day during a rehabilitation programme. An AFO is considered to be a biomechanical device that changes the forces applied to the human body. Its greatest impact is likely to be during weight bearing, where forces caused by body weight are acting around the joints. Therefore typical recommendations made by an orthotist will be to use the orthosis at all times for standing and walking (Royal Berkshire NHS Trust, 2013; Sheffield Teaching Hospitals NHS Trust, 2014). However, the AFO may still have functional value when a patient is sitting, in prevention of further deformity. As the amount of time spent in standing or walking activities will vary depending on a range of factors including the presenting condition, age, co-morbidities and activity level, careful consideration must be given to how adherence to AFOs can be appropriately measured. Consequently, the recommended wearing time should be a key factor that is considered when measuring adherence to AFO use.

Despite advances in monitoring technologies to measure adherence (Felton, 1999), the majority of investigations which have investigated adherence to lower limb orthoses have used self-reported measures of adherence. Indeed, all of the studies in Swinnen and Kerckhofs (2015) review, excepting one (Waaijman et al., 2013), used self-reported measures of adherence. The limited number of studies using objective measures may be related to technical challenges associated with using electronic devices to measure outcomes such as humidity, electrostatic build-up (Vandal, Rivard, & Bradet, 1999), and battery capacity (Rahman et al., 2015). Additionally, user awareness of the presence of an adherence monitor can inadvertently influence adherence (Thatipelli et al., 2016). Therefore, there are valid concerns relating to the accuracy of adherence measurement using electronic monitors. Furthermore, increased costs may be incurred in objectively measuring adherence to orthoses by the use of temperature or pressure sensors. Therefore, feasibility of using objective measurement when designing a study, which measures adherence to orthoses, needs to be carefully considered. In addition, objective measures do not provide an understanding of the factors affecting adherence to AFOs. Knowledge of these factors is essential in the design of interventions which might increase adherence. The current knowledge relating to determinants of adherence to AFOs is considered below.

2.7 Potential Determinants of Adherence

Some factors affecting AFO use have been suggested in the literature; however, identification of these factors, with a few notable exceptions (Nakipoğlu-Yüzer et al., 2018; Phillips et al., 2011; Polliack, Elliot, Caves, McNeal, & Landsberger, 2001; Vinci & Gargiulo, 2008), was not the main focus of the majority of the studies detailed below. These factors can be grouped into five main categories: health and socio-demographic factors; fit and comfort of the device; aesthetics; practical issues relating to use; and psychological issues.

2.7.1 Health and Socio-demographic Factors

As highlighted above the type of health condition, may affect adherence behaviour. In addition, the severity of condition has been identified as a possible factor affecting adherence to orthoses. Basford and Johnson (2002) reported that when a functional deficit affecting the body is severe, an orthotic device may be more likely to be accepted. This was supported by Ramdharry, Pollard, Marsden, and Reilly (2012), who found that people with more severe CMT were more likely to use AFOs. Demographic variables such as age, gender and socio-economic status have been shown to affect use of wrist splints (Henderson & McMillan, 2002), reciprocating gait orthoses for spinal cord injury (Sykes et al., 1995) and orthopaedic footwear (van Netten, Jannink, Hijmans, Geertzen, & Postema, 2010a). In contrast, Nakipoğlu-Yüzer et al. (2018), in a retrospective investigation of patients with stroke, found that age, sex, and disease duration were not significantly related to frequency of orthotic use. However, they did identify the rate of orthotic use was significantly higher in patients with a lower Brunnstrom lower extremity neurophysiological stage of recovery[14]. In other words, patients with increased functional recovery were more likely to discontinue use of their orthosis. Similar findings were seen in a retrospective study of patients with spinal cord injury: Koyuncu, Nakipoğlu Yüzer, Çam, and Özgirgin (2016), reported that age, gender, disease duration and level of spinal cord lesion were not significantly related to orthosis use. However, they did identify a difference in usage between incomplete and complete spinal cord injury, and reported that patients with incomplete SCI were more likely to discontinue use due to improvements in function. In summary, there appears to be an association between severity of condition and use of lower limb orthoses, with increased severity of condition associated with increased use, although the influence of other demographic factors is less certain.

2.7.2 Fit and Comfort of Device

If an orthosis does not fit well it is likely to cause discomfort or pain. A number of authors have noted problems with fit of the device (Fisher & McLellan, 1989; Phillips et al., 2011;

[14] The Brunnstrom neurophysiological recovery stage (Sawner, LaVigne, & Brunnstrom, 1992) is a measure of recovery following stroke, which details the extent to which the patient has regained muscle control. There are seven stages, with stage 1 referring to the flaccid paralysis usually seen initially following stroke, and stage 7 referring to a full recovery, with no spasticity and full control of movement.

Vinci & Gargiulo, 2008), which in turn may affect comfort. For patients who have a complex tri-planar foot deformity[15] or multiple gait abnormalities often associated with stroke, a custom-made AFO is considered to be the most appropriate option (Bowers et al., 2009b), which should prevent problems with fitting. The importance of customised AFOs was noted specifically by females (Phillips et al., 2011) with CMT disease who reported problems of fit were barriers to AFO use. In the same study, male users noted rubbing and digging into the skin as key disadvantages, and highlighted discomfort as a potential barrier to AFO use. The main barrier reported by females was restricted space inside the footwear causing bunching of the toes. This could be due to inappropriate footwear choice by females or lack of options of suitable footwear for females. Vinci and Gargiulo (2008) also noted that fit of the AFO inside the shoe was a problem for patients with CMT, although patients were not using custom-made devices in this instance. Nakipoğlu-Yüzer et al. (2018) investigated reasons for non-use of orthoses in people with stroke and noted pressure sensation (i.e. a dislike for the feeling of compression from the AFO), as a reason for discontinuation of use in 15% of people who had been prescribed AFOs. Whilst they did not relate this specifically to discomfort or pain, the choice of phrasing "pressure sensation" might be a very uncritical way of describing discomfort or the effects of a poorly fitting device. Therefore, both poor fit of the orthosis and challenges fitting the AFO inside the footwear may contribute to non-adherence. Furthermore, there may be additional issues for females in relation to footwear choice, which could also impact on fit and comfort.

2.7.3 Cosmesis

Appearance of an orthotic device is critical to user satisfaction (Ghoseiri & Bahramian, 2012). Cosmetic appearance has also been noted as a potential factor affecting use of AFOs by a number of other authors (Bowers, 2008; Phillips et al., 2011; Tyson & Thornton, 2001). For some patients the aesthetics of the device may be the most important factor. For example, Basford and Johnson (2002) describe a case study of a patient following stroke who required an orthosis for their thumb. The plastic orthosis prescribed interfered with the female patient's perceived ability to do her job which involved her hands being highly visible to the public, and in turn, her self-esteem was negatively impacted. By changing the material to gold, the orthosis appeared to be an item of jewellery to the casual observer. The authors

[15] A tri-planar foot deformity refers to a deformity that is occurring in 3 planes (or directions), sagittal (anterior-posterior), coronal (medial-lateral) and transverse (rotational) planes.

reported that the patient found the gold orthosis to be attractive, and it reduced her feelings of helplessness.

Vinci and Gargiulo (2008) reported that patients described their splints as ugly and visible to others. In agreement with this, Doğğan, Mengüllüogglu, and Özgirgin (2011) investigated opinions regarding desirability and undesirability of AFOs in stroke patients in Turkey, and also found that a high percentage (60.8%) of patients reported that the AFO was poor cosmetically. In contrast, another study in the UK, which primarily looked at effects on AFOs on functional mobility, reported that only three out of 20 participants with stroke found the appearance of the AFO off-putting (Tyson & Rodgerson, 2009). In line with this finding, Swinnen et al. (2017a), in an observational study about use and satisfaction with lower limb orthoses for patients with neurological conditions, reported that factors associated with functionality and comfort were more important than the cosmetic or psychological aspects of the orthosis. It appears that the importance of cosmetic appearance may vary depending on the country and cultural context.

An AFO is not worn in isolation, but is designed to be worn with appropriate footwear. Footwear choice, as well as impacting on fit and comfort of the orthosis, has implications for orthotic users, in terms of their overall cosmetic appearance (Phillips et al., 2011). For example, a person prescribed an AFO might be advised to use trainers which have increased width and depth to accommodate an AFO, compared to court or dress shoes (Royal Wolverhampton NHS Trust, 2016). Bulley et al. (2014) specifically highlighted implications for footwear and clothing, such as a preference to wear trousers rather than a skirt when wearing an orthosis. Polliack et al. (2001) found that participants expressed concern about limitations in footwear choice for patients who are prescribed AFOs, with 77% preferring more footwear options. In summary, perceptions of the cosmetic appearance of the device may be related to footwear choice and the patient's feelings about footwear, and resultant limitations in clothing, as well as material choice of the AFO. Additional gender and cultural influences may be further determinants of adherence specifically related to the cosmetic appearance. The cosmetic appearance of an orthotic device, is therefore likely to be influenced by a person's underlying beliefs about the value of appearance, and the importance of aesthetics to the individual.

2.7.4 Practical Issues

2.7.4.1 Perceptions of Weight

A number of authors have highlighted that AFOs were perceived to be heavy. Tyson and Thornton (2001) reported that six out of 24 patients with stroke reported that they felt the AFO was too heavy. Also, Doğğan et al. (2011) found that 15.7% of 51 stroke patients, reported difficulty in walking due to the weight of their AFO. Phillips et al. (2011) also highlighted that from the patient perspective, a lightweight device was an important characteristic of an AFO to enable use. However, Polliack et al. (2001) in a study using custom-made thermoplastic AFOs for people with myelomeningocele, noted that weight was not identified by users as a problem. Perceptions of weight appears to be an issue for a significant minority of patients. These contrasting findings could be related to the underlying condition, and associated functional losses. Additionally, if an AFO does not fit well, the weight of the device may be perceived to be greater, because there is more movement between the skin and the orthosis.

2.7.4.2 Heat Build-up

It is recommended that an interface such as a cotton sock or stocking is worn between the AFO and the patient's skin (Royal Wolverhampton NHS Trust, 2016). This acts as an interface and also absorbs sweat. There are a few reports in the literature of excessive heat and sweating when using AFOs. Problems reported are likely due to climatic conditions, such as a build-up of heat in hot weather or while using AFOs in warmer climates (Phillips et al., 2011), but even in the UK heat build-up has been reported (Bowers, 2008). Contrary to this, in the USA, Polliack et al. (2001) reported that heat was not a problem for a sample of AFO users with myelomeningocele, although this could be due to sensory loss and poor circulation often seen in this condition. In summary, excessive heat and sweating can be a concern for some patients even when using an appropriate interface.

2.7.4.3 Donning and Doffing

The ability to don (put on) and doff (take off) an orthosis by oneself gives more independence and also choice to the patient as to when the device will be worn. If a patient cannot put on the AFO himself or herself, and has no assistance to do so, this could result in non-adherence. This can be a challenge for patients who have conditions in which their upper limb may also be affected (e.g. stroke, multiple sclerosis, cerebral palsy). Tyson reported that 14 of 24

(56%) of patients with stroke were able to don and doff the AFO independently. Other authors have also reported challenges with donning and doffing AFOs (Bowers, 2008; Phillips et al., 2011), which may be a barrier to AFO use.

2.7.5 Psychological Issues

A number of authors have noted problems related to body image, and self-esteem in people who have been prescribed orthoses or orthopaedic footwear. Vinci and Gargiulo (2008) noted that all patients (n=25) in their study had a poor relationship with their own body, with 96% reporting feelings of discomfort when looking at their own feet and legs, and 4% avoiding looking at their lower limbs all together. They also described the multi-sensorial effect of the AFOs; being seen, felt and even heard by patients, which could be a constant reminder of their disability when patients may wish to feel as normal as possible. Comments from patients (p.29) included *"I am not yet ready to accept them"* and *"I can still manage without them for a while"* (Vinci & Gargiulo, 2008), despite being assessed for and prescribed an AFO by a medical professional. Bulley et al. (2014) also reported psychological barriers to AFO and FES use were patient's reluctance to rely on the device and difficulty in admitting to oneself that the device was required.

Additionally, depression is associated with non-adherence to medical treatment, with depressed patients being three times more likely to be non-compliant with medical treatment recommendations (DiMatteo, Lepper, & Croghan, 2000). While depression has been used as an outcome measure in a few orthotic studies (Davidson et al., 2009; Guest et al., 1997), its relationship with orthotic use has not been investigated. Given higher rates of depression in conditions that may require orthotic intervention such as stroke (Sinyor et al., 1986) and multiple sclerosis (Siegert & Abernethy, 2005), depression may be a factor in poor adherence to orthoses.

Although not reporting on AFO use, Williams, Nester, and Ravey (2007) investigated the experiences of women with rheumatoid arthritis who had been fitted with orthopaedic footwear. These findings are relevant because some patients prescribed with AFOs may also be prescribed orthopaedic footwear to accommodate the AFO. They found that orthopaedic footwear reinforced negative feelings about patients' self-image. Also therapeutic footwear was found to impact on user behaviour by restricting activities, due to concerns by users about the appearance of the footwear and the reactions of others whilst wearing the therapeutic footwear. Female participants reported they were less likely to attend social events because of the footwear and reported feelings of shame, sadness and anger. Such feelings are important to acknowledge as a potential aspect of the orthotic user's experience.

2.7.6 Satisfaction with AFOs

The issues described above are likely to affect satisfaction with AFOs, which has been reported in a number of studies. Fisher and McLellan (1989) reported a 16% dissatisfaction rate with AFOs, although this was across multiple conditions, with comments that the thermoplastic AFOs were poorly moulded or did not fit into footwear. Milani and Huang (2001) noted a significant difference between satisfaction depending on type of AFO supplied with 100% satisfaction reported for custom-made AFOs and 33.3% satisfaction for prefabricated AFOs. Patient satisfaction is not only related to fit and function of the orthosis, but also aesthetics of the AFO, and to other aspects of service delivery, including quality of service, empathy of staff and responsiveness (Basford & Johnson, 2002; Geertzen, Gankema, Groothoff, & Dijkstra, 2002). Satisfaction with AFOs may also relate to benefits that are not commonly measured in the literature, but have been noted by some authors, such as falls prevention, increased confidence in walking, and reduced anxiety in mobilising (Bowers et al., 2009b; Hung et al., 2011; Phillips et al., 2011; Zissimopoulos et al., 2013).

In summary, it appears that there are multiple determinants of AFO use. Factors, which may affect someone's decision to use an orthosis, include the health condition; sociodemographic status; the fit of the device; the cosmetic appearance; practical concerns about use; and patient satisfaction. Whilst knowledge of the effects of health condition, and socio-demographic characteristics on adherence are of interest, and may offer explanations of adherence behaviour, they are generally quite difficult to modify or target with interventions, because they are generally not amenable to change (Guenette et al., 2016). Therefore, in order to design interventions, which might increase adherence to use of orthoses, other determinants which can be modified should be considered. Consequently, an understanding of the underlying behavioural mechanisms that underpin the behaviour can offer opportunities to influence adherence behaviour. Health psychology theories offer a new perspective on understanding adherence to orthoses.

2.8 A Theory-based Approach to Understanding Adherence to Orthoses

Adherence has previously been conceptualized as a health behaviour when investigating other activities which might improve health and well-being; including physical activity (Downs & Hausenblas, 2005a), diet (McConnon et al., 2012), and self-care (Toljamo &

Hentinen, 2001). However, adherence to orthoses has not previously been investigated as a health behaviour. Consideration of adherence to orthoses as a health behaviour offers a novel approach to understanding orthotic use, which recognises the importance of self-management of long-term conditions, because it focuses on the patient's ability to change their behaviour. More specifically, it recognises that people can contribute to their own health and well-being by adopting behaviours which can improve health outcomes (Conner & Norman, 2005). In addition, such an approach is aligned with current government policy because it enables and supports patients to be equal partners in their own health and well-being (Scottish Government, 2017). Furthermore, a theory-based approach allows the application of theories of behaviour to provide an improved understanding of adherence, because it allows the relationship between different constructs to be explored and potentially manipulated. Beliefs which influence a patient's decision to use an orthosis can subsequently be identified. These underlying belief structures have the potential to be modified, and, therefore, can enable this knowledge to be used in the development of interventions, which might increase adherence to orthoses. This in turn may allow the identification of patients who would be less likely to engage in adhering to orthotic management, and, thus, enables specific targeting of interventions to individuals who are less likely to be adherent.

Theory-driven research, refers to conducting research from a conceptual basis (Wallander, 1992): that is formulating hypotheses from theory and testing them, rather than collecting data and then finding a theory that fits. A theory-based approach is particularly valuable in not only offering a framework for interpreting data and deciding relevant variables that should be measured, but it also provides a useful tool to develop interventions. The Medical Research Council's framework for complex interventions identifies the need for theory-driven research to inform interventions (Medical Research Council, 2008; Moore et al., 2015). Furthermore, interventions are more likely to be successful in behaviour change when they target theory-based determinants of that behaviour (Michie & Abraham, 2004). In order to design effective behaviour change interventions, an understanding of health behaviours and behaviour change is required (Davis, Campbell, Hildon, Hobbs, & Michie, 2015; Michie & Abraham, 2004; Michie et al., 2018; Michie & Johnston, 2012). In addition, it is important to identify the most relevant theoretical framework and develop an understanding of the likely processes involved in behaviour change, in order to effectively implement behaviour change (Michie et al., 2018).

Therefore, use of a theory-based approach to understanding adherence as a health behaviour is fundamental to developing evidence-based effective interventions which can increase adherence behaviours (Martin et al., 2010). This requires identification of a suitable theory, an understanding of relevance of the theory to the behaviour, and testing the efficacy of the theory in relation to the behaviour. To the author's knowledge no previously published work has used a theoretical approach in understanding adherence to lower limb orthoses. Therefore, this thesis makes a significant contribution to knowledge by using psychological theory to understand and explain adherence to use of orthoses as a health behaviour in a clinical population. By using psychological theory to understand adherence to orthoses, a structured framework is provided which will enable relationships between the potential determinants of adherence to be identified, and measured. In turn, this knowledge will provide a basis for future interventions which could increase adherence to orthoses.

There are several theoretical models of behaviour which have been used to understand health and social behaviours. These can be divided into models which focus on the individual, in which behaviours are primarily determined by internal factors (e.g. knowledge, attitudes, beliefs), and models which focus on factors which are external to the individual (e.g. social, institutional and environmental factors) (Davis et al., 2015). Many health and social behaviours can have a negative effect on an individual's health outcomes, and are, at least to some extent, under an individual's control (Conner & Norman, 2005). Consequently, a focus on theoretical models which aim to understand the internal factors, which determine behaviour is essential to influencing behaviour change. Such models of behaviour are termed social cognitive models. Social cognitive models posit that individuals hold beliefs which can influence the way in which they interpret information and experiences, which in turn influences behaviour (Conner & Norman, 1996). Cognition is the mental process of gaining knowledge, the way in which input is transformed, stored, recovered and used (Neisser, 1967). Cognitions are important determinants of behaviour, and can also provide targets for interventions to change future behaviour (Conner & Norman, 1996). Unlike socio-demographic variables, which are largely non-modifiable, cognitive variables can be altered by use of interventions which target the underlying beliefs (Armitage & Conner, 2000). Social cognitive models have been applied widely to predict and explain an extensive range of health behaviours such as physical activity, cessation of smoking and medication adherence (Armitage & Conner, 2001; Hagger, Chatzisarantis, & Biddle, 2002; Munro et al., 2007; Sutton, 2010; Topa & Moriano, 2010; Young, Plotnikoff, Collins, Callister, & Morgan, 2014), and have been shown to be effective predictive models across varied health behaviours. In addition, social cognitive models can enable the determinants of behaviour to be identified, they offer possibilities to change health behaviours. Indeed, social cognitive models have also been applied in the design of behaviour change interventions with some success (Davis et al., 2015; Steinmetz, Knappstein, Ajzen, Schmidt, & Kabst, 2016; Tougas, Hayden, McGrath, Huguet, & Rozario, 2015).

Therefore, social cognitive models provide a sound theoretical basis for understanding health behaviours, and may also enable the development of interventions to increase adherence, and in turn improve health outcomes. Indeed Haynes et al. (2008), in a Cochrane review of interventions for enhancing medication adherence, reported that increasing the efficacy of interventions designed to improve adherence would be likely to have a far greater impact on people's health than any individual improvement in medicine. In the same way, if adherence to orthoses can be increased, this could positively impact on individual health outcomes as much as, or even more than, improved technologies or designs of orthoses. Therefore, whilst much of the current orthotics research espouses the benefits that advanced computing and material technologies can offer (Kumari & Kumar, 2018; Mukhopadhyay & Poojary, 2018), effective interventions which improve adherence to orthoses may offer alternative methods of improving health and well-being, along with enhanced outcomes. Consequently, this thesis focuses on understanding adherence to orthoses using a social cognitive model of behaviour. An understanding of the cognitive factors affecting orthotic use offers opportunities to increase adherence to use of orthoses. This is important because non-adherence may lead to reduced health outcomes, and non-adherence is a potentially modifiable behaviour.

2.9 Aims of Thesis and Research Questions

Therefore, this thesis has three overarching aims: to examine the prevalence of AFO use; to examine the use of the ICF in understanding the outcomes for patients who use/don't use their AFO; and to test the efficacy of a theoretical model of behaviour in understanding adherence to AFO use in a relevant clinical population. In order to achieve this aim, the following research questions have been developed.

2.9.1 To what Extent do People, who have been Prescribed an AFO, Adhere to Use of AFOs as Recommended?

Whilst adherence rates to orthoses have been reported in a number of previous investigations, only one peer reviewed investigation has specifically focused on measuring adherence to

AFOs. Vinci and Gargiulo (2008) reported a very low adherence rate of 20% in patients with CMT. They opted to measure adherence, or compliance, by using a dichotomous measure of use or non-use which did not reflect any recommendations given for use of the AFO. Although some investigations have measured discrepancies between recommended and actual use (Bakker et al., 1997; Sangiorgio et al., 2016), no previous investigations have specifically investigated adherence to AFOs in relation to their use as recommended, which offers a more specific and accurate definition of adherence. Therefore, the first objective is to measure the adherence rate to use of AFOs as recommended, in a NHS setting in Scotland. This question will be addressed in the first study of this thesis, and is described in Chapter 3. In addition, this question is also investigated in a later study, in a stroke-specific population, and is detailed in Chapter 6.

2.9.2 Do People Who Adhere to Use of AFOs as Recommended have Reduced Levels of Impairment, Activity Limitation and Participation Restriction, compared to People who do not Use AFOs as Recommended?

Whilst it is known that some people choose not to adhere to using AFOs as recommended, it is not known, if people who do adhere to treatment recommendations have better outcomes. In addition, outcomes, which reflect the users' experience of health and disability should be measured because, unlike experiments conducted in a gait laboratory, they provide information about the impact of an AFO on a person's day-to day life. The ICF offers a framework for identification of suitable outcomes for understanding AFO use. Use of the ICF framework to identify outcomes is important because it provides a biopsychosocial approach to understanding a patient's health, which recognises the physical, mental and social aspects which affect well-being (WHO, 2002). If, as expected, people who use AFOs as recommend display better outcomes than people not using AFOs as recommended, this knowledge will be of critical importance in supporting an enhanced understanding of adherence to AFOs, and can provide justification for the need to apply theoretical models to understanding AFO use. Therefore, Question 2, which seeks to explore differences in health outcomes in people using AFOs as recommended and those not using AFOs as recommended, is explored in Chapter 3.

2.9.3 Is the Theory of Planned Behaviour (TPB) a Useful Model for Understanding Adherence to Health Behaviours in Conditions for which Orthoses may be Prescribed?

In order to understand adherence as a health behaviour and target people's beliefs in future interventions to increase adherence, an understanding of the cognitions relating to adherence is required. Therefore, identification of a suitable social cognitive model, to investigate AFO adherence behaviour, is required. The Theory of Planned Behaviour (TPB) (Ajzen, 1991) is one of the most widely used psychological models used to investigate health behaviours behaviour, and it has generally been shown to explain more variance in behaviours than other psychological theories of behaviour (Ajzen, 2014; Armitage & Conner, 2001; Taylor et al., 2006). However, it is necessary to identify if the TPB might be a useful model in explaining adherence to AFOs. Therefore, the objective of this study is to conduct a meta-analysis of studies, which have used the TPB to understanding adherence to health behaviours in people with health conditions for which orthoses may be required. The relevance of the TPB applied to adherence behaviours in people with pertinent health conditions will therefore be considered. The investigation described in Chapter 4, aims to answer the above research question.

2.9.4 What are the Underlying Behavioural, Normative and Control Beliefs affecting Use of AFOs in People with Stroke?

Assuming that the TPB is shown to be a suitable theoretical model in explaining adherence to health behaviours in conditions for which orthoses might be prescribed, a study to investigate the utility of the TPB in predicting adherence to AFOs will be conducted. The first stage of a TPB investigation is usually the elicitation of beliefs about the behaviour from a representative sample of the population. An elicitation beliefs study provides information about the cognitive processes which can underpin intention to perform a behaviour and the actual behaviour itself and details the attitudinal, normative and control beliefs affecting the behaviour of interest (Ajzen & Fishbein, 1980). Therefore, the beliefs elicitation investigation, described in Chapter 5, aims to address this research question. These beliefs can then be used to design a TPB questionnaire, and ensures correspondence of beliefs in participants across the elicitation study and the follow-up TPB investigation (Downs & Hausenblas, 2005b). An elicitation beliefs study is of particular value because it offers insights into thoughts and feelings about performing a particular behaviour in a specific population (Downs & Hausenblas, 2005b). The information obtained in an elicitation beliefs investigation can then be used to design and develop a suitable intervention (Ajzen, 2006). Therefore, the information obtained in this investigation, may support the design of future interventions which aim to increase adherence to use of AFOs.

2.9.5 Can the Theory of Planned Behaviour (TPB) Predict Intention and Adherence to Use of AFOs in People with Stroke?

The beliefs identified in the previous investigation (described in 2.8.4) will be used in the development of a TPB questionnaire. This questionnaire will then be utilised in a prospective design to test the efficacy of the TPB to explain adherence to use of AFOs as recommended in people with stroke. Chapter 6 will detail this study, which aims to answer the research question, above. This structured, theoretical approach to understanding adherence is, to the author's knowledge, the first study, which aims to use a coherent psychological framework to investigate adherence to an AFO. This approach addresses the need for theory-driven research to inform interventions (Medical Research Council, 2008). Furthermore, interventions are more likely to be successful in behaviour change when they target theory-based determinants of that behaviour (Michie & Abraham, 2004).

2.10 Conclusion

Despite the evidence base for use and effectiveness of AFOs across a range of conditions, highlighted in Chapter 1, little is known about people's use of AFOs in real-life settings. Therefore, this chapter has explored the definition of adherence, and outlined adherence rates reported in the literature. In addition, the measurement of adherence to use of orthoses has been considered and determinants of adherence to orthoses have been highlighted.

Whilst several investigations have highlighted a number of factors affecting adherence to orthoses (Bulley et al., 2011; Phillips et al., 2011; Swinnen & Kerckhofs, 2015), no previous investigations have used a theoretical framework to understand adherence to AFOs as a health behaviour. In addition, adherence has generally been measured using vague terminology such as "frequent use" or "limited use", which is difficult to quantify. Therefore, this thesis will define adherence as use of an AFO as recommended, and this recognises the importance of the user in following recommended guidelines, and also accommodates for prescriptions of different amount of use in individuals. Through a series of investigations this thesis aims to: demonstrate the importance of adherence to use of AFOs; to apply a theoretical model (the TPB) to understand the factors effecting adherence to orthoses, and then use this model to predict adherence to use of AFOs.

Key Points from Chapter 2

1. Adherence to AFOs has been highlighted by a number of authors as an important concern.
2. There are challenges in defining and measuring adherence to AFOs. This creates difficulties in comparing adherence rates across different studies. Few studies have considered the recommended or appropriate use of orthoses when investigating adherence.
3. In this thesis adherence will be defined as “use of the AFO as recommended”. Typical recommendations suggest that the AFO is being used at all times when standing and walking.
4. Whilst objective measures of adherence are usually considered to be more accurate, there are valid concerns about the feasibility and cost of using objective monitors. In previous orthotic investigations measuring adherence to lower limb orthoses, the vast majority of studies have used self-reported measures of adherence. Advantages of subjective measures include ease of administration and low costs.
5. The literature suggests a number of determinants of adherence to AFOs: health condition; sociodemographic factors; fit and comfort of the AFO; practical issues such as weight and heat build-up; psychological issues and patient satisfaction. However, these factors have been suggested as potential determinants of adherence to orthoses without reference to a theoretical framework, which considers AFO use as a health behaviour.

Next Steps

Before using a theoretical framework to understand adherence behaviour, it is important to demonstrate that there are benefits in increased adherence for orthotic users. Therefore, Chapter 3 will investigate if use of AFOs as recommended is associated with reduced levels of impairment, activity limitation and participation restriction.

If people who use AFOs as recommended have better health outcomes, then identification of modifiable determinants of adherence, using a suitable theoretical framework, will potentially offer knowledge that might be used to increase adherence to use of AFOs.

Chapter 3 Use of the ICF to Investigate Impairment, Activity Limitations and Participation Restrictions in People Using AFOs

3.1 Introduction to Chapter

Ankle-foot orthoses (AFOs) are used to manage mobility disabilities caused by a wide range of conditions such as stroke, multiple sclerosis, poliomyelitis, arthritis and peripheral nerve injury. As described in Chapter 1, AFOs have been shown to improve timed walking speed, step length and clearance of the toe in the swing phase of gait (Bowers et al., 2009a; Bowers et al., 2009b; Gok et al., 2003; Lannin et al., 2011; Lehmann, Condon, de Lateur, & Price, 1986; Leung & Moseley, 2003; Morris, 2002). 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 focus on the impact of interventions on a person's quality of life. Measurement of psychological and social well-being recognises that health encompasses not only physical health, but also mental and social well-being (WHO, 2018a). In addition, physiological measures of health or disability (e.g., blood pressure, oxygen consumption when walking, blood sugar levels), which are often the outcomes of interest for medical professionals, do not necessarily reflect a patient's view of their health situation (Øvretveit et al., 2017). Therefore, patient reported measures such as quality of life and well-being can provide a better understanding of the impact of treatment on a person's day-to-day life.

This chapter focuses on AFO use in a real life setting, across a range of conditions, and describes a cross-sectional survey of people prescribed AFOs by NHS Greater Glasgow and Clyde (NHS GGC). This study investigates differences in outcomes between people using AFOs as recommended and those not using AFOs as recommended. These differences have not previously been investigated, and, therefore, it is not known if use of AFOs can lead to better outcomes for individuals in their daily lives. If it is found that people who use AFOs as recommended, have better outcomes, this will provide evidence of the need to increase levels of adherence in order to optimise outcomes of AFO use. Therefore, this will offer a strong argument for designing and applying interventions, which aim to increase adherence to AFO use as recommended. This study uses the International Classification of Functioning

Disability and Health (ICF, WHO, 2001), which provides a framework for defining appropriate outcomes related to day-to-day use of AFOs. Differences in experiences of impairment, activity limitation and participation restriction will be investigated in people using AFOs as recommended and people not using AFOs as recommended. In addition, measures of psychological distress will be included. This is important because psychological factors such as emotional well-being and cognitive processes can affect functional outcomes (Bonetti & Johnston, 2008; Johnston, Morrison, Macwalter, & Partridge, 1999; Schröder et al., 2007). This structured approach to defining outcomes, and use of outcome measures which provide a holistic perspective of the participant's experience of AFO use, offers an innovative approach to investigating variances across groups of participants who use AFOs in different ways.

3.2 Use of AFOs

As highlighted in Chapter 1, Section 1.8, AFOs have been shown to improve a range of different gait outcome measures in a people with different mobility disabilities. The ability of an AFO to improve gait is dependent on a patient adhering to AFO use as recommended. Despite this, whilst non-adherence to use of orthoses has been highlighted as a major concern (Swinnen & Kerckhofs, 2015), few previous investigations have specifically investigated adherence to AFOs. The investigation by Vinci and Gargiulo (2008) has particular relevance because they investigated adherence rates in patients prescribed with AFOs. They reported a worryingly low adherence level of 20% in a sample of 25 people with CMT disease who had been prescribed AFOs. Twelve out of 25 of the patients had refused to even attend an appointment with the orthotist because they were not interested in using an AFO. Vinci and Gargiulo (2008) did not specifically define adherence or compliance, although they considered people as being compliant if they used AFOs outside of their house. Chapter 2 previously highlighted a wide of variety of definitions and ways of classifying adherence to orthoses, which creates challenges when attempting to compare adherence rates across different conditions, or with different orthoses. Therefore, careful consideration will be given to the definition of adherence in this investigation.

When provided with an orthosis a patient should be given specific wearing instructions (Felton, 1999), 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 (Aubert, 1999), and under-use or non-use can lead to falls (Vinci & Gargiulo, 2008), progression of deformity (Lannin et al., 2011), and ulceration (Burton, 2007). The benefits of AFO use include pain relief (Huang et al., 2006), joint stabilisation (Bowers et al., 2009b), improved balance (Cakar et al., 2010; Tyson & Kent, 2013), and an improved gait pattern (Leung & Moseley, 2003; Tyson et al., 2013). In addition, the AFO can prevent the foot from dragging along the floor, as is often seen in hemiplegic gait (Leung & Moseley, 2003), and potentially reduces the likelihood of falls or trips in people with a dropped foot.

When patients choose not to use an AFO they will not experience the advantages AFO use, or if they use an AFO less than recommended, they will only obtain partial benefits. Sections 2.4 and 2.5 of Chapter 2, highlighted some of the challenges of defining and measuring adherence to orthoses. The majority of authors, with a few notable exceptions (Bakker et al., 1997; Sangiorgio et al., 2016), did not considered the recommended wearing time or instructions provided regarding appropriate use, when measuring adherence. This, therefore, calls into question the validity of measures in previous studies investigating adherence to orthoses. However, by defining adherence as use of AFOs as recommended, this recognises the individual nature of wearing instructions, which might be provided to patients fitted with AFOs, and also allows for adherence to be investigated across different conditions in which different recommendations may be made. No previous investigation has specifically investigated differences in outcomes between adults using AFOs as recommended and those not using AFOs as recommended. Consequently, this investigation seeks to identify if adherence to AFOs as recommended is associated with better outcomes.

3.2.1 Factors affecting AFO Use

To identify differences in outcomes across people using AFOs as recommended and those not using AFOs as recommended, consideration should be given to factors that might affect AFO use. These determinants have been outlined in Chapter 2 but are summarised below. Seriousness of the underlying health condition has been related to AFO use. Increased severity of Charcot-Marie-Tooth (CMT) disease (Ramdharry et al., 2012) and greater functional impairment in stroke have also been related to increased use of AFOs by patients (Teasell, McRae, Foley, & Bhardwaj, 2001). Other factors include gender, age, other health conditions, lifestyle, and individual psychological assets as well as other characteristics that may play a role in disability (WHO, 2002). Demographic variables such as age, gender and socio-economic status have been shown to affect use of wrist splints (Henderson & McMillan, 2002), reciprocating gait orthoses for spinal cord injury (Sykes et al., 1995), and orthopaedic footwear (van Netten et al., 2010a), although these variables have not been investigated in AFO use. Therefore, these determinants are potential confounding variables, which should also be considered when investigating differences between people using AFOs as recommended and those not using AFOs as recommended.

3.3 Identification of Health Outcomes

A structured approach to understanding use of AFOs and their impact on patient-centred outcomes is important. Use of a framework to determine appropriate health outcomes would facilitate the identification of appropriate outcome measures and therefore offer a more structured approach to the development of future interventions (Medical Research Council, 2008). The International Classification of Functioning, Disability and Health (ICF, WHO, 2001), described in Chapter 1, and seen Figure 1.1, offers a framework for conceptualising disability, which recognises the impairments caused by a disability or health condition but also acknowledges broader social aspects of disability, as well as the personal and environmental factors which impact on the individual's experience. The ICF can be used as a framework to examine the impact of health interventions on specific outcomes; impairment, activity limitation and participation restriction (Ayis et al., 2010; Fleming, Kuipers, Foster, & Smith, 2009). This is important as it then allows the identification of different aspects of health and disability, which might be targeted in future interventions.

3.3.1 Measurement of Impairment, Activity Limitation and Participation Restrictions

The demand for evidence-based practice in rehabilitation has grown in recent years with the aim of improving quality of health care. Measurement of outcomes is viewed as an essential component of continued progress in this field (Jette & Haley, 2005). This not only enables health professionals to demonstrate the efficacy of their own practice, and also track individual improvements during rehabilitation, but also enables variations in outcomes across different groups to be measured. When selecting outcome measures, it is important to ensure that outcomes measure the specific construct and do not overlap with other constructs in the same theory (Pollard, Johnston, & Dieppe, 2011). 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 (Johnston et al., 2014).

As this study considers AFO use across a number of conditions, there is a need to select measures, which are relevant to both condition and treatment. This creates a challenge in deciding appropriate measures for impairment, activity limitation and participation restriction. Generic measures are required, but any measures should also reflect the aims of the AFO to reduce activity limitation and increase participation. Whilst, ICF core sets have already been developed for specific conditions such as stroke (Geyh et al., 2004) and multiple sclerosis (Coenen et al., 2011; Khan & Pallant, 2007), they have not been developed for less common conditions. Therefore, core sets of outcome measures developed for these conditions do not provide a definitive guide to selecting outcome measures when investigating AFO use across a range of conditions which might be expected in an orthotic clinic.

Only one previous investigation (Burger, 2011), has used the ICF to determine functioning in orthotic patients, and, whilst codes from the ICF were used to describe functioning in prosthetic and orthotic users, the ICF was not used to identify appropriate outcome measures, and outcomes specific to AFO use were not reported. A candidate core set of outcome measures has been proposed to assess outcomes for lower limb orthotic interventions (Brehm et al., 2011). These core sets can be used to define impairment, activity limitation or participation restriction (Bickenbach, Cieza, Rauch, & Stucki, 2012). For example, Brehm et al. (2011) 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. In addition, Brehm et al. (2011) note that evaluation of activities and participation are important because this can highlight improvements caused by the intervention and therefore provide information to the patient and clinician about the clinical relevance of the orthosis.

However, although the most successful results are achieved in well-motivated patients (Brehm et al., 2011), 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 in rehabilitation (Bonetti & Johnston, 2008; Davidson et al., 2009; Johnston et al., 1999; Schröder et al., 2007). Within the ICF, psychological well-being indicators such as depression and anxiety are classified as impairments to the cognitive system. However, a number of authors have argued that psychological factors sit more comfortably within the personal factors component of the ICF (Dekker & de Groot, 2018; Grotkamp et al., 2012); and others have incorporated measures of mood into the personal factors of the ICF (Cruice, Worrall, & Hickson, 2005; Dixon et al., 2008; Kuijer et al., 2006). Irrespective of which domain under which psychological well-being or distress is measured, indicators of psychological well-being/distress may offer greater insight into the functional outcomes of people who have been prescribed orthoses.

Standardised measures of psychological well-being or distress have rarely been included in orthotic studies. The few studies, which have investigated the relationship between orthotic use and psychological distress, have not reported on AFO use using standardised measures. However, an evaluation of the outcome measures used in other orthotic investigations may offer some insight into appropriate measures, which might be used. Guest et al. (1997), used the Beck Depression Inventory to evaluate a physiotherapy training programme to use an ambulation system for people with SCI, and measured statistically significant changes in physical self-concept and depression. Davidson et al. (2009) found a significant decrease in depression scores using the Hospital Anxiety and Depression Scale (HADS) in a multidisciplinary rehabilitation programme, which included an orthotic intervention for patients with post-polio syndrome. They demonstrated increased exercise endurance, decreased perceived exertion and a decrease in depression levels, which was maintained for 6 months. Other studies have used qualitative measures of psychological well-being and reported improved confidence and self-esteem in people using AFOs (Bowers et al., 2009b; Bulley et al., 2014; O'Connor et al., 2016). 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. Given the established relationship between functional outcomes and psychological well-being/ distress (Noël et al., 2004; Wells, Stewart, Hays, & et al., 1989), it was therefore considered important to include a validated outcome measure of anxiety and depression in this study.

3.4 Aims and Hypotheses

The aims of this study were threefold. Firstly, this investigation aimed to measure adherence to AFOs in a general clinical population. Adherence rates to orthotic interventions previously investigated by others, have been conducted with small samples and with limited consideration for the definition of adherence (Nakipoğlu-Yüzer et al., 2018; Swinnen et al., 2017a; Vinci & Gargiulo, 2008). Additionally, adherence rates have demonstrated significant variance across different orthotic devices (Swinnen & Kerckhofs, 2015). Therefore, adherence levels in the general population of people using AFOs are not known. The second aim of this investigation was to investigate differences in impairment, activity limitation, and participation restriction in participants who used AFOs as recommended, and participants who did not use their AFO as recommended, in line with ICF outcomes. As highlighted previously, investigation of these differences as defined by the ICF has not previously been conducted among a clinical population of people who have been prescribed AFOs. Finally, this investigation also aimed to measure differences in psychological distress in participants who used AFOs as recommended, and participants who did not use as their AFO as recommended. As highlighted above, measures of psychological well-being/ distress can impact on functional outcomes. Therefore, inclusion of psychological distress measures provides a more holistic and comprehensive assessment of outcomes. The following hypotheses were tested:

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

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

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

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

3.5 Method

3.5.1 Pilot Questionnaire

A questionnaire was devised and piloted amongst ten AFO users, who previously attended the National Centre for Prosthetics and Orthotics, Department of Biomedical Engineering to assist with clinical teaching. Ethical approval for this pilot study was sought from University of Strathclyde (UEC 0910/39).

3.5.2 Measures

3.5.2.1 Sociodemographic 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 (McLoone, 2004). 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 (Hampson, Glasgow, & Strycker, 2000; Janssens et al., 2004). Furthermore, many patients using AFOs present with co-morbidities, which could also explain higher levels of impairment and activity limitations.

3.5.2.2 Measurement of ICF Constructs

The ICF constructs of impairment, activity limitation and participation restriction were measured using different aspects of the RAND-36 Item Short Form Health Survey (Hayes & Morales, 2001). 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. In order to ensure that the measurements did not overlap with other constructs (Pollard et al., 2009), consideration was given to how elements of the RAND-36 linked specifically to impairment, activity limitation and participation restriction.

3.5.2.2.1 Measures of Impairment

Items from the RAND-36 (Hayes & Morales, 2001) were used to measure four 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 (Pollard et al., 2009). 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]”).

3.5.2.2.2 Activity Limitations

Seven items from the RAND-36 (items 6-12) physical functioning sub-scale were used to measure activity limitations. 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 (Pollard et al., 2009).

3.5.2.2.3 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 two items (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]”).

3.5.2.2.4 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 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 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]”).

3.5.2.2.5 Psychological Distress and Well-Being -Hospital Anxiety and Depression Scale (HADS) and Positive and Negative Affect Scale (PANAS)

The HADS (Zigmond & Snaith, 1983) was used to measure anxiety and depression; two further indicators of psychological distress. 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].

Positive and negative affect were measured using the Positive and Negative Affect Schedule (PANAS, Watson, Clark, & Tellegen, 1988), a 20 item self-report measure including positive affect and negative affect. The PANAS asks participants to state the extent to which they have felt a range of feelings and emotions over the last week (e.g. interested, distressed, excited: very slightly or not at all [scored 1]; a little [scored 2]; moderately [scored 3]; quite a bit [scored 4]; or extremely [scored 5]). The PANAS is a valid and reliable measure, which has been tested in both clinical and non-clinical populations (Crawford & Henry, 2004; Kwon, Kalpakjian, & Roller, 2010; Ostir, Smith, Smith, & Ottenbacher, 2005).

3.5.3 Evaluation of Questionnaire

An additional short questionnaire was also provided to participants, which asked for feedback on the following aspects of the questionnaire: layout and format, clarity of questions, relevance of questions to the individual, and time taken for completion of the questionnaire. Participants were generally positive about the questionnaire. A few users commented that they would have preferred not to write as much, when documenting their health issues. Also it became apparent that if participants were bilateral users of orthoses, their responses could be different depending on if the participant was considering their left or right leg. Average time for completion of the questionnaire was 20 minutes. Although this was considered to be acceptable, a few participants reported that they felt the questionnaire was excessively long. As a result of the piloting exercise the following changes were made to the questionnaire before final dissemination: tick boxes for health conditions in order to reduce the amount of writing for the participants; an additional section was added to distinguish between left and right AFOs as some patients wore an AFO on both sides, and may have had different experiences of a left and right AFO; removal of the PANAS scale to reduce length of the questionnaire; and a few additional minor layout changes, and additional explanatory statements were added. The final questionnaire (V2.3) can be seen in Appendix 3.1.

3.5.4 Main Study: Participants

Participants were 157 patients who had been fitted with an AFO between 2010 and 2012, from NHS Greater Glasgow and Clyde, 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 were prescribed an AFO for a range of different conditions, seen in Figure 3.1. The most common condition for which an AFO was prescribed was stroke (26.1%, n=40), followed by multiple sclerosis (17.2%, n=27), then peripheral nerve injury (10.8%, n=17). Nine participants (5.7%) reported more than one condition or structure of the body affected, for which an AFO was required, and these participants were classified as 'presenting with >1 condition'. Four participants did not know the reason for which the AFO was prescribed. Six participants in the 'other' group had conditions which did not fit the other categories, each of which was reported only once e.g. muscular dystrophy, complex regional pain syndrome, hip abnormality, lower limb deformity, osteosarcoma[16], and POEMS syndrome[17].

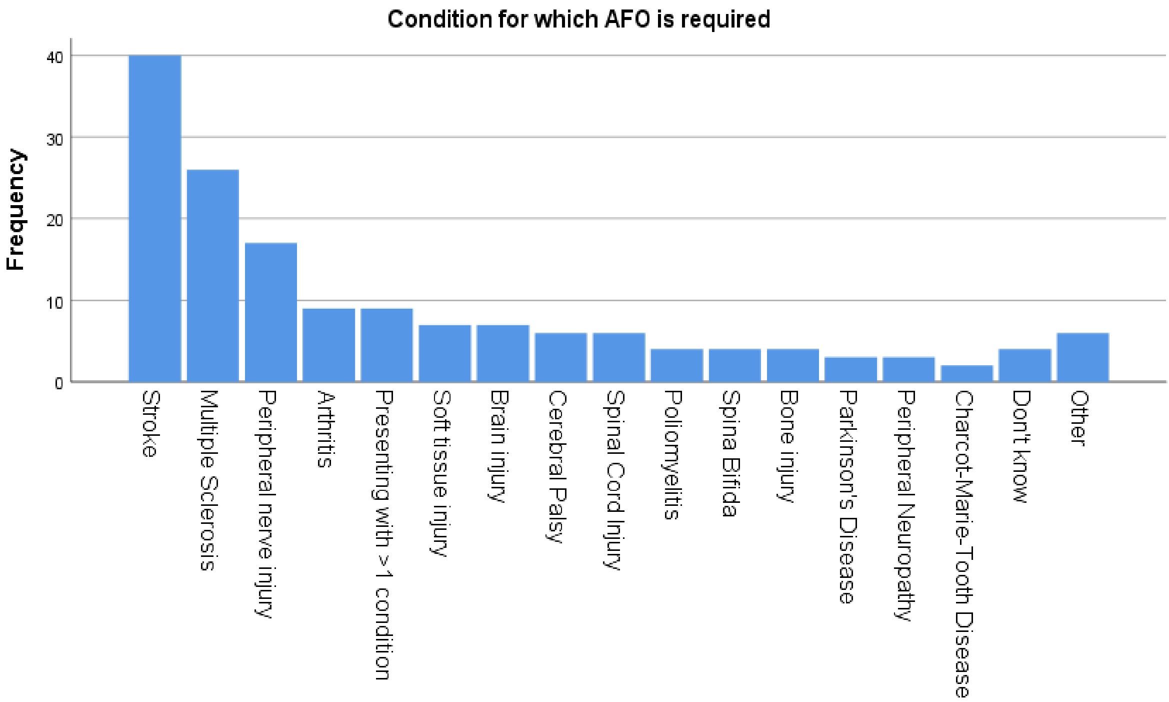

Figure 3-1: Frequency of Conditions for which AFOs were Prescribed

Given the wide range of different conditions reported, participants were grouped into two groups: 82 participants (53.6%), prescribed an AFO because of a condition caused by damage

[16] A type of bone cancer, usually occurring in the ends of long bones
[17] POEMS syndrome is a rare blood disorder which causes polyneuropathy, organomegaly (enlarged organs such as the liver or lymph nodes), endocrinopathy (abnormal hormone levels), the presence of monoclonal protein (caused by abnormalities in bone marrow cells) and skin changes (Dispenzieri et al., 2003)

to the brain (e.g., stroke, multiple sclerosis, traumatic brain injury, 53.6%), and 71 participants (46.4%), prescribed an AFO because of damage to another part of the body (e.g., peripheral nerve injury, bone or soft tissue damage, 46.4%).

The mean length of time since the AFOs were fitted to participants was 19.1 (*SD* 11.8) months. Forty-one per cent 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 per cent (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 they were compared to participants who used their AFOs as recommended and those who did not know the recommendations for use.

3.5.5 Main study: 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 NHS GGC 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, seen in Appendix 3.2. The information sheet stated that: participation was voluntary, that there were no right or wrong answers to any of the questions, 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, and a completed and returned questionnaire was accepted as consent. 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 (Gontkovsky, Russum, & Stokic, 2007; Hatcher, Whitaker, & Karl, 2009). Out of the 161 participants who responded, four 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 endorsed by the University of Strathclyde Ethics Committee (UEC 110102). The letter for ethical approval is seen in Appendix 3.3.

3.6 Statistical Analysis

All questionnaire data were coded and entered into SPSS® Version 20. The scales used to measure different aspects of impairment, produced reliable composite scales for general health (α= .84), pain (α= .91), energy/fatigue (α= .74), and emotional well-being (α= .86). Items from the physical functioning sub-scale of RAND-36 were used to measure activity limitations and exhibited high internal consistency (α= .91). Participation was measured using the social functioning subscale of the RAND-36 and also demonstrated good internal consistency (α= 0.86). Two mixed measures, which combined elements of both activity limitations and participations: role limitations due to physical health problems (α= .86) and role limitations due to emotional problems (α= .87) also provided reliable scales. Finally, Cronbach's alpha for the anxiety (α= .77) and depression (α= .86) scores measured by HADS, displayed good internal consistency.

The large number of participants who did not know recommendations for use (n=42) was an unexpected finding. Rather than excluding these participants from the analyses, it was decided to create a third group to enable comparisons to be made between participants using AFOs as recommended, those not using AFOs as recommended and those participants who did not know recommendations for use. It was considered that inclusion of this group might shed light on outcomes for these participants, who for a range of reasons did not know recommendations for use of their AFOs.

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 and 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.

3.7 Results

3.7.1. Demographic and Clinical Characteristics of the Sample

The demographic and clinical characteristics of the three groups are shown in Table 3.1. There were no significant differences in demographic or clinical characteristics between the three groups. Therefore, the subsequently reported differences between these participant groups on the ICF outcomes and HADS sub scores cannot be attributed to any between-group differences in demographic or clinical status.

3.7.2 Adherence to Orthoses

In this investigation, adherence was defined as use of AFOs as recommended. To calculate the adherence rate, the participants who did not know recommendations for use were excluded, leaving a sample size of 115. Sixty-four participants reported that they used their AFOs as recommended, providing an adherence rate of 56%.

Table 3-1: Comparison of Demographic and Clinical Characteristics of Sample between People Using AFOs as Recommended, People Not Using AFOs as Recommended, and People who did Not Know Recommendations for Use

	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 (22.3%)	19 (12.1%)	18 (11.5%)	3.68	0.16
Female (n (%))	85 (54.1%)	29 (18.5%)	32 (20.4%)	24 (15.3%)		
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%)		
Stroke	40 (26.1%)	12 (7.8%)	15 (9.8%)	13 (8.5%)	2.81	0.25
Condition other than stroke	113 (73.9%)	51 (33.3%)	34 (22.2%)	28 (18.3%)		
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

3.7.3 Descriptive Statistics

The means and standard deviations in Table 3.2 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 (Zigmond & Snaith, 1983).

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.

3.7.4 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 3.2). 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, no differences were found 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 the groups. Follow-up t-tests indicated lower role limitations due to emotional problems $t(df=89.54) = 3.25$, $p<0.01$, $d=0.91$, in participants using AFOs as recommended.

Table 3-2: 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 impairment, activity limitation, participation restriction and psychological distress

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

* $p < 0.05$; ** $p < 0.01$ RAND 36 was used to measure impairment (I), activity limitations (A), and participation restrictions (P). HADS was used to measure psychological distress: Anxiety and Depression

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 significantly lower levels of anxiety $t(df=148)=2.71$, $p<0.01$, $d=0.91$, in participants using AFOs as recommended, providing some support for hypothesis 4.

3.8 Discussion

The aims of this study were to identify adherence rates to AFOs in a general clinical population, and investigate differences in the three ICF outcomes of impairment, activity limitation and participation restriction, and psychological distress in participants using AFOs as recommended and participants who did not use AFOs as recommended. Inclusion of a third group, participants who did not know recommendations for use, as identified by the adherence data, enabled information about the outcomes for these participants to also be investigated. This is the first investigation, which has used the ICF framework to define outcomes, and compare these outcomes in patients who have used AFOs as recommended and those who have not use AFOs as recommended.

The adherence rate of 56% identified in this study compares favourably with the 20% adherence rate found in participants with CMT (Vinci & Gargiulo, 2008), although is lower than the 70% adherence rate found in participants with stroke (Bowers, 2008). The current investigation used a much larger sample size (n=157) than these previous investigations and participants reporting a wide range of health conditions were used to investigate adherence. Therefore, the 56% adherence rate may be a more accurate reflection of the levels of adherence seen across the whole population of AFO users. The level of non-adherence to the AFOs, at 44%, suggests than non-adherence should be an important concern for NHS Greater Glasgow and Clyde, and consequently requires an understanding of reasons for non-adherence to AFOs and consideration of how the challenge of non-adherence might be addressed.

3.8.1 Outcomes in Impairment, Activity Limitation and Participation Restrictions

The ICF (WHO, 2001) offers a framework for understanding and theorising about disability and the management of a wide range of health conditions. It can be used to guide the selection of appropriate outcomes in order to measure impairment, activity limitation and participation restriction, thus providing a broad and holistic understanding of the patient's experience of disability. For impairment outcomes, participants using their AFO as recommended reported higher levels of energy (a medium to large effect size (Cohen, 1988)), 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 (Balaban et al., 2007; Corcoran et al., 1970; Franceschini et al., 2003). In the current study, people using AFOs as recommended did not report lower pain levels compared to the other two groups. In contrast, reduction in pain following use of AFOs has been reported in other studies (Attard & Singh, 2012; Jagadamma et al., 2010; Johnson & Alvarez, 2012) with Jagadamma et al. (2010) reporting the importance of appropriate tuning of the AFO-footwear combination in reducing knee pain. However, due to the research design, it was not possible 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 significant differences were not seen. There was no difference in general health between the groups when comparing people using AFOs as recommended and those not using AFOs as recommended. General health is a very generic measure of health status in such a heterogeneous group, with a range of co-morbidities, and may therefore have value in providing an indicator of overall health status, rather than demonstrating differences across groups.

Participants who reported using their AFOs as recommended also reported lower activity limitations (a small-medium effect size (Cohen, 1988)) than those not using their AFOs as recommended. This finding is consistent with a systematic review and meta-analysis (Tyson & Kent, 2013) 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), concentrate on the participant's performance 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 reflective of the actual benefits of orthotic use to the patient.

Higher scores in role limitations due to emotional problems (a large effect size) were seen in participants who used AFOs as recommended meaning that role limitations experienced by people using AFOs as recommended were significantly less than people who did not use AFOs as recommended. However, this measure is not a pure measure of activity limitation but a combination of activity and participation restrictions. Therefore, while this is an important finding, the lack of discriminant validity poses challenges in understanding the relationship between ICF constructs. However, it does suggest a possible relationship between activity level, participation, emotional well-being and AFO use, and may offer potential opportunities to increase adherence rates, and activity level by improving emotional well-being in individuals.

Contrary to hypothesis 3, no significant difference was found in the pure measure of participation restrictions between people using AFOs as recommended and those not using AFOs as recommended, 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. Environmental factors recognise the importance of the environment on functioning (e.g., physical factors such as terrain or accessibility of buildings), and personal factors may include gender, age, race, education and lifestyle. Therefore, these constructs may also enable or hinder activities and social participation. Another possible reason for a lack of significance in this current study may be that the effect of the AFOs on people using AFOs as recommended, may have increased the participation levels to a similar level of people who did not use their AFOs as recommended (i.e. people not using their AFOs as recommended had higher levels of participation prior to the AFO intervention). 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 patients who did not use their AFO (a large effect size (Cohen, 1988)), 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 (Bowers et al., 2009b). The lower levels of anxiety in participants using their AFOs as recommended is an important finding, and provides support for including psychological measures of well-being/ distress in orthotic outcome measures. Additionally, it may be suggestive of future potential interventions to improve adherence to AFOs.

3.8.2 Participants Not Aware of Recommendations for AFO Use

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 (Bowers et al., 2009b), 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. Careful consideration should be given to the need for information, which is accessible and easily understood.

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 identify potentially modifiable determinants of adherence, which could pave the way for the design of interventions that could increase adherence to AFOs. This could offer potential opportunities to reduce impairment, and improve activity levels and psychological well-being by identification of strategies to increase the levels of adherence in patients who have been prescribed orthoses.

3.8.3 Use of 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 operationalised and related specifically to orthotic use. The relationships between impairment, activity limitations and participation are complex, with personal and environmental factors adding increased complexity. Pollard, Dixon, and Johnston (2013) investigated the mental representations of people with osteoarthritis and found that they were consistent with the ICF, following a causal model of disability with impairment followed by activity limitation and in turn activity limitations followed by participation. Therefore, they concluded that interventions, which aim to reduce impairment, may have a weak impact on activity limitation and participation restriction, and may only affect participation indirectly. Brehm et al. (2011) noted that currently there is no consensus on the most appropriate outcome measures, and further work is needed to identify suitability of instruments, which also consider the context being investigated. The ICF was found to be a relevant and instructive model in understanding differences in outcomes across people using AFOs as recommended and people not using AFOs as recommended, and highlighted that people using AFOs as recommended had reduced impairment and activity limitations compared to people not using AFOs as recommended. In addition, the results of this study suggest the need to incorporate psychological well-being/ distress measures from the ICF such as energy and drive, and emotional functions to better understand AFO use.

3.8.4 Strengths and Limitations

This study is the first study, to the author's 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, which require to be acknowledged. 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 (Bowers et al., 2009b; Hanger & Mulley, 1991; Tyson & Thornton, 2001). Furthermore, inclusion of non-users of AFOs is regarded 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 important differences between the groups to be identified.

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, it is not certain if the findings would be generalizable 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. Self-reported measures of adherence may be prone to bias (National Collaborating Centre for Primary Care, 2009). However, it was considered 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"*), encouraged an honest response regarding use of AFOs 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 this is considered 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.

3.9 Conclusion

This study adds to the literature by focusing on the important and often under-investigated topic of adherence to AFOs in a real life setting. In this study, the ICF has been used as a framework to investigate differences in impairment, activity limitation and participation restriction across three groups of AFO users; people using AFOs as recommended, people not using AFOs as recommended, and people who did not know recommendations for use. This study has demonstrated significantly lower levels of impairment in people using AFOs as recommended, as measured by higher energy levels, and higher levels of activity limitations as measured by physical functioning. In addition, the inclusion of measures of psychological distress provided additional insight into differences in people using AFOs as recommended and those not using AFOs as recommended: people using AFOs as recommended had significantly lower levels of anxiety than people not using AFOs as recommended. The differences highlighted in this investigation demonstrate the importance of using an AFO as recommended and therefore justify the need to investigate adherence to AFOs in more depth.

This study has identified a 56% adherence rate to AFOs as recommended in a general orthotic service, and the level of non-adherence demonstrates room for improvement. There is a complex range of reasons why people may not use AFOs when prescribed them. Depending on the individual, an orthosis may be either a barrier or a facilitator to a range of activities, which may in turn negatively or positively affect patient outcomes. Therefore, it is necessary to understand why people who are prescribed AFOs choose to use them or not, to enable the design of interventions which may potentially increase use of AFOs, and, in turn, reduce impairment, activity limitation, participation restriction and psychological distress.

The patient's decision to use an AFO can be considered a health behaviour, and therefore to improve understanding of the cognitive process underlying AFO use, psychological models can be utilised to increase understanding of adherence to AFOs. Importantly, because cognitive variables are important determinants of behaviour (Armitage & Conner, 2000), and cognitions are potentially modifiable, this enables the development of interventions which can target cognitions and in turn facilitate behaviour change (Conner & Norman, 1996). In order to advance knowledge about why people choose to use AFOs or not, it is necessary to identify a suitable model of behaviour which would be relevant to AFO adherence behaviour. Chapter 4 begins by providing an overview of possible psychological models of behaviour, and then identifies the Theory of Planned Behaviour (Ajzen, 1991) as a potentially suitable model to investigate adherence to AFOs.

Key Points from Chapter 3

1. The ICF was used as a framework to identify outcomes of AFO use, which are of relevance in a person's day-to-day life. This study investigated differences in impairment, activity limitation and participation restriction across three groups of AFO users; people using AFOs as recommended, people not using AFOs as recommended, and people who did not know recommendations for use.
2. Adherence to use of AFOs as recommended, across multiple conditions was 56%. There was a high percentage of participants (27%) who did not know recommendations for use.
3. This study found: significantly lower levels of impairment, as measured by higher energy levels ($p<0.01$); lower levels of activity limitations as measured by increased physical functioning ($p<0.01$); and decreased role limitations due to emotional problems ($p<0.01$) (a measure of both activity limitation and participation restriction); in people who used AFOs as recommended.
4. In addition, inclusion of psychological distress as an outcome measure, demonstrated significantly lower levels of anxiety ($p<0.01$) in people using AFOs as recommended compared to people who did not use AFOs as recommended.

Next Steps

Given these differences, there is a need for researchers and health professionals to understand factors affecting AFO use as recommended, especially if there is potential to modify these factors, and therefore increase user adherence to AFOs.

Before determinants of AFO use can be identified, a suitable model of behaviour must be selected, and the use of the model appropriately justified. Chapter 4 identifies the Theory of Planned Behaviour (Ajzen, 1991), as the most suitable model to investigate adherence to AFOs. Chapter 4 then describes a meta-analysis of studies using the TPB to investigate adherence to prescribed health behaviours in conditions for which orthoses might be prescribed. Therefore, Chapter 4 provides a theoretical rationale for using the TPB to investigate AFO use as recommended.

Chapter 4 Using the Theory of Planned Behaviour to Explain Adherence to Prescribed Health Behaviours in Conditions for which an Orthosis might be Prescribed: A Review and Meta-analysis

4.1 Introduction to Chapter

Chapters 1 and 2 highlighted the high percentage of reported non-adherence to orthoses (Swinnen & Kerckhofs, 2015; Vinci & Gargiulo, 2008), and the potential negative effect on individual health outcomes. In Chapter 3, a survey was conducted to investigate differences in health outcomes, using the ICF as a framework, in people using AFOs as recommended, and those not using AFOs as recommended. It was found that people using AFOs as recommended had lower levels of impairment and activity limitations, and lower levels of anxiety, compared to people not using AFOs as recommended. With this in mind, it is therefore important to understand better why people choose to adhere to orthoses or not, so that adherence to AFOs can potentially be increased, and in turn improve health outcomes.

Psychological models of behaviour are potentially useful for helping researchers and practitioners understand the reasons why people might or might not adhere to recommendations regarding use of their orthoses. This is because they contain constructs (e.g., attitudes and intentions) that are proposed as causal determinants of behaviour, and are potentially modifiable. They therefore provide useful frameworks for researchers to identify causes of behaviour that might constitute effective targets for interventions (e.g., to enable users to increase use of orthoses). The application of these models to understand adherence to orthoses as a health behaviour offers a framework for investigating a real world health challenge, and can potentially improve patient outcomes and provide a more cost-effective orthotic service, as described in Chapter 1. Furthermore, interventions are more likely to be successful in behaviour change when they target theory-based determinants of that behaviour (Michie & Abraham, 2004). Therefore, in line with recommendations from the Medical Research Council (2008) and Moore et al. (2015) which identify the need for theory-driven research to inform interventions, the efficacy of a psychological model applied to understanding health behaviours in conditions for which orthoses are prescribed, is investigated in this chapter.

There are a range of psychological models of behaviour, that can be used to predict behaviour and a brief explanation of some of the most widely utilised models is provided in Table 4.1., below. All of the theories described in Table 4.1, have been utilised extensively to explain health behaviours, although each model is not without criticism. One of the most widely used behavioural theories is the Theory of Planned Behaviour (TPB) (Ajzen, 1991), and its predecessor the Theory of Reasoned Action (TRA)(Ajzen & Fishbein, 1980; Fishbein & Ajzen, 1975), which have both been applied across a wide range of social and health behaviours. Previous investigations have generally supported the theoretical framework and the relationships hypothesized by the model (Ajzen, 2014). Furthermore, the TPB /TRA have typically been shown to explain more variance in behaviour than other models (Armitage & Conner, 2001; Conner & Armitage, 1998; Taylor et al., 2006), making them potentially the most appropriate psychological theory for understanding adherence to orthoses.

Although the TPB/TRA have not been used to understand adherence to orthotic intervention, they have been used to understand many health behaviours in the general population such as exercise (Downs & Hausenblas, 2005a; Hagger et al., 2002), condom use (Albarracin, Johnson, Fishbein, & Muellerleile, 2001), smoking (Topa & Moriano, 2010), and blood donation behaviour (Bednall, Bove, Cheetham, & Murray, 2013). In addition, the TPB/ TRA have been used to help explain why people with health conditions adhere to exercise (Blanchard et al., 2003; Gucciardi, 2016), diet (McConnon et al., 2012; White, Terry, Troup, Rempel, & Norman, 2010), medication (Conner et al., 1998; Saal & Kagee, 2011), and self-care behaviours (Matterne, Diepgen, & Weisshaar, 2011; Shankar et al., 2007). The findings of these studies have already shed light on the reasons underpinning adherence behaviour generally and are likely to provide insight into whether the TPB/ TRA is likely to provide a useful theoretical framework for understanding adherence to orthoses.

In this chapter, the TPB is therefore detailed, along with applications of this model, within the context of various health conditions. In addition, there are various factors that potentially determine how well the theory can predict adherence behaviour, including the type of adherence behaviour under investigation (e.g., exercise, diet, self-care behaviours, or medication), the type of medical conditions that require individuals to adhere to a course of action (diabetes, musculoskeletal conditions, trauma or neurological conditions), and different aspects of measurement of the constructs of the TPB. This chapter will consequently review these factors. Finally, this chapter reports a review and meta-analysis of previous TPB/ TRA studies that have been applied to prescribed adherence behaviours in conditions

Table 4-1: Overview of Commonly Used Theories of Behaviour

Theory	Brief Description	Key constructs	Criticisms
Health Belief Model (Rosenstock, 1974)	Developed in an attempt to explain people's failure to use preventative health behaviours (e.g. screening, vaccinations). Behaviour is determined by a number of beliefs about threats to health or well-being and effectiveness and outcomes of particular actions	• Perceived susceptibility to condition • Perceived seriousness of condition • Perceived benefits • Perceived barriers • Cue to action • Self-efficacy	Wide variation in operationalisation of constructs (Jones, Smith, & Llewellyn, 2014) Explains low levels of variance in health behaviour (Rosenstock, Strecher, & Becker, 1988) Ambiguity about relationships between constructs (Champion & Skinner, 2008)
Social Cognitive Theory (Bandura, 1986)	Developed from Bandura's Social Learning Theory (Bandura, 1977b). A dynamic and reciprocal model in which personal factors, environmental influences, and behaviour interact. People learn through own experience, but also by observation of behaviour of others, and results of their actions	• Observational learning • Reinforcement • Self-control • Self-efficacy	A very broad and loosely organised theory, which is often only used in part and is difficult to operationalise (Munro et al., 2007) Model accounts for only small to medium variances in behaviour (Armitage & Conner, 2000; Keller, Fleury, Gregor-Holt, & Thompson, 1999)
Common Sense Model of Illness Representations (Leventhal, Brissette, & Leventhal, 2003)	Explains how individuals respond to and manage health threats. Leventhal described five components of illness representations: identity; cause; time-line; consequences; curability/ controllability	• Patient's perceptions of illness or health threats • Coping responses • Success or failure of coping response (health outcomes)	It is likely that other constructs affect the pathway from illness representations to outcomes (e.g., role of significant others) (Hale, Treharne, & Kitas, 2007) Illness beliefs from CSM has been shown to be very weak predictors of adherence behaviours (Aujla et al., 2016)

Theory	Brief Description	Key constructs	Criticisms
Stages of Change model, also referred to as the Transtheoretical Model (Prochaska & DiClemente, 1983)	Highlights that people are at different stages of readiness to adopt healthy behaviours. Five categories have been identified which represent levels of motivational readiness. These are: pre-contemplation, contemplation, preparation, action, and maintenance	Movement between categories is determined by 2 factors: • Self-efficacy • Decisional Balance	Categories outlined by model are artificial and process of behaviour change occurs on a continuum (Bandura, 1998) Proposed stages are not mutually exclusive, and there is limited evidence of movement through individual consecutive stages (Littell & Girvin, 2002)
Theory of Planned Behaviour (TPB) (Ajzen, 1991)	The TPB is an extension of the Theory of Reasoned Action (TRA, Fishbein & Ajzen, 1975) with addition of Perceived Behavioural Control. It is a general theory of behaviour, which assumes that behaviour is rational or 'reasoned'. Individuals' attitudinal, normative and control beliefs influence intention, and in turn, behaviour. PBC influences both intention and behaviour directly	• Attitude (and attitudinal beliefs) • Subjective norms (and normative beliefs) • Perceived Behavioural Control (and control beliefs) • Intentions • Behaviour	Focus on rational reasoning and exclusion of unconscious processes, which affect decision-making. Does not account for effect of emotions on behaviour (Sniehotta, Presseau, & Araújo-Soares, 2014) Model does not fully account for behaviour. Addition of other variables can add to the predictive validity of the model (Conner & Armitage, 1998)
Protection Motivation Theory (Rogers, 1975)	Attempts to explain the impact of fear as a motivating factor for health behaviour. Two threat appraisal constructs and two coping appraisal constructs are the motivators to protect oneself from harm (protection motivation)	• Severity of disease • Vulnerability to disease • Effectiveness of precautionary measure • Self-efficacy	Rogers (1975) acknowledges that some variables which might affect behaviour change (e.g., social norms) are not accounted for in the model The theory explains only moderate effects on behaviour (Floyd, Prentice-Dunn, & Rodgers, 2000)

for which orthoses might be provided, in order to gauge the potential usefulness of the model in understanding adherence to orthoses.

4.1.1 The Theory of Planned Behaviour

The Theory of Planned Behaviour (TPB, Ajzen, 1991, see Figure 4.1), is an extension of the Theory of Reasoned Action (TRA, Fishbein & Ajzen, 1975). The TRA proposes that behavioural intentions (BI) are the direct proximal determinants of behaviour (B). BI are an indication of an individual's readiness or willingness to perform a behaviour. BI are, in turn, predicted by attitudes (ATT), which represent a positive or negative evaluation of performing the behaviour (e.g., 'For me, using an AFO to walk around my environment is bad/good'), and subjective norms (SN), which are perceived social pressures from significant others to adopt the behaviour (e.g., 'People important to me would want me to use an AFO to walk around my environment'). The TPB extends this framework by adding perceived behavioural control (PBC), which refers to beliefs about the ease or difficulty of performing a behaviour (e.g., 'Using an AFO to walk around my environment is easy/ difficult'). PBC is posited as a predictor of both BI, along with ATT and SN, and B (Ajzen, 2006).

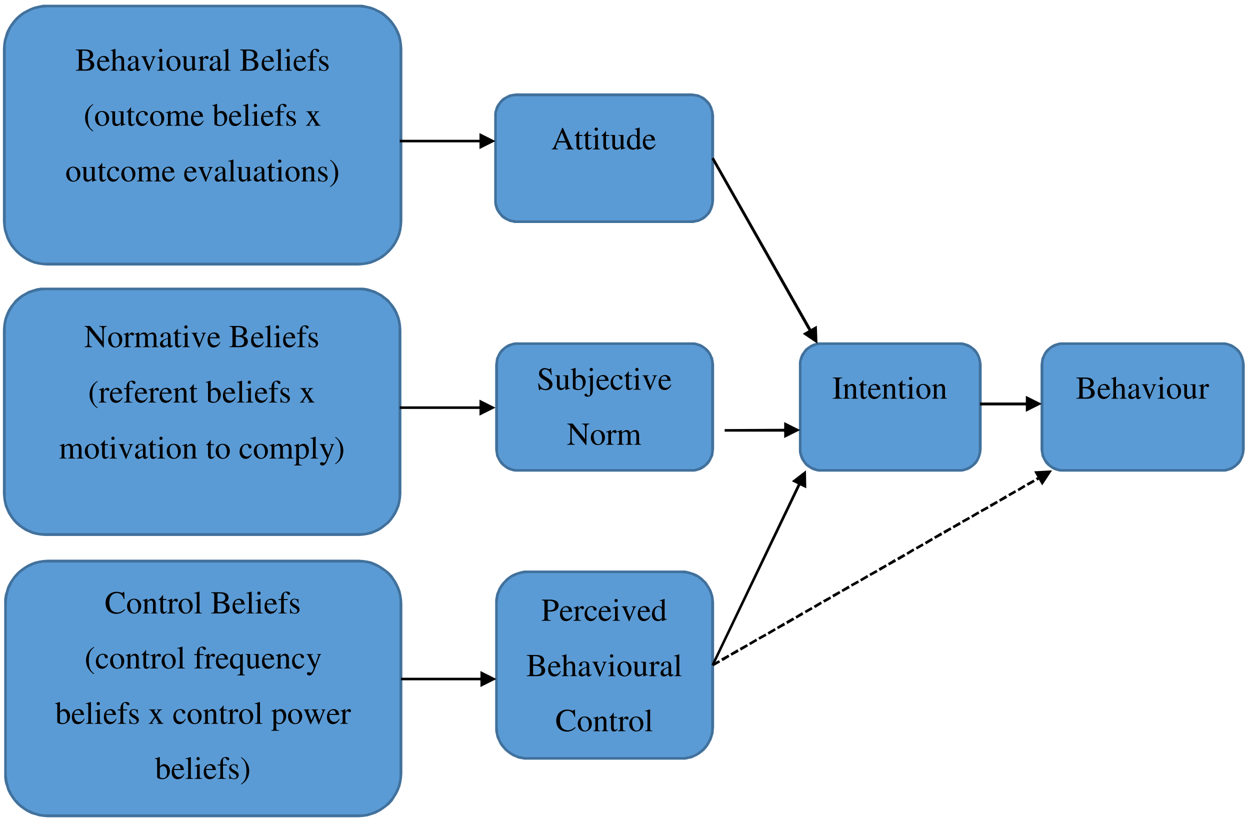

Figure 4-1: The Theory of Planned Behaviour (Ajzen, 1991)

In turn, ATT, SN and PBC are each determined by underlying beliefs. Attitudes are underpinned by behavioural beliefs, which are beliefs about the likely outcomes of the behaviour (outcome beliefs e.g., 'Using an AFO will help me to walk safely'), and the evaluations of those outcomes (outcome evaluations e.g., 'Walking in a safe manner is good/ bad'). Subjective norm is influenced by normative beliefs, which are beliefs about whether specific groups of people would approve of the behaviour (referent beliefs e.g., 'My family think I should use an AFO') and an individual's motivation to comply with those groups (motivation to comply beliefs e.g., 'I want to do what my family think I should do'). PBC is influenced by control beliefs about the extent to which an individual will encounter or experience factors that are likely to facilitate or inhibit the behaviour (control frequency beliefs e.g. 'When using my AFO to walk, I am likely to receive adequate training to use it') and the power of these factors to facilitate or inhibit behaviour (control power beliefs e.g., 'If I receive adequate training to use my AFO, this would make using my AFO easy/ difficult').

Thus, if an individual believes that positive rather than negative outcomes are likely to result from using an AFO, (s)he is likely to develop a positive attitude to using an AFO; if an individual is motivated to comply with groups of people who are perceived to approve rather than disapprove of AFO use, (s)he is likely to perceive social pressure (SN) to use an AFO; and if an individual perceives that (s)he will frequently encounter factors that facilitate rather than inhibit AFO use, (s)he is likely to perceive control over this behaviour. Positive ATT and high levels of SN and PBC will in turn lead to strong BI to use an AFO, and strong BIs and high levels of PBC will increase actual use of AFOs.

The TPB is one of the most extensively used theoretical frameworks for understanding human behaviour (McEachan, Conner, Taylor, & Lawton, 2011), and a number of meta-analytic reviews have investigated the efficacy of the theory. A previous meta-analysis of TPB studies investigating a wide range of social behaviours by Armitage and Conner (2001), found that behavioural beliefs (BB) accounted for 25% of the variance in ATT, normative beliefs (NB) accounted for 25% of the variance in SN, and control beliefs (CB) accounted for 27% of the variance in PBC. ATT, SN and PBC accounted for 39% variance in BI, and BI and PBC accounted for 27% variance in behaviour. Weighted correlations for the individual relationships of the TPB were $r=0.47$ (I-B), $r=0.37$ (PBC-B), $r=0.49$ (ATT-I), $r=0.34$ (SN-I), and $r=0.43$ (PBC-I). These findings were similar to an earlier meta-analysis by Godin and Kok (1996), which looked at the application of the TPB to a range of health behaviours, including addictive, screening, driving, eating, exercising, and HIV/AIDS related behaviours. They reported that ATT, SN and PBC accounted for 41% of the variance in BIs; and 34% of the variance in behaviour was accounted for by BI and PBC (note that these researchers did not examine the variance in ATT, SN and PBC accounted for by behavioural, normative and control beliefs respectively). Individual weighted correlations were: r=0.46 (I-B), r=0.39 (PBC-B), r=0.46 (ATT-I), r=0.35 (SN-I), and r=0.46 (PBC-I). McEachan et al. (2011) also investigated health behaviours, and found a similar percentage (44.3%) of the variance in BIs was accounted for by ATT, SN and PBC, although a lower 19.3% of the variance in behaviour was accounted for by BIs and PBC. They reported the following weighted correlations between the TPB variables: r=0.43 (I-B); r=0.31 (PBC-B); r=0.57 (ATT-I); r=0.40 (SN-I); r=0.54 (PBC-I). The effect sizes (R^2 and r values) reported in these meta-analytic studies are regarded as medium (R^2= 0.10 and r= 0.30) to large (R^2=0.25 and r=0.50) sized effects in the social sciences (Cohen, 1992), and demonstrate the predictive validity of the TPB across a range of health and social behaviours.

In addition, there have been two more recent meta-analyses, which have specifically looked at adherence behaviours, such as exercise, medication, self-care and diet, using the TPB as a framework. Husebo, Dyrstad, Soreide, and Bru (2013) used the TPB to understand adherence to exercise in patients with cancer, and found the following weighted correlations for the relationships proposed by the TPB: r=0.22 (I-B) and r=0.17 (PBC-B). Correlations between BB-ATT, NB-SN, CB-PBC, ATT-I, SN-I, and PBC –I were not reported. Additionally, Husebo et al. (2013) did not calculate the overall percentage of variance that the TPB constructs accounted for intention and behaviour. More recently Rich, Brandes, Mullan, and Hagger (2015) presented a more comprehensive investigation of adherence to a range of health behaviours (adherence to e.g., programmes of exercise, diet, self-care and medication) in patients with a chronic illness, using the TPB/ TRA, and found the following weighted correlations: r= 0.28 (I-B), r=0.24 (PBC-B), r=0.41 (ATT-I), r=0.32 (SN-I), and r=0.51(PBC-I). They also conducted a path analysis, in which ATT, SN and PBC explained 33% variance in BIs, and BI and PBC explained 9% variance in behaviour. Whilst these studies found lower correlations for the relationships proposed by the TPB, and accounted for lower variances in BIs and behaviour than those reported in the above cited meta-analyses of general health and social behaviours (Armitage & Conner, 2001; Godin & Kok, 1996; McEachan et al., 2011), the effect sizes were still statistically significant and are regarded as medium effect sizes (Cohen, 1992).

Overall it can be seen that the TPB/ TRA has been shown to be a good predictor of general social behaviours (Armitage & Conner, 2001), health-related behaviours (Godin & Kok, 1996; McEachan et al., 2011), and adherence behaviours (Husebo et al., 2013; Rich et al., 2015). However, none of the above-cited meta-analyses investigated the extent to which the TPB/ TRA is a useful predictor of adherence behaviours for specific medical conditions that are likely to give rise to an orthotic intervention. Rich et al. (2015) investigated chronic conditions only, including diabetes, heart disease, epilepsy, HIV and obesity. While some of these conditions are directly relevant to orthotic management (e.g., diabetes), and some are not (e.g., epilepsy and obesity), the researchers did not separate these two types of conditions in the meta-analysis. Additionally, as orthoses can be used in the management of both chronic (e.g., spinal cord injury) and short term (e.g., anterior-cruciate ligament injury) conditions, the meta-analysis of Rich et al. (2015), on its own, does not provide justification for using the TPB/ TRA to understand adherence to orthoses. The research presented in this chapter is therefore a new, up-to-date meta-analysis of studies in which the TPB/ TRA has been applied to adherence behaviours. It specifically investigated how well the TPB/TRA can predict adherence behaviours in individuals diagnosed with medical conditions that often give rise to an orthotic intervention (e.g. brain injury, diabetes, back pain, ligament injury). Adherence to orthotic interventions has not previously been investigated using the TPB/ TRA. Therefore, this meta-analysis enabled the relevance of the model to be assessed, thereby providing justification for its use in subsequent studies in this thesis. This study also investigated the strength of the relationships proposed by the TPB as a function of different adherence behaviours (e.g., exercise, self-care) and health conditions (e.g., diabetes, musculoskeletal). In addition, between-study differences in methodology were also explored including: operationalisation of the PBC component of the model (e.g. self-efficacy, controllability or a combined measure); whether studies tested the model using self-reported or objective measures of behaviour; the extent to which studies adhere to the principle of compatibility; and whether study designs are cross-sectional or prospective. These moderating variables are considered in more detail in the following subsection.

4.1.2 Moderating Variables

4.1.2.1 Adherence Behaviours

The TPB has previously been used to predict a range of different adherence related behaviours including adherence to rehabilitation (Bains et al., 2007; Blanchard, 2008), diet (Gardner & Hausenblas, 2004; White et al., 2010), medication (Conner et al., 1998; Shankar et al., 2007), and self-care behaviours such as self-monitoring of blood glucose (Costa, 2012) or checking skin for signs of damage (Sheppard, Kennedy, & Mackey, 2006). In order to be confident that the TPB is likely to provide a useful framework for predicting AFO use, and, thus, identify constructs that might be suitable targets for intervention to increase AFO use, it is important that the model has been shown in previous research to be predictive of this wide range of other adherence behaviours. This may then provide justification to use the TPB when investigating adherence to orthoses. Previous research has shed very little light on this subject. For example Godin and Kok (1996) found that the TPB was better at predicting some behaviours than others. They considered a range of health-related behaviours including addictive, clinical and screening, driving, eating, exercising, HIV/AIDS and oral hygiene behaviours. Whilst overall the average explained variance in intention was 41%, this ranged from 32% for eating behaviours to 47% for oral hygiene behaviours. In relation to behaviour, the average explained variance was 34%, ranging from 15.6% for clinical screening behaviours to 42.3% for HIV/ AIDS related behaviours. Similarly McEachan et al. (2011) also found differences in explained variance across different health-related behaviours: they found that physical activity and dietary behaviours (23.9% and 21.2% respectively) were better predicted than safe sex, detection, risk and abstinence programmes (between 13-15%). However, the behaviours in these meta-analyses were either not related to adherence or they were related to adherence but not in samples of individuals diagnosed with conditions that may give rise to the need for an orthosis. Rich et al. (2015) reported no significant differences in the weighted correlations across different adherence behaviours. However, as noted above only some of these studies were relevant to the conditions under investigation in this study. Therefore, one of the aims of the present meta-analysis was to investigate how well the TPB can predict a range of adherence behaviours in patients diagnosed with conditions that are known to give rise to the need for an orthosis (e.g., diabetes, neurological conditions such as stroke, and musculoskeletal conditions such as joint pain), in order to investigate how useful the theory might be, if it is used to predict adherence to orthoses. Due to the limited knowledge about the effect of adherence behaviours on the strength of correlations between the TPB constructs, no specific hypotheses were set, and this moderator analysis was considered as exploratory.

4.1.2.2 Health Conditions

In order to identify the suitability of the TPB model for investigating adherence to orthoses it is important to investigate the efficacy of the TPB in predicting adherence behaviours across a range of health conditions. This is essential because orthoses can be used across a wide variety of different health conditions. Therefore, if all conditions are found to demonstrate statistically significant effect sizes across the TPB constructs, this will provide justification for using the TPB, not only in conditions that have already been investigated, but also in conditions that have not previously been investigated. Again, previous research has shed very little light on this issue, because the above cited meta-analyses have either not focused on studies of patients diagnosed with the relevant medical conditions (Godin & Kok, 1996), or have not analysed these studies separately (Rich et al., 2015). However, it is known that adherence rates to medical recommendations differ across samples of patients diagnosed with different conditions. For example, DiMatteo (2004) in a meta-analysis investigating variance in adherence to medical recommendations, found that adherence was highest in HIV, arthritis, gastro-intestinal disorders and cancer (>80%), and lowest in pulmonary disorders, diabetes and sleep disorders (<70%). It is therefore possible that there might be differences in how well models, such as the TPB, can predict behavioural intentions and behaviours across individuals with different conditions.

When considering conditions for which orthoses are prescribed, it can be seen that orthoses are used for a wide range of conditions, both chronic and acute, affecting different parts of the body, including the lower limb, upper limb and spine. Conditions for which orthoses can be prescribed can be grouped into the following broad groupings: **neurological conditions** such as stroke, multiple sclerosis, and cerebral palsy, **musculoskeletal problems** such as arthritic conditions or overuse injuries such as posterior tibial tendon dysfunction (PTTD), **traumatic injuries**, such as fractures, nerve or soft tissue injury, or **diabetes** related conditions causing neuropathy. Therefore, this meta-analysis investigated the extent to which the TPB predicted BI and adherence behaviours in patients with different conditions, separately. It was hypothesised that the effect sizes between the proposed constructs of the TPB would demonstrate statistical significance across different conditions, although no specific hypotheses were set regarding differences in effect sizes across the variety of conditions.

4.1.2.3. Between-study Differences in Methodology

While the TPB has been shown to be a good predictor of a range of social and health behaviours, the meta-analytic evidence reviewed above still shows that the model does not account for all the variance in BI or B. As a result, the above-cited meta-analyses have examined how various methodological procedures dictate the extent to which the TPB can predict BI or B. In particular, researchers have focused on the extent to which the following methodological factors, also examined in this research, have mediated the relationships proposed by the TPB:

4.1.2.3.1 Operationalisation of PBC Measure

In the TPB, PBC is considered to consist of two separate but closely related constructs, self-efficacy' or 'capacity' and 'perceived controllability' or 'autonomy' (Armitage & Conner, 2001; McEachan et al., 2016). Self-efficacy (SE) is defined as a person's confidence that they can perform the behaviour in question (Bandura, 1977a). Perceived controllability (PC) is defined as a person's beliefs that the performance of the behaviour is up to them, rather than external factors (Trafimow, Sheeran, Conner, & Finlay, 2002). A number of studies have demonstrated that SE and PC are empirically separate constructs, thus supporting the conceptual differences between the two (Ajzen, 2002; Pertl et al., 2010; Rhodes & Courneya, 2003; Trafimow et al., 2002). Some studies use measures of SE in tests of the TPB (Kagee & van der Merwe, 2006; Levy, Polman, & Clough, 2008; White et al., 2012) whereas other use measures of PC (Ajzen & Madden, 1986; Kimiecik, 1992). There are also studies in which researchers use combined measures (i.e. measures of PBC are captured using items which measure both SE and PC despite the theoretical and empirical distinction) (Carroll & Whyte, 2003; Gucciardi et al., 2007; Johnson et al., 2016). In meta-analyses, it has been shown that SE is a better predictor of BI and B than PC (e.g. Armitage & Conner, 2001). These findings imply that TPB studies should measure PBC using items that relate to SE rather than PC or a combination of the two because they account for more variance in both BI and B. However, previous research has not established these relationships for adherence behaviours in samples of people diagnosed with health conditions that may give rise to orthotic intervention. Therefore, this meta-analysis investigated the efficacy of the TPB in predicting both BI and B, when the following different components of PBC were utilised: SE, PC, and a combined measure of both SE and PC. In line with findings of other TPB meta-analyses (Armitage & Conner, 2001; Cooke, Dahdah, Norman, & French, 2016; McEachan et al., 2016) it was hypothesised that studies in which PBC is measured using SE items will provide higher correlations between PBC and I and PBC and B than studies in which PBC is measured using PC items.

4.1.2.3.2 Self-reported versus Objective Measures of Behaviour

The majority of researchers who have investigated the TPB have used self-reported measures of behaviour. Examples of self-reported measures of behaviour include asking participants to complete a diary of exercise behaviour over a set time frame (Niven et al., 2012) or asking patients to report their dietary behaviour on a 7-point scale (White et al., 2010). Many TPB studies are administered by questionnaire design, and this has several advantages over more objective measures of behaviour, including low cost, feasibility, reduced effort on the part of the participant, and ease of administration (Miller & Hays, 2000). However, self-reported measures have the potential to be open to a range of biases: self-presentational biases such as desirability bias refers to the tendency of participants to present a positive image of themselves (Johnson & Fendrich, 2005), response biases which refer to the tendency of an individual to answer in the same way, regardless of the question being asked (e.g. a bias towards using the same number on a Likert scale; Bosworth, 2012), and accuracy of participant's recall (e.g., when participants do not remember experiences accurately; Johnson, 1992).

The use of self-reported or objective measures to quantify behaviour may also affect the correlations obtained in a TPB investigation. Armitage and Conner (2001) reported that while the TPB accounted for a significant proportion of the variance of both observed (i.e. independently rated or objective) and subjective measures of behaviour, observed behaviour was lower and the difference between objective and self-reported behaviour was significant. This finding was also supported in a later meta-analysis by McEachan et al. (2011). However, previous research has not determined if there is a difference in self-reported or objective measures in adherence measures for people diagnosed with health conditions that may give rise to orthotic intervention. Therefore, this moderator analysis aimed to investigate if the BI-B and PBC-B relationships proposed by the TPB differ according to whether self-report or objective behavioural measures are used.

4.1.2.3.3 The Compatibility Principle

Ajzen (2011) has identified compatibility of the TPB constructs measured in questionnaires as a critical component of appropriate study design. Fishbein and Ajzen (1975) detailed four dimensions of a behaviour: target, action, context and time (TACT) that should be used to investigate behaviours accurately. The principle of compatibility states that all of the constructs of the TPB (attitude, subjective norm, PBC, intention and behaviour should be measured at the same level of specificity including these 4 dimensions of target, action, context and time (Ajzen, 2006). So, for example, in an adherence study in diabetes, the participant may be asked to adhere to checking the skin condition of the feet at least once a day (action) in order to ensure he/she does not have any signs of skin breakdown due to the diabetes (target) in their own home (context), over a period of 4 weeks (time). It is important to maintain consistency of all these elements across all of the constructs being measured. Kim and Hunter (1993) found, using meta-analytic techniques, that increased compatibility between TPB measures led to a significantly stronger ATT-B correlation (r= 0.62) when the measures of attitude and behaviour were high in compatibility than when they were low in compatibility (r=0.28). Therefore, it would be reasonable to expect that, in line with Ajzen's (2006) recommendations, studies adhering to the compatibility principle in this meta-analysis would demonstrate higher effect sizes between the TPB constructs, than would studies adhering less strongly to the compatibility principle. Consequently, it was hypothesised that studies meeting the compatibility principle would demonstrate higher effect sizes than those not meeting guidelines for compatibility across the measures. The results of this moderator analysis may have implications for questionnaire design in future investigations that use the TPB as a guiding framework.

4.1.2.3.4 Study Design

Studies investigating the efficacy of the TPB in explaining adherence to health behaviours have used both cross-sectional (Costa, 2012; Fai, Anderson, & Ferreros, 2017), and prospective designs (Gucciardi, 2016; Levy et al., 2008). Cross-sectional studies which measure intention and behaviour at the same time, predict past behaviour, and therefore do not reflect the causal associations underlying the theory (i.e. TPB --> subsequent behaviour, Godin & Kok, 1996). A measure of behaviour, at a time point after the measure of intention and the other TPB variables, will theoretically provide a more accurate prediction or correlate, as cross-sectional designs have a tendency to overestimate the intention-behaviour correlation (Armitage & Conner, 2001; Randall & Wolff, 1994). Despite this, many TPB studies investigating adherence still use a cross-sectional design.

The effect of study design (cross-sectional or prospective), on the strength of the relationships between the TPB constructs, has been identified as a moderating factor in previous meta-analytic studies (Albarracin et al., 2001; Randall & Wolff, 1994; Topa & Moriano, 2010). These authors have consistently found that prospective designs have reported lower correlations than cross-sectional designs. However, it is not known if studies investigating adherence behaviours in health conditions, which may require orthotic treatments, will demonstrate significantly different correlations when using cross-sectional or prospective designs. Therefore, this moderator analysis aimed to investigate if both prospective and cross-sectional designs demonstrate statistically significant relationships between the TPB constructs, and to identify if there was any difference in the I-B and PBC-B correlations for prospective and cross-sectional study designs. It was hypothesised that effect sizes in prospective designs would be lower than the effect sizes in cross-sectional designs, yet still demonstrate statistical significance.

In summary, the TPB has demonstrated an enduring acceptance by health researchers. It has been shown to be an effective model in explaining a considerable amount of variance in intentions and behaviours and has been applied to a range of adherence behaviours as well as a range of different health conditions. Adherence behaviour category, and health condition, as well as a range of between-study differences in methodology, detailed above, have been identified as potential moderators of the relationships proposed by the TPB. This current meta-analysis therefore incorporates a wide but selective group of conditions and considers a range of adherence behaviours to understand how people adhere to prescribed heath behaviours. This study therefore enables investigation of the potential relevance of the TPB as a model to understand adherence to orthoses.

4.2 Aims

The primary aim of this meta-analytic review was to integrate research, which investigates the utility of the Theory of Planned Behaviour in predicting or explaining adherence to prescribed or recommended health behaviours in health conditions, which may give rise to an orthotic intervention. The present study examined the strength of all the relationships between the TPB variables and adherence to prescribed health behaviours.

A secondary aim was to investigate the effect of six moderator variables in explaining any variance in the size of the correlations between the constructs of the TPB: the health condition (diabetes, musculoskeletal, neurological, and trauma), type of adherence behaviour (diet, exercise/ rehabilitation, medication, and self-management), operationalisation of PBC (self-efficacy, controllability or combined measure), measurement of adherence (self-reported vs. objective), the compatibility principle (compatibility or non-compatibility), and study design (prospective vs. cross-sectional).

The final aim was to conduct a meta-analytic path analysis (Hagger, Chan, Protogerou, & Chatzisarantis, 2016), to simultaneously test theoretical predictions using the corrected correlations from the meta-analysis. The path analysis allows investigation of the mediation hypothesis of the theory, that intention mediates the effect of attitude, subjective norm and perceived control on behaviour. It was hypothesised that the TPB would show significant relationships between the proposed variables and demonstrate that intention mediates the effects of attitude, subjective norm and PBC on intention.

4.3 Methods

4.3.1 Literature Search

A literature search was carried out using the following databases up until January 2019: Psych Info (EBSCO), Medline (OVID), EMBASE (OVID), CINAHL (EBSCO) and the Cochrane Database of Systematic Reviews. A key word search was used, which combined the 'theory of planned behaviour' and alternate phrasing (See Table 4.2), with the following words: adherence, compliance, and concordance, along with types of adherence behaviour such as self-care, exercise and medication. The most common conditions for which an AFO might be prescribed, including: stroke; multiple sclerosis; diabetes; trauma; and musculoskeletal were added to the search, as well as the functional problems resulting from these conditions such as pain, paralysis, deformity and neuropathy. This is because orthoses may also be prescribed for people with very rare conditions; for example, Guillain-Barre Syndrome (Gupta, Taly, Srivastava, & Murali, 2010), an autoimmune disorder affecting the peripheral nerves; or facioscapulohumeral muscular dystrophy, an inherited muscle wasting disorder (Tawil & Van Der Maarel, 2006). In attempting to identify adherence behaviours in health conditions for which orthoses are prescribed, it would not be feasible to include every single condition in a literature search. However, identification of studies by searching functional losses would not offer the ideal search strategy, as the vast majority of published literature in health and disability is categorised by condition. Therefore, a comprehensive approach was selected which included both health conditions for which an orthosis may be prescribed, and the generic reasons (e.g., pain, deformity, paralysis, neuropathy etc.) for which an orthotic prescription may be given. The combination of search terms is detailed in Table 4.2 below.

Wild cards were used to accommodate different spellings and alternate words. A key word search rather than MESH terms was used, as not all databases use MESH terms, and this ensured a more systematic approach. The Theory of Reasoned Action (TRA) was also included in the search, because it is the precursor model to the TPB, and would therefore reveal studies with information about most of the TPB variables. The reference lists of key

TPB meta-analyses, and the reference lists of all included full text articles were also searched, and further articles potentially meeting the inclusion criteria were sourced. Additionally, citation searches were also conducted for articles meeting the inclusion criteria on Web of Science and Scopus. Article titles and abstracts were scanned and highlighted if the article appeared to meet the relevant inclusion criteria. Full texts were sought if additional clarity was required to confirm inclusion criteria were met.

Table 4-2: Search Strategy for Meta-analysis showing Combination of Key Words

Key Words Combination				
"theory of planned behavio*r"		adher* or complia* or concord*		Diabet*
TPB		"self-care" /care/ rehab* or exercise or "physical activity"/ diet/ medication or drug*		Musculoskeletal/ MSK/arthrit*
"theory of reasoned action"	**and**		**and**	Neurolog* / stroke or CVA or "cerebrovascular accident"/ "cerebral palsy" or CP/ "multiple sclerosis" or MS / spina*/ polio*
"planned behavio*r"				Trauma* / fracture*/ injur*
				Pain*/ deform*/ abnormal* paraly*/ *paresis/ weakness/ *plegia neuropath*/ ulcer*/ spastic*/ "muscle tone"/ contracture/ "range of motion"
OR		**OR**		**OR**

Two other researchers reviewed the articles and assessed them against the inclusion criteria. In situations where relevant papers were identified but key correlations were not detailed, authors were contacted directly for this information. A flow diagram of the search strategy and results of the search are shown in Figure 4.2. The two researchers also independently reviewed, coded and extracted data for the selected articles. In cases where there was ambiguity regarding inclusion/exclusion criteria, or disagreement regarding the coding, a consensus approach through discussion was used to agree coding of the articles. Full agreement was reached after a second round of discussions.

4.3.2 Inclusion and Exclusion Criteria

The main inclusion criteria were: articles that explicitly used the TPB or the TRA as a theoretical framework to investigate adherence to health behaviours in health conditions for which an orthosis might be prescribed, the behaviour was a prescribed or recommended intervention by a health or allied health professional to manage a health problem (e.g., exercise, diet, medication, self-care or monitoring by health professionals), or an intervention as part of a clinical trial (if adherence to a treatment or intervention is being measured). Conditions for which an AFO may be prescribed include diabetes, musculoskeletal problems, neurological conditions such as stroke, and trauma, as well as other conditions where participants reported symptoms, e.g. pain, or deformity. The population were adults over the age of 18 years. Cross-sectional, prospective, quasi-experimental and experimental studies, and articles published in peer reviewed journals were included.

The main exclusion criteria were: TPB studies which did not measure adherence or intention to an adhere as the primary behaviour, studies which did not report at least one correlation between the TPB constructs, studies which measured health behaviours in the general population such as exercise, diet, or condom use; adherence to prophylactic medicines, studies which reported on conditions where an orthosis would not be required (e.g., cardiovascular disease, obesity, high blood pressure), studies which measured health behaviours where there was no evidence the behaviour has specifically been prescribed, studies which reported on multiple conditions and could not provide separate data for conditions for which an AFO might be required, studies which reported on children or adolescents, and papers not published in English were also excluded due to limitations in budget which prevented translation.

4.3.3 Data Extraction and Coding

The following study characteristics were entered into a spread sheet: author and year of publication, sample size (number of participants who had completed TPB measures), condition affecting the participants, the behaviour to which participants were adhering, conceptualisation of PBC, the type of adherence measure (self-reported or objective or both), the research design, and the correlations (effect sizes) between the TPB variables.

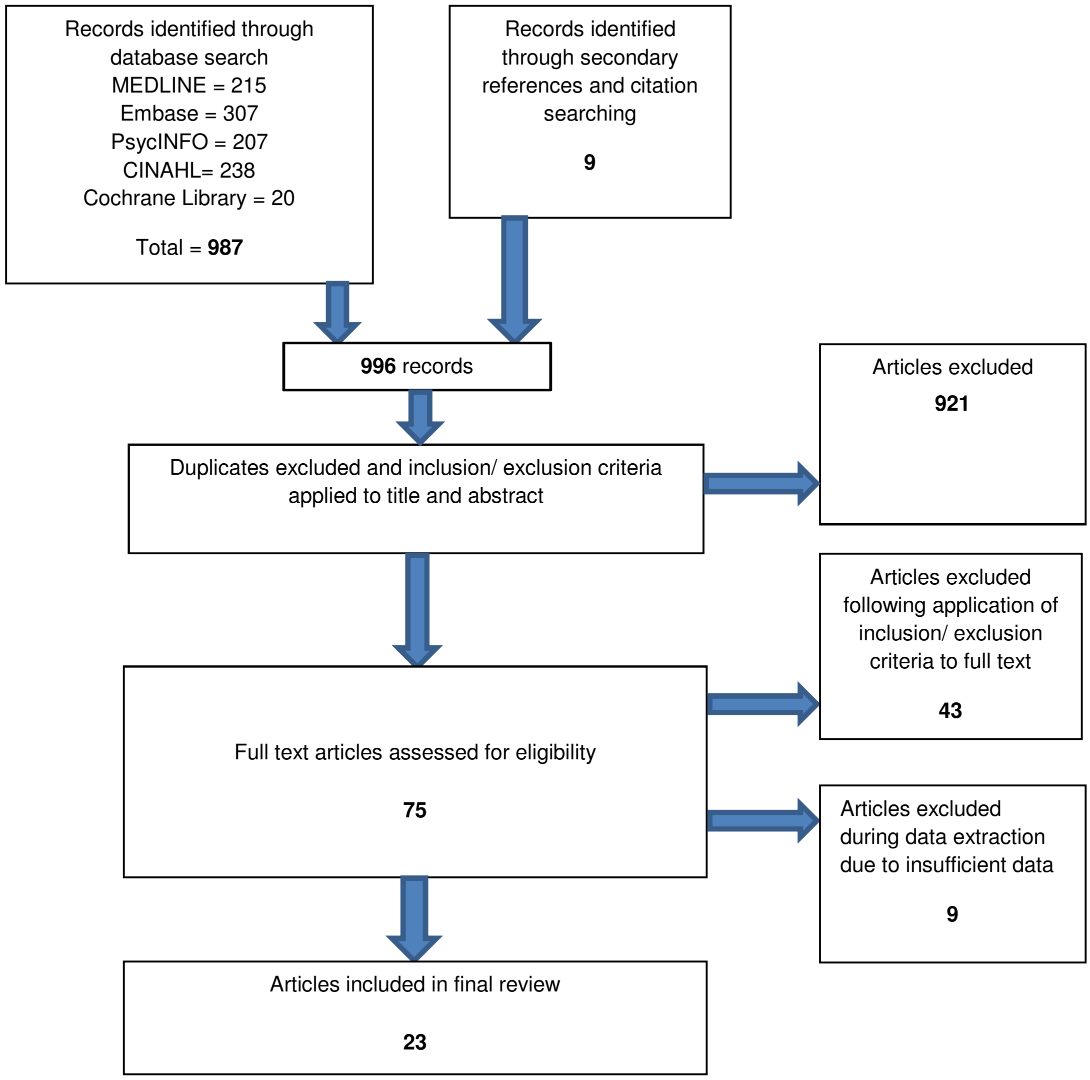

Figure 4-2: Flow Diagram showing Stages of Literature Search

Health behaviours were grouped into the following conditions: exercise/ physical rehabilitation, diet, medication, and self-care. Whilst diet and exercise may also be considered self-care behaviours (Shrivastava, Shrivastava, & Ramasamy, 2013), these behaviours are lifestyle behaviours which are also relevant to the general population. The specific area of interest in this thesis is prescribed adherence behaviours. Therefore, self-care behaviours were only included in this meta-analysis as adherence behaviours if they were specifically prescribed, or if the health behaviour was specific to the health condition under investigation (e.g. checking blood glucose levels in diabetes). **Health Conditions** were categorised as follows: diabetes or diabetic related conditions, musculoskeletal conditions affecting muscles, ligaments or bones e.g., arthritis, a soft tissue injury or fracture, neurological conditions which cause a neurological deficit and difficulties in controlling the MSK system e.g., Stroke, Multiple Sclerosis, and other conditions, to include any studies which investigated conditions which did not fit any other categories. Studies were categorised in relation to **operationalisation of the PBC measure**[18] used: self- efficacy (SE), controllability (PC), a combined measure, in which both controllability and self-efficacy are measured and combined as a single construct, or not clear, in which insufficient information was provided in the paper to enable categorisation. **Measurement of adherence behaviour** was coded as using self-reported, objective or combined measures of adherence, which included both self-report and objective measures, or self-reported and objective measures separately. If measures of adherence were provided by clinicians these were categorised as objective, as although they have an element of subjectivity, they are not patient-reported measures.

Studies were also coded in relation to meeting the **compatibility principle** as: compatible, non-compatible, or unclear, if there was insufficient detail given to make a judgement. Cooke et al. (2016) noted that the literature is not always clear in defining these terms: although the target is usually reported, variable descriptions of action and time-frame are provided with limited consideration of the context (Cooke & French, 2011). Ajzen (2006) notes that defining the TACT elements is, to an extent subjective, and it may be necessary to generalise the context or action to ensure the questions are of practical use. Therefore, with these considerations in mind, each study was categorised either as using compatible measures or not, and the relevant correlations were compared. Studies were judged to meet the compatibility principle if it could be ascertained from the questionnaire description that questions were compatible across the TPB measures. Another category used was **study design**: studies were classified as cross-sectional, prospective or experimental. This analysis

[18] The other variables, which predict intention (attitude and subjective norm), can also be separated into affective and instrumental attitude, descriptive and injunctive subjective norm. Affective attitudes refer to the emotional effects of carrying out a behaviour (e.g. pleasant or unpleasant), whereas instrumental attitudes refer to an evaluation of the costs and benefits of performing a behaviour (e.g. healthy or unhealthy) (Ajzen & Driver, 1991). Descriptive norms refer to how important others actually behave (i.e. what others actually do) and injunctive norms refer to whether behaviours are approved of or disapproved by important others. Use of these different variables as a moderator were also considered. However, there was an insufficient number of papers in each group to explore heterogeneity across different attitudinal and subjective norm measures.

sought to investigate differences in effect size depending on if the TPB variables were measured at the same time as behaviour, or prior to behaviour being measured, in line with the theoretical tenets of the TPB. Therefore, experimental studies were grouped with prospective studies for the purposes of analysing study design.

4.3.4 Meta-analysis Procedure

Reported associations between cognitive variables of the TPB were synthesised to create a mean effect size, *r*. To provide an estimate of the effect size, the weighted average of the sample correlations were calculated. This provides the direction and strength of the relationship between two variables between -1.0 to +1.0. To calculate the weighted average, the correlation was transformed into Fisher's *z* scale and analyses were carried out using these transformed values. This enables correlations derived from larger sample sizes to be given more weighting than smaller samples. The summary values were then transformed back into correlations. Calculations were carried out using CMA (v2), Comprehensive Meta-analysis, a software package which is designed for meta-analytic analysis (Borenstein, Hedges, Higgins, & Rothstein, 2005). Correlations were calculated for all the relationships proposed by the TPB variables: intention-behaviour (I-B), perceived behavioural control-behaviour (PBC-B), attitude-intention (ATT-I), subjective norm-intention (SN-I), and perceived behavioural control-intention (PBC-I). The attitude-subjective norm (ATT-SN), attitude-perceived behavioural control (ATT-PBC), attitude-behaviour (ATT-B), and subjective norm-behaviour (SN-B) relationships were also calculated in order to perform the path analysis (see Section 4.4.4). If multiple outcomes were reported across the same groups (e.g., multiple time points, multiple adherence behaviours or multiple measures of adherence behaviour), these effects were meta-analysed to provide a synthetic effect size, with was then used in the meta-analysis. This was done by calculating a new variance based on correlations between the outcomes, which was then entered into the meta-analyses. For studies where no correlations between outcomes were available (Chapman, Ham, Liesen, & Winter, 1995; de Weerdt, Visser, Kok, & van der Veen, 1990; Kleier & Dittman, 2014; McNeely et al., 2012; Sheppard et al., 2006), the mean effect size was calculated and used with the smallest n to provide a conservative estimate of the weighted average effect size.

An assumption was made that studies included in the meta-analysis were sampled from populations where the mean effects vary, therefore, a random-effects model was used. A random effects model accounts for both between and within-study variability, which would be expected in researching adherence across different conditions and behaviours, and provides a more accurate and conservative method of summarising information from a range of studies. Therefore, a random effects model provides more appropriate estimates of effect sizes and confidence intervals that can be generalised to a whole population (Hunter & Schmidt, 2000).

Heterogeneity analyses were also conducted using the Q statistic, and I^2. The Q statistic is a type of chi-squared test, which measures the significance of any heterogeneity present. A significant Q statistic suggests heterogeneity across studies and the need for moderator analysis. I^2 is a complementary measure of heterogeneity which provides the percentage of the variability in effect estimates that is due to heterogeneity between studies (rather than sampling error or chance) (Higgins & Thompson, 2002). In interpreting the I^2 statistic, I values above 75% should be considered high (Higgins, Thompson, Deeks, & Altman, 2003), suggesting the need to search for moderators which explain any heterogeneity.

A moderator analysis was conducted using sub-group analysis. Studies were separated into groups according to the moderator and new average weighted correlations were calculated for each group. The following categorical variables were used in the moderator analysis: health condition (diabetes or musculoskeletal), category of behaviour (adherence to medication, adherence to an exercise/ rehabilitation programme, adherence to diet; self-care behaviour), conceptualisation of PBC (self-efficacy vs controllability vs. combined), type of adherence measure (self-reported or objective), principle of compatibility (compatibility vs non-compatibility), and study design (cross-sectional or prospective design). This analysis compared the mean effect for the different subgroups using a Q test based on an analysis of variance. Statistical significance of each moderator was identified by a Q test, with a significant between-group Q value indicating a significant difference in effect sizes between the groups.

There is no accepted minimum amount of studies required for subgroup analysis in meta-analysis, with authors suggesting anywhere between two and 10 studies as a minimum (Higgins & Green, 2011), although with no real rationale for this. However, the higher the number of studies in subgroup analysis, the more robust and accurate the results of the subgroup analysis. Given the small number of studies meeting the inclusion criteria for this study, a minimum of four studies per subgroup was selected as recommended by Fu et al. (2011). Therefore, if subgroups had less than four studies they were eliminated from the moderator analysis.

In the subgroup analysis, the general approach was to use a mixed effects analysis (i.e. a random effects analysis is used within subgroups but a fixed effect model is used across the subgroups) as recommended by Borenstein, Hedges, Higgins, and Rothstein (2009). However, if k<5, due to the small number of groups in each subgroup, the data was pooled to estimate tau squared (the between-study variance) across all groups, thereby assuming a fixed effect, as with such a small number in each subgroup the estimates are likely to be imprecise if using mixed effects (Borenstein et al., 2009).

To assess the risk of publication bias, Rosenthal's fail-safe N was calculated - this is the 'fail safe' sample size (i.e. the number of studies with a null finding, which would be required to reduce the effect size to a trivial level). If Rosenthal's Fail-safe N is large (>5k +10), where k reflects the number of studies included in the meta-analysis, effect sizes are considered robust (Rosenthal, 1991). This provides confidence that the file drawer effect would be unlikely to have a significant effect on the outcome.

Meta-analytic path analysis (Hagger et al., 2016) was carried out to simultaneously test theoretical predictions using the weighted average correlations from the meta-analysis. Path analysis also allows investigation of the unique effects of the TPB variables on intention and behaviour and tests the key mediation hypothesis of the theory, that intention mediates the effect of attitude, subjective norm and perceived control on behaviour. The smallest sample size for the meta-analytically derived correlations was used in the path analysis as a conservative strategy to manage the variation in sample sizes.

4.4 Results

4.4.1 Study Characteristics

Twenty-three papers were identified which met the inclusion criteria, 20 of which measured adherence behaviour and three which measured intention to adhere (McGuckin, Prentice, McLaughlin, & Harkin, 2012; Sheppard et al., 2006; Trafimow & Trafimow, 1998). Twenty one studies investigated the TPB, one study investigated the TRA (de Weerdt et al., 1990), and one paper used a modified TRA with self-efficacy (Didarloo et al., 2012). Details of the study characteristics are seen in Table 4.3, including number of participants, type of adherence behaviour, health condition, study design, the measure of adherence used, conceptualisation of PBC measure, and compatibility of the measures to target, action, context and time (TACT).

The total number of participants who completed TPB measures across the 23 studies was 3266. The average number of participants per study was 131 with the smallest number of participants being n=20 (Carroll & Whyte, 2003), and the largest number of participants being n=901 (Guenette et al., 2016).

Studies investigated the following health conditions or diagnoses: diabetes (n=15), musculoskeletal problems (n=6) including anterior cruciate ligament injury (n=1), back pain (n=2) joint pain (n=2), tendonitis (n=1), and neurological conditions (n=2) including acquired brain injury and stroke (n=1) and spinal cord injury (n=1). Where studies investigated several conditions, some of which did not meet the inclusion criteria (Kagee & van der Merwe, 2006; McGuckin et al., 2012; White et al., 2010; White et al., 2012), the authors were contacted and kindly provided data for the relevant condition which may require orthotic management (e.g., diabetes).

Behaviours were grouped into type of adherence behaviour (or intention to adhere): exercise or rehabilitation programme (n=10), self-care behaviour (n=9), diet (n=5), medication (n=2), or a combined measure for adherence behaviours described above (n=2), with three studies reporting more than one category of behaviour separately. The following types of study design were seen: prospective correlational (n=6), experimental designs (n=4), and cross-sectional (n=13)[19].

Of the 20 studies that measured adherence: 12 used self-reported measures, two used an objective measure (Johnson et al., 2016; McNeely et al., 2012), one used an estimate of adherence from health professionals (Bains et al., 2007), and five used both self-reported and objective measures of adherence (Costa, 2012; Fai et al., 2017; Gucciardi et al., 2007; Kleier & Dittman, 2014; Levy et al., 2008).

In terms of compatibility, eight studies demonstrated compatibility across the TPB measures in terms of target, action, context and time; 13 studies did not exhibit compatibility, and two studies (Fai et al., 2017; Guenette et al., 2016) provided insufficient information to categorise as compatible or incompatible, and were excluded from this moderator analysis.

[19] Although four studies were experimental studies (Gucciardi et al., 2007; Johnson et al., 2016; McNeely et al., 2012; White et al., 2012), this analysis sought to investigate differences in effect size depending on when behaviour was measured, and therefore these studies were grouped with prospective studies for the purposes of analysing study design.

Table 4-3: Characteristics of Studies included in Meta-analysis

Study Name	Subjects (*n*)	Health Condition	Adherence Behaviour	Research design	Adherence Measure	PBC measure	Compatibility with TACT
Bains (2007)	40	Acquired brain injury & stroke	Engagement with rehabilitation	X-sectional	O	COMB	N
Carroll (2003)	20	Back pain	Intention to adhere to exercise	X-sectional	SR	COMB	N
Chapman (1995)	48	Diabetes	Adherence to diet	Prospective	SR	NC	Y
Costa (2012)	179	Type 2 Diabetes	Adherence to diet, exercise, foot care and self-monitoring	X-sectional	O and SR	NC	N
Didarloo (2012)	352	Type 2 Diabetes	Self- care behaviour	X-sectional	SR	SE	Y
De Weerdt (1990)	558	Diabetes	Self-care behaviour	X sectional	O and SR	NM	N
Fai (2017)	115	Type 2 diabetes	Adherence to oral medication	X-sectional	SR	NC	NC
Gatt (2008)	100	Type 2 diabetes	Self-care behaviour in type 2 diabetes	Experimental	SR	COMB	N
Gucciardi (2007)	61	Type 2 diabetes	Nutrition adherence and glycaemic control	Prospective	O and SR	COMB	N
Gucciardi (2016)	136	Knee Pain	Adherence to exercise rehabilitation	Prospective	SR	NC	Y
Guenette (2016)	901	Diabetes	Adherence to Non-insulin anti diabetic drug treatment	X-sectional	SR	NC	NC
Johnson (2016)	102	Type 2 Diabetes	Adherence to Physical Activity	Experimental	O	COMB	N
Kagee (2006)	38	Diabetes	Adherence to treatment, taking medication, diet and exercise	X-sectional	SR	SE	N
Kleier (2014)	100	Diabetes	Adherence to diet, exercise and self-care activities	X-sectional	SR and O	SE	N
Levy (2008)	70	Tendonitis related overuse injury	Adherence to rehabilitation programme	Prospective	SR and O	SE	N
McGuckin (2012)	74	Diabetes	Intention to self-monitoring	X-sectional	NM	NC	Y
McNeely (2012)	52	Shoulder pain and dysfunction following cancer	Adherence to exercise programme	Experimental	O	PBC & SE	N
Niven (2012)	48	ACL reconstruction	Adherence to rehabilitation	Prospective	SR	PBC & SE	Y
Shankar (2007)	54	Type 1 diabetes	Self-monitoring of blood glucose	Prospective	SR	PBC & SE	Y
Sheppard (2006)	59	Spinal Cord injury	Adherence to self- management behaviour	X- sectional	NM	NC	Y
Trafimow (1998)	23	Chronic Back Pain	Intention to adhere to exercise	X- sectional	NM	PBC & SE	N
White (2010)	157	Type 2 Diabetes	Adherence to food low in saturated fat	Prospective	SR	NC	N
White (2012)	122	Diabetes	Adherence to physical activity and healthy eating	Experimental	SR	SE	Y

O-Objective measure of adherence; SR- self-reported; O and SR-both measures reported independently C- a combined measure is used which is not reported separately; NM-Adherence not measured PBC Measure: SE- self-efficacy; PBC- Controllability; NC-not clear; COMB-combined measure used containing elements of self-efficacy and controllability Compatibility: Y- measures are compatible across Target, Action, Context and Time; N-measures are not compatible across Target, Action, Context and Time; NC- insufficient information provided to ascertain compatibility

4.4.2 Meta-analysis Results

Table 4.4 shows a summary of the meta-analysis of TPB correlations. Within the table the number of independent studies on which the meta-analysis is based is denoted by the letter k. N refers to the sample size across all included studies. The average weighted correlation effect size, r, and confidence levels and p values are also presented. Forest plots showing the correlations between the constructs and confidence intervals are seen in Appendix 4.1.

Table 4-4: Meta-analysis of Correlations between TPB Variables

TPB construct association	*k*	*N*	*r*	CI (95%) lower limit	CI (95%) upper limit	*p* value	Q	*p* value for Q	*I*²	FSN
Intention-Behaviour (I-B)	18	3024	0.35	0.28	0.42	0.00	80.30	0.00	78.83	1735
PBC-Behaviour (PBC-B)	18	2575	0.27	0.20	0.34	0.00	66.53	0.00	74.45	881
Attitude- Intention (ATT-I)	19	3266	0.36	0.27	0.44	0.00	118.40	0.00	84.80	1748
Subjective Norm-Intention (SN-I)	17	2208	0.29	0.11	0.44	0.00	261.99	0.00	93.89	681
PBC-Intention (PBC-I)	18	2623	0.49	0.37	0.60	0.00	241.30	0.00	92.96	3452
Attitude-Subjective Norm (ATT-SN)	14	1498	0.34	0.25	0.42	0.00	43.14	0.00	69.86	621
Attitude- PBC (ATT-PBC)	17	2512	0.33	0.23	0.42	0.00	102.56	0.00	84.40	1304
Subjective Norm–PBC (SN-PBC)	13	1393	0.45	0.33	0.56	0.00	84.36	0.00	85.78	953
Attitude-Behaviour (ATT-B)	18	2597	0.22	0.16	0.28	0.00	45.31	0.00	62.48	600
Subjective Norm-Behaviour (SN-B)	15	2396	0.19	0.13	0.26	0.00	28.35	0.01	50.63	244

k=number of studies (individual data sets); N= total sample size; r=sample weighted average correlation; CI=confidence interval; Q=between-study heterogeneity; I=% variability attributed to heterogeneity FSN=Rosenthal's Fail-safe N (number of additional studies required to reduce effect size to zero)

All of the weighted mean correlations in Table 4.4 were statistically significant. Cohen (1992) provides guidelines for interpreting correlation effect sizes and notes that r=0.1 is considered small; r=0.3 is medium and r=0.5 is large. Using these guidelines, this suggests a large effect for the PBC-I correlation, a medium-large effect size for the ATT-I, I-B, and SN-PBC correlations, a medium effect size for the SN-I, ATT-SN, ATT-PBC, PBC-B correlations, and a small-medium effect size for the ATT-B and SN-B correlations.

Rosenthal's Fail-safe N demonstrated values between 244 and 3452, with the lowest Fail-safe N seen for the subjective norm-behaviour relationship. The lowest FSN was > ($5k+10$), indicating that any possible effect of excluding unpublished studies is negligible.

To identify any heterogeneity, the Q Statistic and I^2 were used. The Q value for all correlations was significant, which identifies that the variation observed between studies is real. Eight out of the 10 weighted average correlations had I^2 values of 70 or greater, indicating that at least 70% of the variance observed reflects real differences between studies. All effect sizes reported, therefore, have a moderate to high level of heterogeneity, highlighting the need to look for moderators, which can potentially explain the between-study variation.

4.4.3 Moderator Analysis

Six categorical moderators were evaluated: behaviour category (adherence to diet; exercise/ rehabilitation, attendance, self-management etc.), the health condition (diabetes or MSK), elements of the PBC measure (perceived controllability or self-efficacy or combined), type of adherence measure (self-reported vs. objective), compatibility of the measures across target, action, context and time (compatible vs. non-compatible), and research design (cross-sectional vs. prospective).

4.4.3.1 Adherence Behaviour Category

Studies were grouped into the following behaviour categories: studies measuring adherence to an exercise or rehabilitation programme (n=10), adherence to a diet (n=4), adherence to medication (n=3), and adherence to self-care behaviour (n=7). Studies that measured adherence across a range of behaviours and provided a combined measure of adherence, were not included in this moderator analysis, seen in Table 4.5.

Differences in the correlations were examined across behaviour categories. Correlations (e.g., ATT-SN, ATT-PBC, SN-PBC and SN-B) were not compared between different behavioural categories if the number of studies from which the correlations were derived was less than four. With the exception of the SN-I correlation for studies focusing on both exercise/ rehabilitation and self-care), all correlations were statistically significant. The ATT-B correlation demonstrated heterogeneity with Q(1)=13.68 p=0.00, between self-care and exercise behaviours, with a significantly higher ATT-B correlation seen for exercise behaviour. However, none of the other correlations differed between the studies focusing on exercise/ rehabilitation and self-care. Thus, excepting the ATT-B correlation, the TPB's relationships were found to be equally strong across the studies focusing on these two different kinds of behaviour.

Table 4-5: Moderator Analysis for Different Behaviour Categories

Correlation	Behaviour	Number of independent groups	Correlation	Lower limit	Upper limit	Q value	p value
I-B	Ex/ rehab	7	0.34	0.27	0.40	0.32	0.57
	Self-care	4	0.36	0.31	0.41		
PBC- B	Ex/ rehab	9	0.25	0.18	0.31	0.82	0.37
	Self-care	4	0.21	0.15	0.26		
ATT-I	Ex/ rehab	7	0.37	0.15	0.56	0.34	0.56
	Self-care	5	0.28	0.01	0.50		
SN-I	Ex/ rehab	6	0.30	-0.11	0.62	0.28	0.60
	Self-care	5	0.14	-0.30	0.54		
PBC-I	Ex/ rehab	7	0.43	0.37	0.50	0.48	0.49
	Self-care	4	0.40	0.31	0.48		
ATT-B	Ex/ rehab	7	0.28	0.21	0.35	13.68	0.00*
	Self-care	4	0.09	0.02	0.16		

ATT-SN and ATT-PBC, SN-PBC & SN-B not calculated due to insufficient numbers for moderator analysis

4.4.3.2 Health Condition

Twenty-one studies were included in this moderator analysis, 15 of which investigated diabetes and six of which investigated MSK conditions (see Table 4.6). All conditions affecting the musculoskeletal (MSK) system were combined into one group, as symptoms for MSK conditions such as pain, stiffness and swelling, are similar; as are risk factors and treatments, irrespective of the part of the body affected.

All correlations for studies investigating both diabetes and MSK conditions were significant. One moderator effect was found for the ATT-PBC correlation (Q(1)=18.52, p=0.00), with diabetes having a significantly higher correlation, as seen in Table 4.6. There were no other moderator effects for different conditions, meaning that TPB variables were similarly correlated with intentions and behaviour in studies investigating adherence in diabetes, as they are in studies of adherence in MSK conditions.

Table 4-6: Moderator Analysis for Health Conditions

Correlation	Health Condition	Number of independent groups	Correlation	Lower limit	Upper limit	Q value	p value
I-B	Diabetes	13	0.36	0.27	0.44	0.11	0.74
	MSK	5	0.33	0.18	0.47		
PBC-B	Diabetes	12	0.29	0.21	0.37	1.30	0.25
	MSK	5	0.19	0.03	0.34		
ATT-I	Diabetes	13	0.35	0.24	0.45	0.00	0.97
	MSK	5	0.36	0.15	0.53		
SN-I	Diabetes	12	0.32	0.28	0.36	1.22	0.27
	MSK	4	0.25	0.13	0.36		
PBC-I	Diabetes	12	0.55	0.43	0.66	1.93	0.16
	MSK	5	0.38	0.13	0.58		
ATT-PBC	Diabetes	12	0.44	0.41	0.48	18.52	0.00*
	MSK	4	0.24	0.14	0.33		
ATT-B	Diabetes	13	0.20	0.16	0.23	2.18	0.14
	MSK	4	0.27	0.18	0.35		
PBC-B	Diabetes	11	0.19	0.14	0.23	0.69	0.41
	MSK	4	0.13	0.03	0.23		

ATT- SN and PBC-SN correlations not calculated due to insufficient number of studies for moderator analysis

4.4.3.3 Between-study Differences in Methodology

4.4.3.3.1 PBC Components

The moderator analysis comparing different elements of the PBC measure is seen in Table 4.7. Four studies used both measures of PC and SE and reported the correlations separately; three studies used a measure of SE only, one study used a measure of PC only, and five studies used a combined measure, which contained both components of the PBC construct. Seven studies were excluded from this analysis as six studies did not give sufficient information to categorise them, and the remaining study was an investigation of the TRA.

With the exception of the PC-B correlation, all correlations in Table 4.7 were statistically significant. The type of PBC measure (SE, PC or combined) moderated the strength of both the PBC-I and the PBC-B relationships with significant heterogeneity found in both cases: for

PBC-I, Q(2)=27.96, p=0.00, and for PBC-B Q(2)=19.84, p=0.00. Examination of the confidence intervals showed that the SE measure provided a significantly higher correlation with I, than did the PC measure or the combined measure, but there was no difference between the combined PBC-I measure and PC-I correlation. The confidence intervals for the PBC-B relationships showed that both the SE, and combined measures of PBC, provided significantly higher correlations with B than did the PC measure, and there was no difference between the SE-B and Combined-B correlation. These results show that SE is consistently found to be the strongest correlate of I and B in previous TPB studies of adherence behaviour, and is joined by the combined measure in the PBC-B relationship.

Table 4-7: Moderator Analysis of PBC Components

Correlation	PBC measure	k	r	Lower limit	Upper limit	Q value	p
PBC- I	Combined	4	0.44	0.34	0.53	27.96	0.00*
	PC	4	0.29	0.17	0.39		
	SE	7	0.58	0.53	0.63		
PBC-B	Combined	5	0.30	0.20	0.39	19.84	0.00*
	PC	4	0.06	-0.04	0.16		
	SE	8	0.31	0.26	0.37		

4.4.3.3.2 Adherence Measure: Self-report vs. Objective Measures of Adherence

Table 4.8 shows the moderator analyses for self-reported vs. objective measures of behaviour. Two studies reported objective measures of adherence, and 14 reported subjective measures. Three studies reported both self-reported and objective data separately and these were included in the sub group analyses to provide intention-behaviour and PBC-behaviour correlations for each subgroup.

All correlations reported in Table 4.8 were statistically significant. However, no moderator effect was found when comparing objective and self-reported behaviours. These results demonstrate that TPB variables were similarly correlated with behaviour in studies using either self-reported or objective measures of adherence behaviour.

Table 4-8: Moderator Analysis for Self-reported vs. Objective Measures of Adherence

Correlations	Measure of adherence	Number of studies	Correlation	Lower limit	Upper limit	Q value	p value
I-B	Objective	3[20]	0.28	0.15	0.41	1.87	0.17
	Self-report	17	0.38	0.35	0.41		
PBC-B	Objective	5	0.21	0.05	0.36	0.66	0.42
	Self-report	16	0.28	0.20	0.35		
ATT-B	Objective	5	0.16	0.03	0.28	0.87	0.35
	Self- report	17	0.22	0.16	0.28		

SN-B correlations not reported due to insufficient number in sub group

4.4.3.3.3 The Compatibility Principle

Eight papers met the compatibility principle (Ajzen, 2006), and 13 papers used measures which did not demonstrate compatibility across the TPB measures. Two papers were excluded as insufficient information was provided to assess compatibility with TACT. The moderator analysis for papers, which either met or did not meet the compatibility principle, is seen in Table 4.9. This moderator analysis shows that all relationships were statistically significant excepting the SN-I relationship for non-compatible measures. One moderator effect was seen in this analysis for the I-B correlation. The I-B correlation demonstrated heterogeneity with $Q(1)=4.81$, $p=0.03$, between compatible and non-compatible measures, with a significantly higher I-B correlation seen for compatible measures. Therefore, these results show that use of compatible measures resulted in higher correlations for the I-B, and use of non-compatible measures resulted in an insignificant effect size for the SN-I correlation, when investigating adherence health behaviours.

[20] One study using an objective behaviour measure (Costa, 2012) was excluded from this moderator analysis due to an unduly high negative correlation for this relationship, which skewed the results, given the small number of studies in this moderator analysis. Therefore, an exception to the rule of having a minimum number of four per sub group was considered appropriate in this case, as otherwise the moderating effect of self-reported vs. objective measures of behaviour on the I-B relationship could not have been investigated. The author was contacted to inquire as to the reason for the high negative correlation, but no response was received.

Table 4-9: Moderator Analysis of Compatibility Principle

Correlation	Compatibility	k	Correlation	Lower limit	Upper limit	Q value	p value
I-B	C	6	0.45	0.35	0.54	4.81	0.03*
	NC	10	0.30	0.21	0.39		
PBC-B	C	4	0.21	0.12	0.29	0.79	0.38
	NC	12	0.25	0.21	0.29		
ATT-I	C	7	0.38	0.20	0.53	0.24	0.63
	NC	10	0.32	0.16	0.46		
SN-I	C	7	0.37	0.09	0.60	0.73	0.93
	NC	9	0.21	-0.06	0.45		
PBC-I	C	6	0.47	0.32	0.59	0.05	0.82
	NC	10	0.44	0.26	0.59		

C=Compatible measures used NC=Non-compatible measures used

4.4.3.3.4 Research Design

Studies were categorised as cross-sectional or prospective based on the time point at which adherence was measured relative to the TPB variables. Three studies, which only measured intention to adhere, were excluded from this sub-group analysis, as behaviour was not measured. The moderator analysis comparing cross-sectional and prospective designs is seen in Table 4.10. This analysis shows that the I-B and PBC-B correlations were significant for both cross-sectional and prospective designs. However, research design was not found to have a moderating effect on the I-B or PBC-B correlations: there was no statistically significant difference in effect size for the I-B or the PBC-B correlation for cross-sectional or prospective studies of the TPB. Thus, contrary to the hypothesised results of this moderator analysis, studies, which have previously investigated adherence health behaviours, have demonstrated similar I-B and PBC-B relationships irrespective of the research design.

Table 4-10: Moderator Analysis for Research Design

	Research Design	Number of independent groups	Correlation	Lower limit	Upper limit	Q value	p value
I-B	Cross-sectional	7	0.34	0.23	0.45	0.09	0.77
	Prospective	11	0.36	0.27	0.45		
PBC-B	Cross-sectional	8	0.29	0.18	0.39	0.13	0.72
	Prospective	10	0.26	0.16	0.36		

4.4.4 Path Analysis

A path analysis was conducted to simultaneously test the relationships between all the TPB variables, along with adherence behaviour. The matrix of the meta-analytically derived correlations was used to input into the hypothesised path–analysis model. The path analysis is shown in Figure 4.3 and provides the direct and indirect effects of the TPB variables on intention and behaviour. The model accounted for 14% of the variance in adherence behaviour and 28.3% variance in intention to adhere. The full model accounted for 37.5% of the variance in adherence behaviour (total direct and indirect effects). A power analysis using G*Power (Faul, Erdfelder, Lang, & Buchner, 2007) was carried out to determine α. For a power of 0.8, to determine a small effect size (f^2 =0.02) for a participant number of 1393 (the lowest number of participants for which correlations were calculated), α was set at 0.00018. Intention was the only direct significant predictor of behaviour. Attitude and PBC predicted intention, but subjective norm did not.

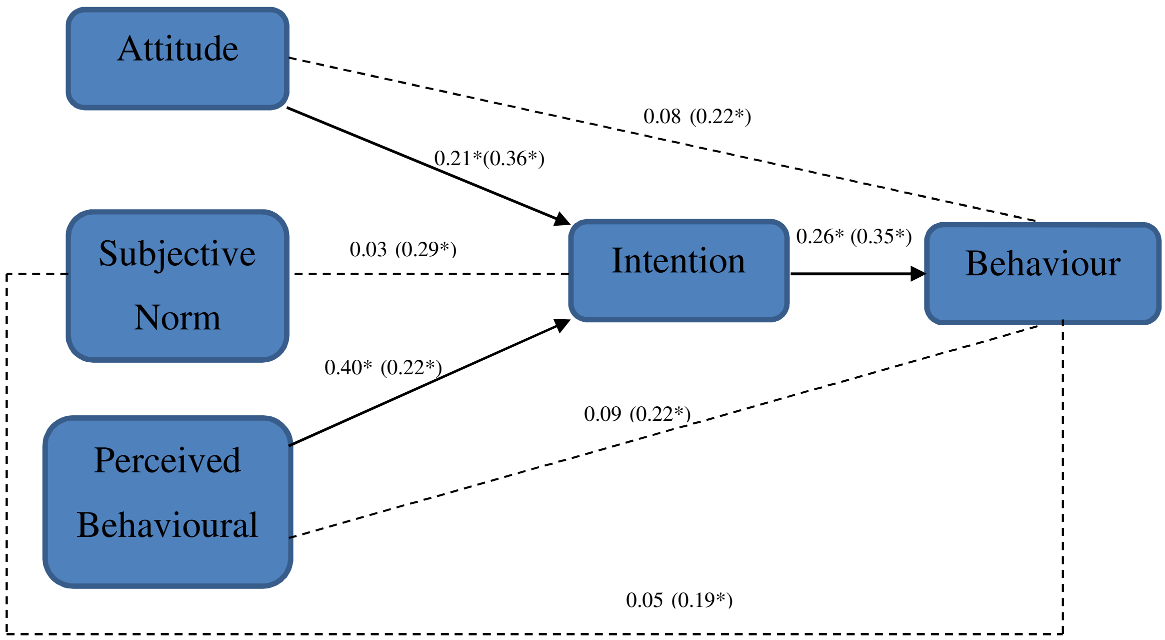

Figure 4-3: Path Analysis of TPB based on Corrected Correlation Coefficients

Standardised beta weights are presented (with correlation coefficients in parentheses.) Solid lines with arrows represent statistically significant effects. $R^2_{\text{(total direct and indirect effects)}} = 0.375$

4.5 Discussion

This meta-analysis provides support for using the TPB as a model for investigating adherence behaviours in conditions for which orthoses are prescribed. It advances a meta-analysis carried out by Rich et al. (2015), which investigated adherence to health behaviours in chronic disease. Adherence to an orthotic device is relevant in both the longer term management of chronic conditions as well as in the rehabilitation context. In this study, inclusion of the rehabilitation setting extends the understanding of adherence behaviours beyond chronic conditions.

4.5.1 Overall Findings

This meta-analytic review identified 23 papers meeting the inclusion criteria and used a random effects meta-analysis to calculate correlations between the components of the TPB, using a weighted mean effect size, r. In this meta-analysis, the TPB accounted for 28.3% of the variance in intentions and 14% of the variance in adherence behaviours. Attitudes and PBC were significant predictors of intention and intention was a significant predictor of behaviour. Intention was shown to mediate the effects of attitude and PBC on behaviour in line with the TPB. Whilst PBC did not predict behaviour, and subjective norm did not predict intention, these findings do not necessarily contradict the TPB. Indeed, Ajzen (2011) notes that perceived behavioural control is a proxy for actual control over a behaviour, and when perceived control and actual control diverge, PBC may be a poor predictor of behaviour. The non-significant effect of PBC on behaviour therefore suggests that for this group of studies, adherence to health behaviours may have been more challenging for participants than initially perceived (i.e., PBC may not have been reflective of the actual control that participants perceived over the ability to perform adherence behaviours). Subjective norm did not predict intention and, given that subjective norm is usually regarded as a weaker predictor of intention, compared to attitude and PBC (Ajzen, 2011; Armitage & Conner, 2001; Godin & Kok, 1996), this finding is not entirely surprising. Previous authors have suggested this could be due to measurement flaws (Armitage & Conner, 2001), with some authors only using a single item to measure subjective norm. In this meta-analysis, some authors used a single item measure (McGuckin et al., 2012; Trafimow & Trafimow, 1998), or two-item measure of SN (McNeely et al., 2012; Niven et al., 2012; White et al., 2010); whilst other authors did not include SN at all (Kleier & Dittman, 2014; Levy et al., 2008); or did not report the SN-I correlations (Bains et al., 2007; Chapman et al., 1995; McNeely et al., 2012). Therefore, the reasons for the non-significant SN-I relationship in the path analysis appear to be due to a combination of factors, including poor reporting and measurement inconsistencies. Given uncertainty around the strength of the SN-I relationship, researchers should attempt to construct a valid and reliable SN measure using multiple items, and report on the relationships between all constructs of the TPB model to enable appropriate synthesis of results.

The finding that the correlation between the TPB variables were between r=0.19 and r=0.49, and that 14% variance in behaviour and 28% variance in intention, was accounted for by the TPB compares well with previous meta-analyses. The correlations and proportions of variance are lower but these are found in meta-analyses of general social and health behaviours (Armitage & Conner, 2001; Godin & Kok, 1996; McEachan et al., 2011). However, they are broadly consistent with Rich et al. (2015), who investigated adherence to health behaviours in chronic conditions, and found that 9% of the variance in behaviour and 33% of the variance in intention was accounted for by the TPB. Overall the findings indicate that the TPB has been a useful model for explaining adherence behaviours, given that R^2=0.14 (i.e. 14% of the variance accounted for in behaviour) is regarded as moderate to large sized effect in the social sciences and R^2 =0.28 (i.e. 28% of the variance accounted for in intention) is regarded as a large sized effect (Cohen, 1992).

4.5.2 Findings of Moderator Analysis

In meta-analyses, identification of heterogeneity is an important finding, which enables investigation of differences across conditions, treatments, and methodological variables. Significant heterogeneity in this meta-analysis was identified and the findings of the moderator analysis provided a partial explanation for this. With regards to the behaviours investigated in the moderator analysis (exercise/ rehabilitation and self-care), heterogeneity was only seen in one of the correlations, for the ATT-B correlation. A significantly higher ATT-B correlation was found for self-care behaviours, compared to exercise behaviours, suggesting that a positive attitude is more highly correlated with adherence to self-care behaviours compared with adherence to exercise/ rehabilitation. This moderator analysis did demonstrate statistical significance across all relationships, excepting the SN-I correlation, for both exercise/rehabilitation and self-care, suggesting that the TPB is an appropriate model, which can be used when investigating adherence to self-care and exercise/ rehabilitation behaviours. In applying the TPB to orthotic use as a health behaviour, orthotic use may be considered as a type of self-care behaviour, as by using the orthosis it can allow a person to mobilise more efficiently or safely, and function more effectively. However, an orthotic device can also be used in rehabilitation or to aid an exercise regime. Therefore, this moderator analysis provides support for use of the TPB to investigate orthotic use, as it contains aspects of both self-care and exercise/ rehabilitation behaviours.

For health condition, only the ATT-PBC behaviour demonstrated significant heterogeneity, with studies investigating diabetes demonstrating a significantly higher correlation between ATT-PBC, than studies investigating MSK conditions, indicating that for diabetes, a positive attitude is more strongly associated with high levels of perceived behavioural control, compared to MSK conditions. However, this moderator analysis did demonstrate statistical significance across all relationships for both MSK and diabetes, suggesting that the TPB is an appropriate theoretical model that is applicable in a range of health conditions for which orthoses may be prescribed.

With regards to the issue of how PBC is measured (SE, PC or a combined measure), it was found that SE measures provided significantly stronger correlations with intention than did either PC or a combined measure, and that SE and the combined measure provided stronger correlations with behaviour than did the PC measures. Thus, SE measures are more consistently found to be the best correlated with intention and behaviour overall. This is in line with findings from other researchers (Armitage & Conner, 2001; McEachan et al., 2016; Rodgers, Conner, & Murray, 2008; Trafimow et al., 2002). SE measures should therefore be used when investigating adherence behaviours in health conditions, which may give rise to an orthotic intervention.

When considering the behaviour measure (a self-reported or objective measure of behaviour), no significant heterogeneity was identified. This finding contradicts results of other meta-analyses (Armitage & Conner, 2001; McEachan et al., 2011) which have found that self-reported measures of behaviour report significantly higher correlations, compared to objective measures. The smaller number of studies using objective measures in this meta-analysis may have contributed to this result. Therefore, this moderator analysis gives some support to using self-reported measures of adherence. Use of self-reported measures of adherence behaviour was the most common method of measuring adherence to prescribed health behaviours in this review. Whilst objective measures of adherence may be considered to be more accurate (Sabaté, 2003), they may not provide a valid representation of the behaviour being measured. For example, some studies used an objective measure of adherence such as attendance at exercise class (e.g. McNeely et al., 2012), but this did not give a true measure of the extent of participation and adherence to exercise during the class. Consequently, if care is taken to ensure the self-reported measure of behaviour has validity, and accurately reflects the behaviour under investigation, correlations between the TPB variables and self-reported or objective measures behaviour may not demonstrate significant differences.

The moderator analysis relating to the compatibility principle, demonstrated a significantly higher mean correlation for the I-B relationship in studies meeting the compatibility principle than those that did not. Although the other TPB relationships did not display any significant differences between studies adhering to the compatibility principle, and those that did not, the main determinant of behaviour in the TPB is intention (Ajzen, 2006). These findings offer some explanation of the intention-behaviour gap that has been observed in the literature (Amireault, Godin, Vohl, & Pérusse, 2008; Gucciardi, 2016; Sheeran & Webb, 2016; Sniehotta, Scholz, & Schwarzer, 2005), and, therefore, highlight the need for careful design of TPB questionnaires, which provide consistency in relation to target, action, context and time.

For study design, no heterogeneity was seen when comparing cross-sectional and prospective designs. It is generally recognised that a prospective design is more appropriate to test the sufficiency of the TPB model because it maintains the causal sequencing that is proposed between the TPB variables and subsequent behaviour (McEachan et al., 2011). McEachan et al. (2016) noted another confounding factor in the length of time between the measurement of intention and behaviour, with longer time intervals between measurement demonstrating lower correlations. This is because a longer time difference between intention and behaviour measures may allow the influence of additional factors to reduce the predictive power of intention (Ajzen, 1991). The studies in this current meta-analysis had a median time interval of 28 days between the measurement of intention and behaviour, which is not dissimilar to the median 3.5 weeks reported by McEachan et al. (2016). Therefore, this does not explain the different results obtained in this moderator analysis. It is possible that the reason for the discrepancy between the results of this meta-analysis and McEachan et al. (2011) was due to this meta-analysis examining adherence behaviours only, and the performance of these behaviours may be more stable over time compared to other behaviours, such as exercise or diet in the general population, in which individuals are known to have difficulty in maintaining over time (Elfhag & Rossner, 2005; Marcus et al., 2000). Regardless, the findings indicate that it does not matter whether researchers use prospective or cross-sectional designs when using the TPB to predict health adherence behaviours. That said, from a theoretical perspective of preserving the causal ordering of the TPB variables and behaviour, prospective designs are still to be preferred.

In summary, whilst the moderator analysis has partly explained some reasons for heterogeneity, it has not fully explained the variance across the studies. A small number of papers meeting the inclusion criteria, and insufficient detail reported in some studies, has limited the comparisons made in the moderator analysis. However, it appears that the TPB offers a suitable theory for investigating adherence to health behaviours across a range of conditions that often lead to people requiring an orthosis. It is therefore likely to provide a suitable framework for understanding why people do, or do not, adhere to recommended advice regarding AFO use. Key moderators of the relationships proposed by the TPB were the measurement of PBC and adherence to the compatibility principle. SE was found to be a stronger correlate of intention and behaviour than PC and in the case of PBC-B relationship, combined measures, and adherence to the compatibility principle provided a significantly stronger I-B correlation. Research using the TPB as a framework to study adherence to orthotic interventions, should, therefore, employ measures of SE when assessing PBC and adhere to the principle of compatibility when testing the model.

4.5.3 Limitations

Studies not found in peer reviewed journals or in the English language were excluded. Although inclusion of unpublished studies and those written up in non-English languages would have increased the number of studies in the analysis, and potentially the generalisability of the findings, it would not be possible to ensure that studies taken from the "grey" literature were a representative sample of that literature. For example, the search process for grey literature often includes studies, which have been sourced using personal contacts of the author or inclusion of studies that are available online, therefore resulting in a high degree of bias in the studies selected. Additionally, calculation of the fail-safe N (Rosenthal, 1991) provides confidence that the file drawer effect, would not have affected the results of this study.

Whilst it is acknowledged that the moderator analysis only provided a partial explanation of heterogeneity, several studies did not report on key data, which excluded them from the moderator analyses. This reduced the power of the moderator analyses, and meant that only some health conditions, behaviours and TPB relationships could be investigated for heterogeneity. Therefore, when the TPB is used to investigate adherence behaviours, it is recommended that the following information is provided: a clear definition of adherence with reference to the target, action, context and time, the way in which adherence is being measured, details regarding operationalisation of attitude, subjective norm and PBC measures, and studies should report variables independently for specific health conditions.

Significant heterogeneity was seen in this meta-analysis, and this is often considered a criticism of meta-analyses, and is sometimes referred to as mixing apples and oranges (i.e., if the fruit (or studies) are very different to each other (e.g., health condition, treatments and/or outcome measure) it makes little sense to combine them together to draw conclusions about them) (Sharpe, 1997). However if the desired outcome is to increase ones' understanding of fruit in general (Abramson & Abramson, 2001), it may be appropriate to combine studies investigating both apples and oranges. In the same way, in order to understand if the TPB might be a useful model for understanding adherence to orthoses, it is fitting to look at how well the TPB might predict adherence to other health behaviours across a range of health conditions for which orthoses might be utilised. Given that different health conditions, adherence behaviours and measurement tools were considered in this meta-analysis, the presence of heterogeneity was not unexpected. Indeed, Higgins (2008) argues that heterogeneity in meta-analyses should be expected. The use of a random effects model was considered to provide a meaningful method of handling real world differences across similar studies, and provides a more conservative and reliable estimate of effect sizes (Borenstein, Hedges, Higgins, & Rothstein, 2010). Additionally, heterogeneity offers an opportunity to investigate differences between studies, and increase knowledge of how well the TPB can predict different adherence behaviours across different health conditions, and to investigate the effect of methodological differences when using the TPB.

4.6 Conclusion

This meta-analysis focused specifically on studies measuring adherence or intention to adhere to a health behaviour, in participants with health conditions for which an orthosis may be prescribed. It therefore contributes to knowledge of how well the TPB predicts adherence as a health behaviour. This study offers support for using the TPB as a theoretical framework for investigating adherence to orthotic devices. It also demonstrates that the TPB is applicable across a range of different health conditions and in investigating different health adherence behaviours. In addition, the moderator analysis has highlighted the need to use SE when measuring PBC, and to ensure that measures of the TPB constructs adhere to the principle of compatibility.

Key Points from Chapter 4

1. A meta-analysis was conducted of investigations using the TPB/ TRA to explain adherence to a range of health behaviours (exercise, diet, medication and self-care) in conditions, which may give rise to an orthotic intervention.
2. Twenty-three articles were identified meeting the inclusion criteria and a random effects meta-analysis was used to calculate correlations between the components of the TPB, using a weighted mean effect size, r. All of the weighted mean correlations between the TPB variables were statistically significant.
3. Meta-analytic path analysis showed that the TPB accounted for 28.3% of the variance in intentions and 14% of the variance in adherence behaviours. Attitudes and PBC were significant predictors of intention and intention was a significant predictor of behaviour. Intention was shown to mediate the effects of attitude and PBC on behaviour in line with the TPB. Overall, this suggests the TPB might offer a useful model to investigate adherence to AFOs.
4. There was no significant difference in correlations between TPB variables seen in different health conditions. This suggests that the TPB might be an acceptable model in investigating a wide range of different health conditions.
5. There was no significant difference in correlations between the TPB variables and behaviour when objective or self-reported measures of behaviour were measured. This therefore offers some support for the use of self-reported measures in TPB investigations investigating adherence behaviours.
6. When self-efficacy (SE) measures of the PBC construct were used they demonstrated significantly higher correlations between the TPB variables compared to the use of PBC or a measure, which combined both SE and PBC. This suggests that future investigations using the TPB to investigate adherence to orthoses should use SE measures, rather than PBC or a combined measure of perceived control.
7. Investigation of the compatibility principle demonstrated a significantly higher mean correlation for the I-B relationship in studies meeting the compatibility principle than those that did not. This suggests that more care should be taken to ensure in TPB investigations that compatibility is met.

Next Steps

The next two chapters in this thesis report research conducted to investigate the efficacy of the TPB in predicting adherence to the use of AFOs. Chapter 5 describes an elicitation study, which identifies the attitudinal, normative and control beliefs of people who have been prescribed AFOs due to a stroke. Then, Chapter 6 uses these beliefs in a TPB study to investigate the efficacy of the TPB in explaining adherence to AFOs in people with stroke.

Chapter 5 A TPB Elicitation Study investigating Behavioural, Normative and Control Beliefs affecting AFO Use in People with Stroke

5.1 Introduction to Chapter

This chapter details the third study of this PhD, a beliefs elicitation investigation, which uses the TPB as a theoretical framework to identify beliefs affecting AFO use in people with stroke. Non-adherence to AFOs, as determined in Chapter 3, can lead to reduced health outcomes for people who have been prescribed AFOs, and is a significant concern for orthotic services, due to an inefficient use of scarce resource when devices are not used. Whilst previous research has identified some potential reasons for non-adherence to AFOs (Swinnen & Kerckhofs, 2015; Vinci & Gargiulo, 2008), no research has examined the underlying beliefs affecting use of orthoses in a clinical population, using a theoretical model of behaviour. The previous chapter established that the TPB is a potentially suitable theoretical model to explain adherence to orthoses in a range of different health conditions. A beliefs elicitation study is the first phase of a TPB investigation, and is essential to understand the beliefs underpinning a person's behaviour, and also informs the subsequent phases of the TPB investigation. This chapter begins by explaining the rationale for the focus on stroke. It then details stroke and its sequelae, and outlines the role of AFOs in the management of stroke. It also provides a theoretical rationale and details the method for conducting an elicitation investigation. The attitudinal, normative and control beliefs about AFO use which were elicited, are presented. The discussion highlights the implications of these findings, and details the limitations and strengths of this investigation.

5.2 Introduction

5.2.1 Stroke

5.2.1.1 Rationale for Focus on Stroke

Stroke is the focus of the remaining chapters of this thesis because it has been shown to be the most common reason for being prescribed an AFO (See Section 3.5.4). Additionally, stroke, is the leading cause of acquired adult disability worldwide (McGrath et al., 2018), and there are 1.2 million stroke survivors in the UK (Stroke Association, 2018b). Six per cent of the NHS budget is spent on stroke care (Wittenauer & Smith, 2012), and more than half of all stroke survivors are left dependent on others for everyday activities (Stroke Association, 2018b). The risk of stroke increases with advancing age, and with a growing elderly population the number of stroke events in the UK is predicted to rise from 1.1 million in 2000 to 1.5 million in 2025 (Truelsen et al., 2006). Therefore, stroke will continue to be a significant societal burden in the near future. Consequently, research into treatment and technologies that increase independence of stroke survivors, and research, which enables better use of currently available technologies, is required.

5.2.1.2 What is stroke?

The World Health Organisation defines stroke as *"rapidly developing clinical signs of focal (at times global) disturbance of cerebral function, lasting more than 24 hours or leading to death with no apparent cause other than that of vascular origin"* (Hatano, 1976, p.541). Stroke occurs when there is a loss of blood to the brain, causing tissue damage and cell death in the brain. This can be because of ischemia (85%), which is caused by a blockage such as seen in arteriosclerosis or a blood clot, or from a haemorrhage (15%) caused by bleeding in the brain. Risk factors in stroke include high blood pressure, poor diet, smoking, diabetes, high cholesterol, and lack of exercise (Stroke Association, 2013).

Worldwide, stroke is the second most common cause of death (WHO, 2014). The lifetime risk of developing a stroke in middle-aged adults is 1 in 6 or more (Seshadri et al., 2006). In the UK there are 1.2 million stroke survivors, and almost two thirds of stroke survivors have a resultant disability (Stroke Association, 2018b). In Scotland, stroke has been a national clinical priority for the last 15 years (Scottish Government, 2014a). Despite improvements in treatments and stroke services for patients in that time, stroke remains the most common cause of severe physical disability in adults (ISD Scotland, 2018b). Of those who survive stroke, approximately 42% will be independent in relation to activities of daily living (i.e. not requiring any help or assistance), 22% have mild disability, 14% have moderate disability, 10% have severe disability, and 12% have very severe disability (Royal College of Physicians, 2011).

5.2.1.3 Effects of stroke

The damage to the brain can cause a range of effects including difficulties in movement, altered sensation, visual disturbances, cognitive and emotional difficulties, depression, speech and language difficulties, swallowing difficulties, bladder and bowel disturbance, and pain

(Stroke Association, 2018a). The disabilities seen in stroke are therefore a combination of physical, cognitive, psychological, emotional, and social. The most common and widely recognised impairment caused by stroke is motor impairment, which often affects control of movement of the face, arm, and leg of one side of the body (Langhorne, Bernhardt, & Kwakkel, 2011). The level of impairment will depend on the resultant damage to specific areas of the brain following stroke. It is estimated that 50-60% of stroke survivors are left with motor impairment following rehabilitation (Hendricks, van Limbeek, Geurts, & Zwarts, 2002). The most common types of motor impairment seen following stroke are hemiplegia, a paralysis of one side of the body, or hemiparesis, a weakness of one side of the body, which creates significant mobility challenges for someone with stroke.

As described in Chapter 1, Section 1.7.1, a person with hemiplegia will typically walk with a 'drop' foot, most easily identified during the swing phase of gait, when a stroke survivor may have difficulty clearing the toes from the ground. However, as highlighted previously, the main biomechanical challenges are seen in stance phase, with initial contact being made with the forefoot, in turn causing extension at the knee throughout stance, and difficulty initiating knee flexion during swing phase. Furthermore, these biomechanical and neuromuscular challenges occur for a person who may also be struggling with cognitive challenges, as well as a range of other physical problems such as visual loss, changes to sensation and co-ordination, and loss of balance.

5.2.1.4 Use of AFOs following a stroke

AFOs are used to maintain the foot in an optimally aligned position in stance phase, allowing clearance of the foot during swing phase and also improve mobility and balance following stroke (Bowers et al., 2009b; Tyson & Kent, 2013; Tyson et al., 2013). However, many people who have been prescribed orthotic devices choose not to use them, or do not use them as recommended (Swinnen & Kerckhofs, 2015; Vinci & Gargiulo, 2008). Chapter 3 reported an overall adherence rate of 56% to AFOs, although this was across multiple conditions. Specifically, in people with stroke, there is limited knowledge about use of AFOs after they have been prescribed. Only two previous investigations have investigated use of orthoses in stroke. Nakipoğlu-Yüzer et al. (2018) investigated use of both AFOs and KAFOs in people following discharge from in-patient rehabilitation and reported that 59.4% of participants used their AFOs every day. Bowers et al. (2009b) specifically investigated use of AFOs following stroke and stated an adherence rate of 70%: this was an NHS quality improvement survey, conducted as background work for the Best Practice Statement: use of AFOs following stroke. However, this study was not peer reviewed or published, and it did not give any detail in relation to how adherence was defined. Therefore, there is a need to examine adherence to AFOs in people with stroke, in more detail.

5.2.1.5 Experiences of using AFOs in people with stroke

In order to understand the factors affecting adherence to AFOs in people with stroke, it is necessary to appreciate their experiences of using AFOs. Three previous investigations have investigated user views and preferences around the use of AFOs following a stroke. The first study was reported as part of the Best Practice Statement (Bowers et al., 2009b). This document identified that use of an AFO can take away fear of falling, improve confidence, and make people feel better about themselves. The second study, which was conducted by Bulley et al. (2011), investigated user preferences between AFOs and FES (See Section 1.9.3, Footnote 12, for a description of FES) in people with stroke, using interpretative phenomenological analysis. Participants described experiences of using AFOs and FES and identified some advantages of AFOs including ease of day-to-day use, ease of donning and reliability. Whilst this study offered some insights into why people might use AFOs, the inclusion of another treatment option, FES, was a confounding factor in understanding the issues relating to adherence to AFOs. The final study, Nakipoğlu-Yüzer et al. (2018), investigated reasons for disuse of orthoses and reported the most common reasons for patients no longer using their AFOs were: because they felt they were unnecessary, did not help with daily life, and were difficult to use.

5.2.2 Applying the TPB to Understanding Adherence to Use of AFOs

Therefore, whilst there is some is limited information about people's beliefs regarding use of AFOs, it is not known if these factors can predict use of AFOs. In addition, none of the previous work conducted in this area, has been theoretically driven. Consequently this current investigation aims to shed light on factors affecting adherence to AFOs following stroke and will use a psychological theory of behaviour, the TPB (Ajzen, 1991) as a framework for eliciting beliefs relating to use of AFOs in people with stroke.

The TPB, previously described in Chapter 4, Section 4.1.1, can also be used as a framework to understand the underlying beliefs which influence health behaviours. This can be done by conducting a beliefs elicitation study, which asks a series of open-ended questions to elicit the most commonly occurring, salient beliefs in relation to the behaviour under investigation (Ajzen, 2006). The main purpose of a TPB elicitation study is to identify the behavioural, normative and control beliefs of a population, and, therefore, understand the cognitive processes affecting people's behaviour (Ajzen & Fishbein, 1980). The lack of knowledge in understanding adherence to AFOs in people with stroke, informs the need to conduct an elicitation beliefs study based on the TPB.

Knowledge of these beliefs is important for three reasons. Firstly, beliefs obtained in the elicitation study are used to develop a valid TPB questionnaire to quantify these beliefs and allow an understanding of the relationship between the underlying beliefs and A, SN and PBC and intention. Secondly, information about which beliefs form the cognitive foundations of decision making about a behaviour can be used to design an intervention which targets modifiable behavioural, normative or control beliefs, in order to positively influence intentions, and in turn, behaviour. Finally, participant responses to questions in the elicitation investigation, give researchers insights into the language and terminology used by the target population, which may be important when designing a future intervention which seeks to change underlying beliefs (Curtis, Ham, & Weiler, 2010).

The TPB has typically been used to predict and explain a wide range of social and health behaviours across different populations (Armitage & Conner, 2001; Godin & Kok, 1996; McEachan et al., 2016). It has been recognised that beliefs will vary according to the behaviour and population, and that different TPB constructs may have varying levels of influence depending on the context and people being investigated (Ajzen, 1991; Ajzen & Fishbein, 2005). Therefore, Ajzen and Fishbein (1980) recommended that whenever the TPB is applied in a new population, or to understand a behaviour that has not previously been investigated, a beliefs elicitation study should be conducted. However, the majority of TPB investigations focus on the relationships between A, SN and PBC, intention and behaviour, without due consideration for the underlying beliefs (Downs & Hausenblas, 2005b). The problem with only measuring direct TPB constructs, is that the beliefs underling these constructs cannot be understood, and, therefore, as an explanatory model of behaviour, the TPB has limited utility (Downs & Hausenblas, 2005b). A further difficulty is seen when researchers use beliefs elicited in previous investigations and apply these to a different TPB study. If the sample used in the elicitation study and the main TPB study do not share the same demographic or clinical characteristics, there may be a lack of correspondence in the beliefs of both groups of participants (Ajzen, 1991). If correspondence between participants taking part in the elicitation investigation and the main TPB study cannot be determined, it is possible that people taking part in the follow-up TPB study may hold different beliefs (Downs & Hausenblas, 2005b). Thus, the beliefs being used may not be relevant to the population, and the findings of such research may not accurately reflect the underlying cognitive foundations of the behaviour being investigated.

As highlighted earlier, no previous investigations have used the TPB to understand adherence to any type of orthotic intervention in any patient group, let alone conducted an elicitation study based on the TPB. Only one previous investigation has used the TPB to predict intentions and behaviour in people with stroke (Bonetti & Johnston, 2008). Specifically, this investigation investigated if recovery and walking limitation were predicted by different conceptualisations of control, such as perceived behavioural control, self-efficacy and locus of control. They found that walking limitation and recovery were predicted by perceived control ($r=-.36$, $r=0.26$) and self-efficacy ($r=-0.30$, $r=0.20$). In relation to the TPB, intention did not significantly improve the capacity of the TPB in predicting walking limitation and recovery. They suggested that interventions might be most effective when attempting to increase perceptions of control of self-efficacy. However, they did not conduct a beliefs elicitation investigation prior to the main investigation, nor did they investigate the relationship between underlying beliefs and the TPB.

Two other previous investigations have used the TPB to investigate the beliefs underpinning health behaviours following stroke. In the first investigation, Lawrence, Kerr, Watson, Paton, and Ellis (2010) explored beliefs and lifestyle behaviours of patients and their families following stroke, using the TPB. This investigation highlighted that provision of information alone was not enough to motivate people with stroke to adopt health behaviours, and suggested a strong influence by significant others on both positive and negative health behaviours. Whilst this investigation was guided by the TPB, it was not described as a beliefs elicitation study. Furthermore, the focus on provision of lifestyle information meant it was not directly relevant to the current investigation. In the second investigation conducted in people with stroke, Desrochers, Kairy, Pan, Corriveau, and Tousignant (2017) investigated the value of practicing Tai Chi in upper limb rehabilitation following stroke. Although this provided information about patient perceptions of an intervention for rehabilitation following a stroke, it did not investigate rehabilitation of the lower limb and did not focus on adherence to the intervention. Therefore, conducting an elicitation study in order to identify the beliefs underpinning adherence to AFOs in people with stroke is an essential phase of this PhD thesis, as this will ensure that beliefs which are relevant to the population being investigated, are captured.

5.3 Aim

Although a growing body of research has begun to recognise the importance of elicitation studies in constructing TPB questionnaires (Araujo-Soares, Rodrigues, Presseau, & Sniehotta, 2013; Curtis et al., 2010; Downs & Hausenblas, 2005b; Pastor et al., 2015; Sainsbury & Mullan, 2011), no previous investigation has conducted an elicitation study of people investigating the beliefs about using AFOs in stroke survivors. Therefore, the aim of this study was to explore the beliefs affecting use of AFOs in people with stroke, using the TPB as a guiding framework. As the first theory-driven study to examine the beliefs of stroke survivors about using or not using an AFO as recommended, this study will use qualitative methods to elicit behavioural, normative and control beliefs in a sample of participants who had previously been prescribed an AFO. Following the guidelines of Ajzen (2006), Francis et al. (2004), and Francis et al. (2010), the beliefs elicited will then be used to develop a questionnaire for a prospective TPB study to enable an understanding of the beliefs which determine AFO use in people with stroke. This follow-up study is described in Chapter 6. Conduction of an elicitation investigation, prior to design of a questionnaire to test the prediction of intention and behaviour, allows the application of the theory as originally intended (Fishbein & Ajzen, 2010), and provides a theory-based approach to enable the development of more effective interventions. Whilst this thesis does not design or test an intervention, the findings of this study could be used in future intervention studies which have the potential to reduce impairment, increase activity levels and participation, and therefore improve quality of life in people prescribed AFOs following a stroke.

5.4 Method

5.4.1 Participants

Participants were a purposive sample of 13 people with stroke, who had previously been prescribed or given AFOs by NHS Lanarkshire. Inclusion criteria were people who: had been prescribed or provided with an AFO by NHS Lanarkshire following a stroke in the last 3 years, were aged 18 years or older, were medically stable, had cognitive ability to consent to participate, and were able to communicate their beliefs. NHS Lanarkshire was identified as a relevant regional area from which to recruit participants, because of the high incidence of stroke in the region. NHS Lanarkshire has the highest adjusted incidence of stroke in mainland Scotland (203 per 100,000 population) (ISD Scotland, 2017). In addition, Lanarkshire is one of the most deprived areas of Scotland, and it is known that prevalence rates of stroke are three times higher in deprived areas (British Heart Foundation, 2018). Participants over the age of 18 were identified as meeting inclusion criteria, because, in a younger population, it would be more difficult to ascertain if use of an AFO was the decision of the parent/carer or young person. Therefore, by excluding participants who were younger than 18 years of age, this ensured that adherence was being measured.

The aim when eliciting beliefs in a sample of the population for a TPB elicitation study is that the sample should be representative of the general population (Ajzen, 2006). Therefore, demographic and clinical data were collected during the interview. The demographic and clinical and orthotic details of each participant can be seen in Table 5.1, including age, gender, marital status, when stroke occurred, if the participant uses an AFO in relation to the recommendations, and when their most recent AFO was provided.

5.4.1.1 Gender, age and living arrangements

The sample included both male (n=6, 46%) and female (n=7, 54%) participants. Four out of the 13 participants were of working age, which is similar to the 25% of people who experience stroke in the UK population (Stroke Association, 2018b). The mean age of the participants was 67.2 years (mean age for females 69.7yrs and mean age for males 64.3yrs), with a range between 50-84 years. This is slightly younger than the general stroke population in Scotland where the average age for females having a stroke is 75, and the average age for men is 71 (ISD Scotland, 2017a). The majority of participants were living with their spouses (n=8, 62%), with the remaining five participants living on their own.

5.4.1.2 Time since stroke

The mean length of time since stroke was 52.5 months, although this figure was skewed somewhat by one participant who had had their initial stroke in 1991. However, the sample included longer term stroke survivors (> one-year post stroke (n=8, 62%)) and participants who had recently had a stroke (< 1-year post stroke (n=5, 38%)).

5.4.1.3 AFO type and use

In terms of AFO use, less than half of the participants reported using AFOs as recommended (n=4, 31%); two participants (15%) reported not using the AFO at all; and seven participants (54%) reported they were using their AFO differently to recommended, with six participants using their AFO less than recommended and one participant using more than recommended. Seven participants had been prescribed customised rigid AFOs, two participants had been prescribed customised Posterior Leaf Spring (PLS) AFOs, and four had been provided with pre-fabricated low profile ankle braces.

In the current study all participants in this study had knowledge of recommendations for use, whereas in the ICF study, described in Chapter 3, approximately one third of participants did not know recommendations for use. Two possible reasons for this were identified. Participants in NHS Lanarkshire are given written information regarding AFO use, whereas participants prescribed with AFOs by NHS Greater Glasgow and Clyde were only given verbal information regarding use. Additionally, it is possible that desirability bias during face to face interviews, as opposed to an anonymous questionnaire, resulted in people being unwilling to admit that they were not aware of recommendations for use. The verbal instructions given during the interview were designed to reduce this desirability bias and, given that participants were willing to suggest disadvantages and factors that made AFO use more difficult, it is not thought that desirability bias was a major concern in the responses. Therefore, the most plausible explanation for this difference lies in the mode of information delivery regarding AFO use between different NHS boards.

5.4.2 Design and Procedure

This study used a qualitative exploratory design, based on the TPB, to elicit beliefs about AFO use in people with stroke. Ethical approval was gained from the NHS (NE/14/1002) and endorsed by the University of Strathclyde (UEC 14/24). The favourable opinion of the NRES Committee North East-Newcastle and North Tyneside 1 can be seen in Appendix 5.1. A research nurse employed by the Scottish Stroke Research Network (SSRN) made the initial approach to potential participants and was also responsible for gaining written consent. The study was briefly explained and a patient information leaflet was provided. Participants were approached from the following groups: people attending a bi-monthly multidisciplinary AFO/stroke clinic at Wishaw General Hospital, and people residing in the stroke, or elderly wards at Wishaw General, Monklands and Hairmyres Hospital in Lanarkshire. Individual semi-structured interviews were carried out with a representative sample of people with stroke who had been prescribed AFOs, between March and May 2015.

Table 5-1: Demographic and Clinical Characteristics of the Sample

Participant No.	Gender	Age	Marital Status	Time Since Stroke	Do you use your AFO?	Use of AFO as recommended	AFO design	Date AFO provided
001	M	59	Single	Jan 2015	Yes	More than recommended	Rigid Custom	Feb 2015
002	M	65	Married	Dec 2014	Yes	About as often as recommended	Prefabricated ankle brace	Mar 2015
003	M	65	Married	Feb 1991	Yes	Less often than recommended	Rigid Custom	Sept 2013
004	F	50	Married	Dec 2012	Yes	Less often than recommended	PLS Custom	Nov 2014
005	F	68	Married	Feb 2015	Yes	About as often as recommended	Rigid Custom	Feb 2015
006	F	64	Divorced	June 2010	Yes	Less often than recommended	PLS Custom	Oct 2014
007	M	67	Married	June 2002	Yes	Less often than recommended	Rigid Custom	Oct 2014
008	F	80	Widowed	Dec 2013	Yes	Less often than recommended	Rigid Custom	Mar 2014
009	M	69	Married	Aug 2013	Yes	About as often as recommended	Prefabricated ankle brace	Sep 2013
010	F	67	Married	Nov 2014	Yes	About as often as recommended	Prefabricated ankle brace	Jan 2015
011	F	84	Widowed	Jan 2014	No	N/A	Prefabricated ankle brace	Feb 2015
012	F	75	Married	Mar 2014	No	N/A	Rigid Custom	Jul 2014
013	M	61	Single	Sep 2014	Yes	Less often than recommended	Rigid Custom	Oct 2014

Following a stroke, people may have a range of functional losses including communication challenges and upper limb dysfunction. These challenges often result in participants being excluded from research, although they may have the potential to take part if appropriate adjustments are made to support their participation. To ensure that the study was open to a maximum number of participants, and that the sample was more representative of the population, it was felt important to include people who may have had communication difficulties including aphasia. Therefore, careful consideration was given to the design of the participant information sheets and consent forms, seen in Appendices 5.2 and 5.3. The Stroke Association Guidelines (Stroke Association, 2012) for creating accessible information were consulted, and the following aspects of design in the participant information sheet and consent form were used: larger font size (size 14) and sans serif font (Ariel); simple sentence structure and short sentences; careful choice of words; use of space and borders to improve readability; bold headings; use of the Flesh-Kincaid Grade Level[21] to check ease of reading; and highlighting of key words to improve readability. Additionally, for people with upper limb difficulties, the participant information sheet noted that other people could fill in the questionnaire under the participant's directions.

Interviews were conducted with both in-patients and out-patients to ensure a representative cross-section of the population was obtained. Two of the participants were in-patients and were interviewed in the hospital wards: one at Wishaw General and one at Monklands Hospital. The remaining participants were interviewed in their own home to minimise disruption to participants. Each interview took approximately 30 minutes (range 20 minutes - 1 hour 10 minutes). An interview schedule, designed in accordance with guidelines of Ajzen (2006) and Francis et al. (2004) to assist in constructing a questionnaire using elicitation interviews, was used to elicit behavioural, normative and control beliefs associated with use of AFOs, and can be seen in Appendix 5.4. Responses from the interviews were written in note-form on each interview sheet. Tape-recording of the interviews was not necessary as the interviews were towards the structured end of the continuum, and there was no requirement for in-depth thematic analysis of the data. Non-verbal signals of the participant and any questions or general comments made by the participant, which could increase understanding of meanings of their answers, were also noted. Immediately after each interview, the

[21] The Flesh Kincaid Grade level can be used to assess the readability of a document in English language. Scores are based on formulae that assess average sentence length and average number of syllables per word. To ensure a document is accessible, a score of 5 or less is recommended by the Stroke Association (2012).

comments were reviewed, and expanded, then further refined to ensure improved accuracy. Once data were collected, names and consent forms were removed and the data was pseudo-anonymised.

5.4.3 Measures

5.4.3.1 Demographic and Clinical Data

The age, gender and marital status of participants were recorded. Time since stroke was also noted.

5.4.3.2 Data relating to AFO Use

The following details regarding the AFO were documented: if the AFO was used or not; the extent to which the AFO was used (more than, less than, or the same as recommended; or if participant was unsure of recommendations for use); length of time since the most recent AFO was provided to the participant; the AFO design, and if the device was customised or prefabricated.

5.4.3.3 TPB Beliefs

A series of questions were used to elicit behavioural, normative and control beliefs, in line with recommendations from Ajzen (2006) and Francis et al. (2004). Questions were reflective of the beliefs underpinning attitude, subjective norm and PBC as seen in Figure 5.1 below.

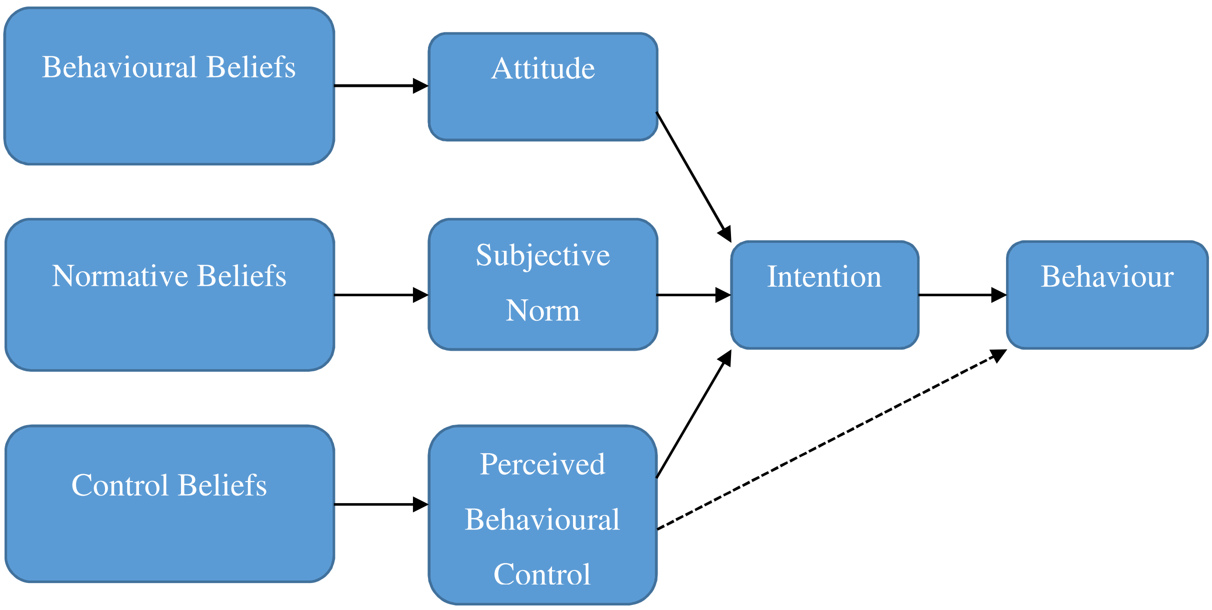

Figure 5-1: The Theory of Planned Behaviour (Ajzen, 1991)

Behavioural beliefs were elicited by asking the following questions: "What do you believe are the advantages of using an AFO (splint)?", "What do you believe are the disadvantages of using an AFO?", and "Is there any other thoughts you have about using the AFO?" Prompts were also used if participants were not able to identify any beliefs relevant to the question: "Is there anything else that is beneficial or good / positive about using an AFO?", "Is there anything else that's negative/ bad/ causes you problems when using an AFO?"

Normative Beliefs In order to elicit the normative beliefs, the following three questions were asked: "Can you think of any individuals who would approve of you using an AFO?", "Are there any individuals or groups who would disapprove of you using an AFO?", and "Are there any other groups or individuals who come to mind when you think about using an AFO?" If participants struggled to identify any normative groups they were also asked "Is there anyone else/ any other group who might think using the AFO is a good thing?", and "Is there anyone else/ any other group who might think using the AFO is a bad thing?"

Control Beliefs were elicited with three questions: "What factors/ circumstances would make it hard for you to use an AFO?", "What factors/ circumstances make it easy to use an AFO?", and "Is there anything else which comes to mind when you think about the challenges of using an AFO?" Finally, for participants who were not able to identify control factors, additional questions were asked to encourage them to identify control beliefs: "Is anything else that makes it hard/ more difficult/ more of a challenge for you/ that stops you from using an AFO?", and "Is there anything else that makes it easy/ straightforward/ reduces effort to use an AFO?"

5.4.4 Analysis of Data

5.4.4.1 Deciding the Sample Size

In deciding the sample size, the data saturation approach recommended by Francis et al. (2010) was followed. The initial sample size was set, a priori, at 10 with a stopping criterion of three. This means that if no new themes emerge after the initial 10 interviews, and this is confirmed by the final three interviews, data saturation has been achieved. Interviews should continue if new themes continue to emerge, until there are three consecutive interviews with no new additional material. Analysis of data began after the tenth interview was conducted. The analysis process then ran concurrently alongside the interview process, with data from each new participant interview being added to the analysis. This was necessary in order to establish the point of data saturation (i.e. at which no new themes emerged from the data), as this would determine if more participants were required for interview. In order to identify the point of data saturation, a frequency graph, identifying the number of new themes emerging for each participant, seen in Figure 5.2 below, was constructed to identify the interview at which no new beliefs were identified. Data saturation was achieved after participant 10, and a further three interviews were conducted to confirm this. Therefore, after a total sample of 13 participants, no further participants were recruited.

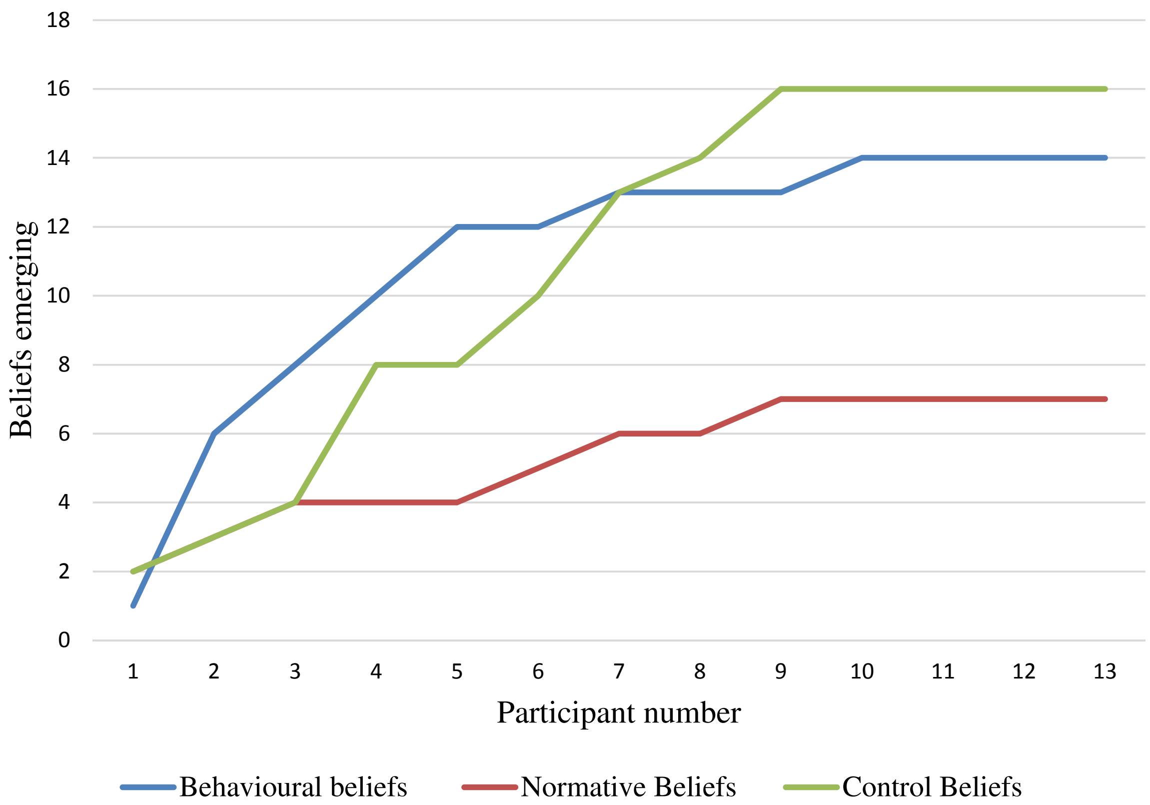

Figure 5-2: Cumulative Frequency Graph for Behavioural, Normative and Control Beliefs Elicited by Participants

5.4.2.2 Content Analysis of Data

Content Analysis was used to code the beliefs into themes as recommended by Ajzen (2006) and Francis et al. (2004). Content analysis has routinely been used to analyse data from elicitation studies in similar investigations using the TPB as a framework (Bai, Middlestadt, Joanne Peng, & Fly, 2009; Curtis et al., 2010; Pastor et al., 2015; Sainsbury & Mullan, 2011). Content analysis provides a systematic and objective method to make valid interpretations of data in order to describe and quantify individual experiences (Downe-Wamboldt, 1992). Content analysis means more than simply counting specific words in a text. It allows the researcher to examine meanings, determine themes, and observe patterns, which can be applied not only to text, but conversation, and other communication forms (Stemler, 2001).

The first stage involved reviewing the transcripts from each interview several times prior to any coding to acquire an overview for the data set, and to enable familiarisation with, and an understanding of, the data. In the next stage, potential themes were documented alongside the transcripts of participant answers. At this point, more than one potential theme or category could be allocated to a statement. The potential themes were then extracted and refined, and a coding frame was then developed to categorise the behavioural, normative and control beliefs. A clear descriptor was given to each theme. This was to ensure that each theme was specific, mutually exclusive, and independent (Krippendorff, 2004). The individual beliefs were then extracted from the transcripts and entered into an excel spread sheet under the key headings of: advantages/ disadvantages of using an AFO (behavioural beliefs), people who would approve/ disapprove of AFO use (normative beliefs), and factors that make using an AFO easier or more difficult (control beliefs). Initial themes were then identified for each belief.

Francis et al. (2004) recommends the use of at least two researchers to independently content analyse the themes, in order to increase validity. In this investigation three researchers, C. McMonagle, S.A. Rasmussen and K. Russell independently coded the themes. Codes and descriptors for each category were provided to the researchers. In order to assess inter-rater reliability, Fleiss' kappa was used. Fleiss' kappa is a statistic which measures the inter-rater agreement for nominal data when more than two researchers are coding data (McHugh, 2012). The analysis takes into account agreement that may have occurred due to chance, and, therefore, is considered to be more accurate than percentage agreements between researchers. Levels of agreement between the coders for the statements reported by each participant for attitudinal, normative and control beliefs are provided in Table 5.2 below. Using the kappa values of Landis and Koch (1977) (0.00 or less- poor; 0.00-0.02 slight; 0.21-0.40 fair; 0.41-0.60 moderate; 0.61-0.80 substantial; 0.81-1 almost perfect); the inter-rater reliability of disadvantages of AFO use was noted to be substantial and the reliability of all other variables of the TPB were noted to be almost perfect. Following this, a consensus meeting was held which allowed further refinement of the themes, to ensure that the themes were clear, concise and reflected the theoretical underpinnings of the TPB. This enabled complete agreement between the researchers

Table 5-2: Fleiss Kappa for Agreement of Coding between Researchers

	Fleiss kappa
Advantages of AFO use	0.81
Disadvantages of AFO use	0.77
People who approve of using AFOs	1
People who disapprove of using AFOs	1
Factors that make AFO use easier	1
Factors that make AFO use more difficult	0.87

5.4.5 Results

The behavioural, normative and control beliefs elicited and their respective themes can be seen in Appendix 5.5. Tables 5.3, 5.4 and 5.5 below, present the main themes and the percentage of participants reporting the theme. In addition, the tables provide an illustrative example of each theme, with the participant number highlighted in brackets.

5.4.5.1 Behavioural Beliefs

Forty-eight behavioural beliefs relating to AFO use were identified and these were grouped into six advantages and eight disadvantages (Table 5.3). The most commonly noted advantages were “increases mobility”, and “supports the position of the leg/foot” both reported by nine (69%) participants. The most commonly noted disadvantages were “discomfort”, commented on by eight (62%) participants, followed by “problems with footwear size” and “problems with footwear style” noted by five (39%) participants. Appendix 5.6 provides the themes identified by each individual participant in relation to behavioural beliefs.

5.4.5.2 Normative beliefs

Fifteen groups of people who approved or disapproved of AFO use were reported, and these were categorised into four normative referents who approved and three normative referents who disapproved of AFO use (Table 5.4). There were more normative beliefs elicited relating to approval of AFO use (n=37), compared to disapproval of AFO use (n=5). The most commonly cited normative group who approved of AFO use were “family”, which was identified by 10 (77%) participants, followed by “health professionals” which were identified by nine (69%) participants, and then “friends”, identified by seven (54%) participants.

Table 5-3: Key Themes for Behavioural Beliefs Elicited in Interviews

Themes	Number of participants	%	Examples
Advantages			
Increases mobility	9/13	*69.2*	*"It's easier to move around- I couldn't move around before I got my AFO, going to toilet, going to the shop (in the hospital) is easier" (1)*
Supports position of leg/ foot	9/13	*69.2*	*"I'm not dragging my leg as much" (6)*
Gives confidence	7/13	*53.8*	*"I would be too scared or worried to walk without it. It supports your ankle"(5)*
Improves balance/ prevents falls	5/13	*38.5*	*"I feel safer-when I wasn't using the splint that was when I fell" (8)*
Improves quality of walking	5/13	*38.5*	*"Walking is more natural" (13)*
Provides improvement in rehabilitation	2/13	*15.4*	*"I was over the moon when I got it ... I could see I was improving" (5)*
Disadvantages			
Discomfort	8/13	*61.5*	*"It's uncomfortable…. it rubs my leg at the ankle" (13)*
Footwear size/ fit	5/13	*38.5*	*" I have to buy a bigger size of footwear" (3)*
Footwear style	5/13	*38.5*	*"When I saw the shoes, I thought they were 'granny' shoes" (6)*
Heavy	4/13	*30.8*	*"It feels like a ton weight" (2)*
Clothing problems	4/13	*30.8*	*"I have a big wedding to go to and what will I wear? I can't look smart if I'm wearing trainers" (5)*
Limits motion	3/13	*23.1*	*"It blocks movement at the ankle, there's a lack of mobility at the joint when it is on" (9)*
Effort required	1/13	*7.7*	*"I can't be bothered to put it on… the goal posts change day by day" (7)*
Swollen leg	1/13	*7.7*	*"My leg is swelling" (10)*

Two of the three normative groups who disapproved of AFO use were only mentioned once, with the exception of "family" which was mentioned by three participants. Appendix 5.7 provides the themes identified by each individual participant in relation to normative beliefs.

Table 5-4: Key Themes for Normative Beliefs Elicited in Interviews

Normative Groups	Number of participants	%	Example
People who would approve			
Family	10/13	*76.9*	*"My children … they wanted to see me walking again" (2)*
Health Professionals	9/13	*69.2*	*"The orthotist… I think if they tell you to use it you should give it a go" (6)*
Friends	7/13	*53.8*	*"My friends…they want to see me going out more" (4)*
Other Users	1/13	*7.7*	*"My friend … is also another AFO user" (7)*
People who would disapprove			
Family	2/13	*15.4*	*"My grandkids make fun of me… have a laugh at me sometimes: 'they're not nice shoes'" (6)*
Acquaintances	1/13	*7.7*	*"I've had a couple of comments from one of the neighbours… 'Oh I wouldn't wear that'" (6)*
Exercise Professionals	1/13	*7.7*	*"The trainers at my strength and balance class" (9)*

5.4.5.3 Control Beliefs

Thirty-six control beliefs which made AFO use easier or more difficult were identified, and these were grouped into 13 factors which made AFO use more difficult and three factors which made AFO use easier (Table 5.5). The most common difficulty identified was "obstacles in the environment", identified by five (39%) participants, followed by the following three themes; "needing help to put the AFO on and off", "the AFO causing pain or discomfort", and feelings of "low mood or tiredness". These were all highlighted by four (31%) participants. Only three factors, which made AFO use easier, were identified and these were noted by two (15%) participants. All other items noted under this question were discarded because they did not address the question, were behavioural (outcome) beliefs, or were too vague (e.g. *"it (the AFO) is not causing any problems"* and *"it makes a difference"*). The three themes identified which made AFO use easier were "practice in using the AFO" identified by two (15%) participants; "having had experience of using the AFO", and "use of wedges to alter the angle/tilt of the AFO", which were both identified by only one

(8%) participant. These themes for control beliefs are detailed in Table 5.5. Appendix 5.8 lists the control beliefs expressed by individual participants, and their respective themes.

Table 5-5: Key Themes for Control Beliefs Elicited in Interviews

Themes	**Number of participants**	**%**	**Example of Theme**
Factors that make AFO use more difficult			
Obstacles in the environment (ramps, stairs, weather)	5/13	*38.5*	*" It's hard to get up inclines or steep slopes" (3)*
Need help to get the AFO on and off	4/13	*30.8*	*"I need someone (the wife) to help me with putting it on and off" (3)*
Feeling low/ tired	4/13	*30.8*	*"My mood might get in the way…some days I don't do anything" (4)*
The AFO causing pain or discomfort	4/13	*30.8*	*" If I'm wearing it all day it rubs against the back of my leg" (13)*
Being Unwell	3/ 13	*23.1*	*"If I was seriously ill I might not be able to use it" (1)*
Muscle weakness or tightness	3/13	*23.1*	*" For people with stroke they've lost a bit of power anyway" (6)*
Poor fit of AFO with shoe	3/13	*23.1*	*" The shoes need to fit" (11)*
Lack of / poor sensation	2/13	*15.4*	*"I can't feel where my foot is" (9)*
Limited/ poor hand function	2/ 13	*15.4*	*"It's not made for someone with one hand" (6)*
Feeling self-conscious	2/13	*15.4*	*"People would be looking at me" (4)*
Weight	2/13	*15.4*	*"If it wasn't so heavy…. It weighed a ton" (12)*
Bulk/ size	1/13	*7.7*	*" If they could make it less bulky"(6)*
Poor fit of AFO on leg	1/13	*7.7*	*" If the AFO fitted better" (8)*
Factors that make using an AFO easier			
Practice in using the AFO	2/13	*15.4*	*"I might need a bit of practice with it" (11)*
Having had experience in using the AFO	1/13	*7.7*	*"I've got used to putting it on. At the beginning it took 1/2 hour and I couldn't budge it- now it takes a few minutes" (7)*
Use of Wedges	1/13	*7.7*	*" The wedges for different shoes help" (7)*

5.5 Discussion

While there are a number of studies which have investigated AFO use and issues with adherence (Nakipoğlu-Yüzer et al., 2018; Phillips et al., 2011; Swinnen & Kerckhofs, 2015; Vinci & Gargiulo, 2008), no previous investigations have used a theoretical approach to understand adherence to AFOs in stroke survivors. Therefore, the aim of this study was to understand the beliefs underpinning adherence to AFOs in people with stroke, using the TPB as a theoretical framework. As the first study, which has investigated AFO use in people with stroke using a theoretical framework, this study offers a novel approach to understanding orthotic use.

In order to apply the TPB framework to understanding adherence behaviour, it is first necessary to identify the underlying beliefs of the target population. Whilst a beliefs elicitation study using a relevant population is strongly recommended (Ajzen & Fishbein, 1980) before testing the efficacy of the TPB applied to a specific behaviour and population, this stage of the research process is frequently neglected (Downs & Hausenblas, 2005b). This is of particular importance, when a new behaviour or new population is being investigated (Ajzen, 2006; Ajzen & Fishbein, 1980; Francis et al., 2004), to ensure that the beliefs measured in a follow-up TPB questionnaire will be relevant and appropriate to the population and behaviour being investigated in a TPB questionnaire study. This investigation therefore provides confidence that the beliefs being measured in the follow-up TPB study (described in Chapter 6) are relevant to the population being investigated. Therefore, the beliefs elicited in this investigation will be used to develop a TPB questionnaire, which can be used to determine the antecedents of intention to use an AFO and actual AFO use. The other value of this beliefs elicitation investigation is new knowledge, which has been obtained about cognitive foundations of decision making in relation to AFO use. The identification of these beliefs may offer potential avenues for design of interventions to improve adherence in people who have been prescribed AFOs following a stroke. This knowledge could support an evidence and theory-based intervention, which could increase adherence to AFO use, and enable stroke survivors to use their AFO optimally. The beliefs identified and their associated principal constructs (i.e. attitude, subjective norms and PBC) are discussed in more detail below.

5.5.1 Behavioural Beliefs and Attitudes

Behavioural Beliefs underpin a person's attitude towards a particular behaviour, and in this investigation, both positive and negative beliefs about AFO use were identified by participants. Participants reported more advantages compared to disadvantages of using AFOs, suggesting that they had a generally positive attitude towards AFO use. In line with previous research the following advantages were reported: increased mobility (Bowers et al., 2009b; Doğğan et al., 2011; Tyson & Rodgerson, 2009; Tyson & Thornton, 2001), supporting the position of the leg or foot (Lehmann, Condon, Price, & deLateur, 1987; Tyson et al., 2013; Tyson & Thornton, 2001), improved quality of walking (e.g. Carse et al., 2014; Mojica et al., 1988; Tyson et al., 2013), and increased confidence in walking (Bowers et al., 2009b) and falls prevention (Cakar et al., 2010).

However, this investigation has highlighted another advantage, which have not previously been identified in the literature: improvements in rehabilitation. For the participants who identified this as an advantage, being able to identify positive changes in function was an important aspect of the rehabilitation process, and could potentially be a motivational factor for continued engagement in rehabilitation (Pickrell, Bongers, & Hoven, 2016). Further investigation is required to understand the role that use of AFOs during rehabilitation may have on perceptions of improvement and engagement in rehabilitation. This investigation also provides an increased level of detail about the meaning of some of the advantages to the patient. For example, in this investigation, participants related their increased mobility to being able to participate in outdoor activities such as gardening: *"I can go about better in the garden"* (Participant 6), or socialising: *"I started to go to some clubs when I was wearing the splint … the British Legion"* (Participant 12). These activities cannot be captured in gait laboratory investigations, which measure quantitative improvements in temporal-spatial parameters, gait kinetics, and kinematics. In addition, whilst quantitative improvements in quality of gait have been documented in the literature (e.g. Carse et al., 2014; Ferreira et al., 2013; Tyson et al., 2013), this qualitative research enables the participant to describe how these biomechanical effects might feel to the individual and their impact on the patient (e.g., "*Walking is more natural*" (Participant 13)). This new knowledge is valuable because it offers insight into the advantages, which are important to individuals, and the way in which these advantages can affect their daily lives, rather than focusing solely on outcomes which are determined by clinicians or researchers. This suggests the need to consider more effective ways of measuring the value of increased mobility and quality of walking for people with stroke (i.e. what additional activities the AFO enables them to do). In addition, this knowledge may offer innovative thinking about the design of interventions, which might increase adherence, through addressing psychological factors, designed to impact of the thoughts and feelings of an individual about their treatment.

In line with previous research which has reported discomfort as a negative side effect of AFO use (Fisher & McLellan, 1989; Phillips et al., 2011), in this investigation discomfort was reported as the most common disadvantage of AFO use. Eight participants noted discomfort or pain, and six of these participants were still using their AFOs, indicating that some users will still use an AFO even though they report discomfort or pain. This highlights that there are several interacting factors, which may influence the decision to use an AFO, and whilst discomfort or pain might be considered a rational reason for not using the AFO, this may not be the most important factor to the patient. Pain or discomfort should not be considered a normal part of the experience of AFO use, and patients must be encouraged to report such concerns to enable them to be resolved, and, therefore, the high number of participants (62%) experiencing pain or discomfort should be of concern to the orthotic service.

The disadvantage of "problems with footwear style" was highlighted by five participants, and whilst differences in gender were not specifically analysed, this disadvantage was exclusively reported by females. Problems with footwear style have not previously been reported in the literature as an issue in relation to AFO use in people with stroke; however, problems with footwear style have been highlighted in the literature for female orthopaedic footwear users (van Netten, Dijkstra, Geertzen, & Postema, 2012; Williams et al., 2007; Williams, Nester, Ravey, Kottink, & Klapsing, 2010). Footwear is an integral component of the success of an AFO (Malas, 2011), and there is the requirement for footwear with increased width and depth to accommodate the increased volume which the AFO adds to the foot and ankle. This finding suggests the need for orthotists to consider the importance of footwear style and choice for female clients with stroke, and manage expectations of this patient group appropriately. Additionally, a pragmatic approach by the orthotist may enable a suitable compromise to be reached, with discussion around a wearing schedule that is acceptable to both the orthotist and user.

5.5.2 Normative Beliefs and Subjective Norms

The TPB states that normative referents (i.e. people who approve or disapprove), and a person's underlying beliefs about what significant others think of that behaviour, will subsequently influence intention and behaviour. In line with TPB theory, this investigation identified several normative groups that participants perceived would hold positive or negative opinions regarding AFO use, which would lead to those groups being perceived as approving or disapproving of AFO use. Overall, a much higher number of beliefs were elicited from participants about people who would approve (n=26) of AFO use compared to people who would disapprove of AFO use (n=7). No previous research has identified normative referents in relation to orthotic use. This therefore offers new knowledge about potential normative influences on a participant's use of AFOs, in a behaviour, which has not previously been investigated, using the TPB. It also provides information about the underlying normative beliefs, and may potentially provide opportunities to increase adherence to AFO use by design of interventions, which target these beliefs. This may also involve interventions which address the supporting role played by significant others to assist patients in AFO use.

The greater number of referents who approved of AFO use, compared with those who disapproved of AFO use, is an encouraging finding, and suggests that in general, normative beliefs and subjective norms may be positive influences on intention to use an AFO and actual AFO use. Three main groups of people who approved of AFO use were identified: family, health professionals, and friends. The number of participants mentioning health professionals (n=9) was almost the same as family (n=10). This suggests that both health professionals and family members may have an equally important role to play in actively encouraging use of AFOs. The most commonly reported family members who approved of AFO use were children (n=7), followed by a spouse (n= 6) and then siblings (n=2). Further investigation is needed to identify if health professional or family member approval is specifically related to intention or the behaviour of AFO use.

Participants reported a range of health professionals that approved of AFO use: physiotherapists (n=6), orthotists (n=3); occupational therapists (n=2); and nurses (n=1). The small number of participants who identified orthotists as people who would approve of AFO use is lower than would be expected, given that all participants were recruited via the orthotic service. There are just over 1,000 prosthetist/ orthotists registered with the Health and Care Professions Council (HCPC, 2017), and orthotics is therefore a relatively small and lesser known allied health profession. However, the low level of recognition of orthotists by the participants is disappointing, and warrants further investigation to identify the reasons for this.

Participants who noted their family would disapprove, described teasing from family members e.g. "*My grandkids made fun of me some times… saying they're not nice shoes" (Participant 6).* These types of comments can be a challenging issue for individuals to contend with, and highlight the stigma faced by people who use assistive technologies (Bichard, Coleman, & Langdon, 2007). Despite legislation to prevent discrimination towards people with disabilities (e.g. Disability Discrimination Act 2005, Equality Act 2010), this comment demonstrates that negative attitudes towards disability continue to exist. This is in line with findings of a survey by Aiden and McCarthy (2014), who explored attitudes towards people with disabilities, and reported that more than 40% of disabled people reported a lack of understanding about their individual needs by others. A range of interventions at different levels are required to change negative attitudes towards disability: at the personal level (e.g. disability awareness training); an organisational level (e.g. access to education, employment and health for people with disabilities); and at government level (e.g. the legislative framework and legal protection against discrimination) (Fisher & Purcal, 2017). In addition, recognition of the purpose and benefits of assistive devices to manage mobility disability is required across the whole of society.

An unexpected normative group who noted disapproval were exercise professionals. This normative group has not been identified previously as being discouraging of orthotic use. This professional group are individuals working in gyms who have a qualification in sport and exercise. Physical activity following stroke have been shown to improve aerobic fitness and walking endurance (Brazzelli, Saunders, Greig, & Mead, 2011). Therefore fitness programmes which encourage exercise post stroke are recommended (Best et al., 2010; Scottish Intercollegiate Guidelines Network, 2010). However, sport and exercise professionals may consider that an AFO is inhibiting exercise for a person attending an exercise class following stroke (Best et al., 2010), and may therefore recommend that a patient who is wearing an AFO does not use the AFO. This is despite the evidence highlighted previously (see Chapter 1) supporting use of AFOs following stroke. Exercise professionals do not have specific training in relation to orthoses, and should therefore direct the user back to the orthotic service for a review, if the orthosis is getting in the way of exercising or causing discomfort during exercise (Best et al., 2010). Consequently, education for exercise professionals about the role of AFOs in people with stroke may be another useful intervention.

5.5.3 Control Beliefs and Perceived Behavioural Control

According to the TPB, factors that make AFO use easier (enablers) or more difficult (barriers) in people with stroke (i.e. control beliefs) are considered to underpin the perceived ease or difficulty of using an AFO. Participants identified more barriers to AFO use, with 13 themes being identified, compared to the identification of only three factors (themes), which made AFO use easier. The far fewer facilitating factors identified by participants suggests that perceived control of AFO use may be low in people with stroke. Further research is required to corroborate this.

'Obstacles in the environment' was identified as the most common factor that made AFO use more difficult. This was identified by five out of 13 participants (38.5%). Examples of obstacles in the environment highlighted by participants were steps, slopes, kerbs, and weather conditions e.g. ice on pavements. Again, because the AFO literature focuses on measuring objective parameters of walking in gait labs, these day-to-day challenges encountered in the real world are not commonly reported in the literature. The next most commonly reported barrier was difficultly donning and doffing the AFO, reported by four out of 13 participants (31%). This finding is consistent with the findings of others (Bulley et al., 2011; O'Connor et al., 2016; Phillips et al., 2011), and suggests that difficulties with donning and doffing an AFO can be a major barrier to AFO use in people with stroke. However, further investigation of the relative contribution of each control belief to PBC and the intention to use an AFO is needed, prior to the design of a possible intervention.

Some of the negative control beliefs reported were related to the stroke, such as muscle weakness or spasticity, poor hand function, swelling and lack of sensation. Many of these negative effects can improve within the initial six months following stroke (Jørgensen et al., 1995), and may continue to improve up until two years post stroke. This highlights a challenging paradox: intervention with an AFO offers improved mobility and balance in the early stages of rehabilitation (Carse et al., 2014; Nikamp et al., 2017), yet the factors that make AFO use more difficult are likely to be at their greatest in the early stages of recovery.

Low mood or feeling tired was considered a barrier to AFO use: "*my mood might get in the way… there are some days I don't want to do anything" (Participant 4).* This is an important finding for a number of reasons. Alongside the findings of the first study, detailed in Chapter 3, this highlights an important relationship between mood and AFO use, which has not previously been investigated in the literature. Additionally, it highlights the importance of motivational factors in being a successful AFO user, and suggests the need to consider the psychological well-being of a person with stroke, as part of the assessment process in rehabilitation. This finding supports the need for psychological provision for people with stroke, particularly if they already experience issues with anxiety or depression (NHS Improvement, 2011) .

It is worthy of note that emotional issues that might influence AFO use were elicited from participants without any specific prompting *(e.g., "I felt sorry for myself" (Participant 11)).* One of the criticisms of the TPB as a model of rational behaviour is that it only considers rational and logical cognitive processes (Sniehotta et al., 2014), and does not consider the emotional aspects of decision making about one's behaviour. However, Ajzen (2011, 2014), has argued that this is a misrepresentation of the theory; affect and emotions are encompassed in the TPB, because they influence underlying attitudinal, normative and control beliefs. Additionally, affective states may also assist in selecting the beliefs that are salient in a particular situation. This elicitation study thus supports Ajzen's argument that affect and emotions are encompassed within the underlying beliefs which are part of the TPB, and, therefore, acknowledges that emotions may also be potential determinants of behaviour.

Far fewer enabling factors relating to AFO use were elicited from participants. This suggests that people prescribed AFOs struggle to identify aspects of the device or orthotic service which can facilitate its' use. As this was the last question of the interview, participant fatigue was considered as a possible cause of this finding. However, as the majority of participants continued to talk with the interviewer after the interview, about a range of different topics, participant fatigue was not considered as the underlying reason for the low number of enabling factors identified. Practice in using the AFO was identified as an enabling factor, highlighted by two participants. Whilst AFOs should be prescribed in combination with physiotherapy as part of a multidisciplinary approach (Bowers et al., 2009b), little is known about provision of supervised practice sessions for new patients with stroke who have been provided with AFOs. It would be useful to identify the amount of supervised practice required, and if supervised or peer support might increase user uptake of AFOs. Use of wedges, which increase the forward inclination of the AFO, was also reported by one participant as a factor that can make AFO use easier and suggests that the AFO has been fine tuned for this particular patient, which made use of the AFO easier. Fine tuning of AFOs has been reported to provide significant improvements in outcomes, such as increased walking speed, step length, and cadence (Carse et al., 2014) or a reduction in knee pain (Jagadamma et al., 2010). Fine-tuning may therefore be an important factor in facilitating AFO use, and further research is warranted to identify if other orthotic users consider using of wedges to be a facilitating factor in AFO use.

5.5.4 Limitations and Strengths

This study is the first study to use a theoretical framework to investigate beliefs affecting use of AFOs following stroke, using an elicitation study. However, there were a number of limitations. The sample size of 13 was the minimum recommended number of participants for a TPB elicitation study (Francis et al., 2010), and many published elicitation studies have used a greater number of participants (Downs & Hausenblas, 2005a). However, guidelines in relation to data saturation (Francis et al., 2010) were followed explicitly, with the initial sample size and stopping criterion being specified a priori, and no new themes emerged for the final three participants. Additionally, it might be considered as unethical to continue to recruit participants to a research project when the research questions have already been answered with a fewer number of participants.

In all TPB elicitation studies, the aim is to recruit a representative sample of the complete population. In this study, purposive sampling was used in an attempt to identify a representative sample. However, it was not possible to recruit any participant younger than the age of 50, who was able to participate within the period for data collection. Additionally, in this study, all participants were Caucasian. Whilst no investigations have previously investigated differences in adherence to orthoses in relation to culture or ethnicity, the broader health adherence literature (Acharya, 2016; Nayak, Paxton, Holmes, Thanh Nguyen, & Elting, 2015; Sabaté, 2003) suggests that there may be differences in adherence rates and motivations to adhere to health behaviours across different ethnic and cultural groups. Therefore, the findings of this study may not be generalizable across different ethnic and cultural backgrounds. Despite these omissions, four out of the 13 participants were under 65 and the wide range of ages from aged 50-80 was reasonably representative of the general population. An even gender split as well as the inclusion of participants who did not use AFOs also provided an acceptable cross-section of the population from which beliefs could be elicited.

It is important to acknowledge that this research is qualitative is nature and therefore aims to understand the thought processes of individuals, and their subjective opinions of using AFOs, rather than obtaining knowledge about a fixed and measurable reality. However, achievement of a representative sample in the elicitation study, and certainty that data saturation was obtained, provides some reassurance that these beliefs are reflective of the wider population.

5.6 Conclusion

As the first study to investigate beliefs affecting AFO use in stroke, this research has enabled the identification of beliefs that form the cognitive foundations of decision making about use of AFOs in people with stroke. This information therefore provides a sound basis for further research. Specifically, this knowledge will be used in the design of a questionnaire used to test the efficacy of the TPB as a model for understanding AFO use in people with stroke. Chapter 6 details the design of this questionnaire and the testing of the TPB model on a sample of participants who had been prescribed an AFO following a stroke. In addition, this study offers some avenues for possible interventions, which might increase adherence to use of AFOs in people with stroke. Chapter 6 will also allow exploration of the specific beliefs which are associated with direct TPB constructs, and therefore guide the development of a future intervention to increase orthotic use.

Key Points from Chapter 5

1. This study is the first study to identify beliefs underpinning AFO use in people with stroke using a psychological model of behaviour. Thirteen participants recruited from NHS Lanarkshire, who had been prescribed an AFO following a stroke, took part in a beliefs elicitation investigation, using the TPB as a guiding framework. This study enabled elicitation of attitudinal, normative and control beliefs, in line with the TPB model.
2. Participants had generally positive attitudes to using AFOs, with six advantages and eight disadvantages of AFO use identified. The most commonly noted advantages were "increased mobility", and "supports the position of the leg/foot" both reported by nine (69%) participants. The most commonly noted disadvantages were "discomfort", highlighted by eight (62%) participants
3. There was a perceived high normative pressure from significant others to use AFOs. The most commonly cited normative group who approved of AFO use were "family", identified by 10 (77%) participants; followed by "health professionals", identified by nine (69%) participants. "Family" was the most common normative group who disapproved of AFO use, but this was only described by two (15%) participants.
4. Thirteen barriers to AFO use were identified, compared to only three enabling factors. The most common difficulty identified was "obstacles in the environment", identified by five (39%) participants, followed by the following three themes; "needing help to put the AFO on and off", "the AFO causing pain or discomfort", and feelings of "low mood or tiredness". These were all highlighted by four (31%) participants. The most common enabling factor was practice in using the AFO, detailed by two (15%) participants.
5. This value of a beliefs elicitation investigation is in providing a sound theoretical grounding for a TPB investigation which tests the efficacy of the model in explaining adherence to AFO use in stroke. Additionally, this beliefs elicitation investigation offers some insight into potential targets of intervention, which could be applied to increase adherence to AFOs in people with stroke.

Next Steps

The advantages, disadvantages, normative groups, and the factors making AFO use easier and more difficult, obtained in this beliefs elicitation study will be used to inform the design of the TPB questionnaire, which can then be used to test the efficacy of the TPB model in understanding AFO use in people with stroke.

The correlations between the beliefs identified, and direct attitude, subjective norm and PBC will be investigated to understand why people with stroke hold specific attitudes, subjective norms and perceptions of control about AFO use in stroke.

An exploratory analysis of correlations between belief-based measures and intention and behaviour will offer insight into which beliefs might be targeted in a future intervention.

Chapter 6 Use of the TPB to Predict Adherence to Use of AFOs as Recommended in People with Stroke

6.1 Introduction to Chapter

This chapter details the final study of this PhD, which investigates the efficacy of the TPB as a model for explaining adherence to AFOs in people with stroke. Chapters 2 and 3 highlighted the challenge of ensuring adherence to AFOs, and the need to identify potentially modifiable factors, which can predict adherence to AFO use. Chapter 4 then identified that the TPB was an appropriate model to explain adherence to health behaviours in conditions for which orthoses might be utilised. It also demonstrated that the TPB is applicable across a range of different health conditions, and in investigating different health adherence behaviours. Chapter 5, which detailed a TPB beliefs elicitation study, laid the ground work for the present investigation, and described the behavioural, normative and control beliefs underpinning adherence to use of AFOs in people with stroke. In this chapter, these beliefs are used to assist in the formulation of a TPB questionnaire, which can be used to test the efficacy of the TPB model for this population. Therefore, the current investigation is a prospective predictive study which aims to explain adherence to use of AFOs in people who have had a stroke, using the TPB as a theoretical explanatory model of behaviour.

6.2 Background

There are over 1.2 million stroke survivors in the UK, and more than 100,000 strokes occur each year (Stroke Association, 2018b). In the UK, Scotland has the greatest percentage of the population (2.2%) who have had a stroke (Stroke Association, 2018b). Approximately 20% of women and 17% of men will have a stroke in their lifetime (Seshadri & Wolf, 2007). As highlighted in Section 5.2.1.1., stroke can be considered as the most common cause of complex disability in the UK (Adamson, Beswick, & Ebrahim, 2004). Stroke can have a major impact on the individual and their families, and is often an overwhelming and disruptive life event (Lutz, Young, Cox, Martz, & Creasy, 2011). Stroke can cause a range of physical impairments including weakness in the lower limb, and increased muscle tone, which can result in disturbances in normal gait.

Importantly, these impairments can be effectively managed with an AFO (Bowers et al., 2009b). AFOs are known to improve mobility, balance, gait biomechanics, and energy cost of walking following stroke (de Wit, Buurke, Nijlant, Ijzerman, & Hermens, 2004; Doğğan et al., 2011; Pavlik, 2008; Tyson & Kent, 2013; Tyson et al., 2013). Stroke was highlighted as being the most common reason for being prescribed an AFO in Section 3.5.4. In addition, given the high incidence of stroke in Scotland (Stroke Association, 2018b), and the clinical priority given to improving treatment and care of stroke (Scottish Government, 2014a), stroke was identified as the most relevant clinical population to focus on in this thesis.

Little is known about use of AFOs after they have been prescribed. Only two previous investigations have reported on adherence/ use of AFOs following stroke. Nakipoğlu-Yüzer et al. (2018) reported that 59.4% of participants in their study used their AFO every day. However, this adherence figure gives little indication of the extent of use each day. Bowers et al. (2009b) found a 70% adherence rate in people with stroke. However, in their investigation, adherence was not clearly defined, and the background survey which informed this best practice statement was not published. The investigation described in Chapter 3 highlighted an overall adherence rate of 56% across multiple conditions, and this low rate was also reflected in a sub-group analysis of the stroke population in the overall sample. Non-adherence to AFOs is an inefficient use of resources by the NHS, and the study described in Chapter 3 demonstrated that non-adherence to use of AFOs as recommended is also associated with poorer outcomes in both physical and mental health. Understanding factors affecting adherence to use of AFOs in people with stroke is essential to ensuring optimal use of AFOs in this patient group, and is therefore the focus of this chapter.

6.3 Theoretical Approach

As detailed in Chapter 3, previous attempts at explaining adherence to orthoses have not utilised a theoretical perspective (Basford & Johnson, 2002; Philipsen et al., 1999; Swinnen et al., 2017a; Vinci & Gargiulo, 2008). The lack of theoretical investigations to understand adherence to orthoses has been unfortunate, as opportunities to design theory-based interventions, which could potentially improve a person's physical and mental well-being, have not been exploited. The TPB (Ajzen, 1991) is one of the most widely used behavioural theories, and has been utilised to explain a wide range of social and health behaviours. Furthermore, the TPB has generally been able to explain more variance in behaviour than other theoretical models (Armitage & Conner, 2001; Conner & Armitage, 1998; Taylor et al., 2006), making it potentially the most relevant psychological theory for understanding adherence to use of AFOs in stroke. In Chapter 4, a meta-analysis demonstrated that the TPB was a useful model in explaining adherence to health behaviours in conditions for which orthoses might be prescribed. This meta-analysis found that the TPB accounted for 14% of the variance in behaviour (a moderate to large sized effect in the social sciences), and 28% of the variance in intention (a large sized effect (Cohen, 1992)) to adhere to health behaviours in conditions for which orthoses might be prescribed. This suggests that the TPB might be a suitable model to explain adherence behaviours in conditions for which orthoses are prescribed.

6.3.1 The TPB

To recap, the TPB (Ajzen, 1991), seen in Figure 6.1, states that the likelihood of a person engaging in a behaviour, is determined by the individual's intention to perform that behaviour. Intention to perform a behaviour is influenced by attitude (A) towards the behaviour, the subjective norms (SN) and the individual's perceived control (PBC) over the behaviour. In addition, the model posits that PBC also directly predicts behaviour. Therefore, in applying the TPB to adherence to AFO use in people with stroke, a positive attitude towards AFO use, perceived support from significant others for using an AFO, and a perceived ease of using the AFO by the individual, may lead to a positive intention to use an AFO, and, in turn, positively impact on adherence to the AFO in people with stroke.

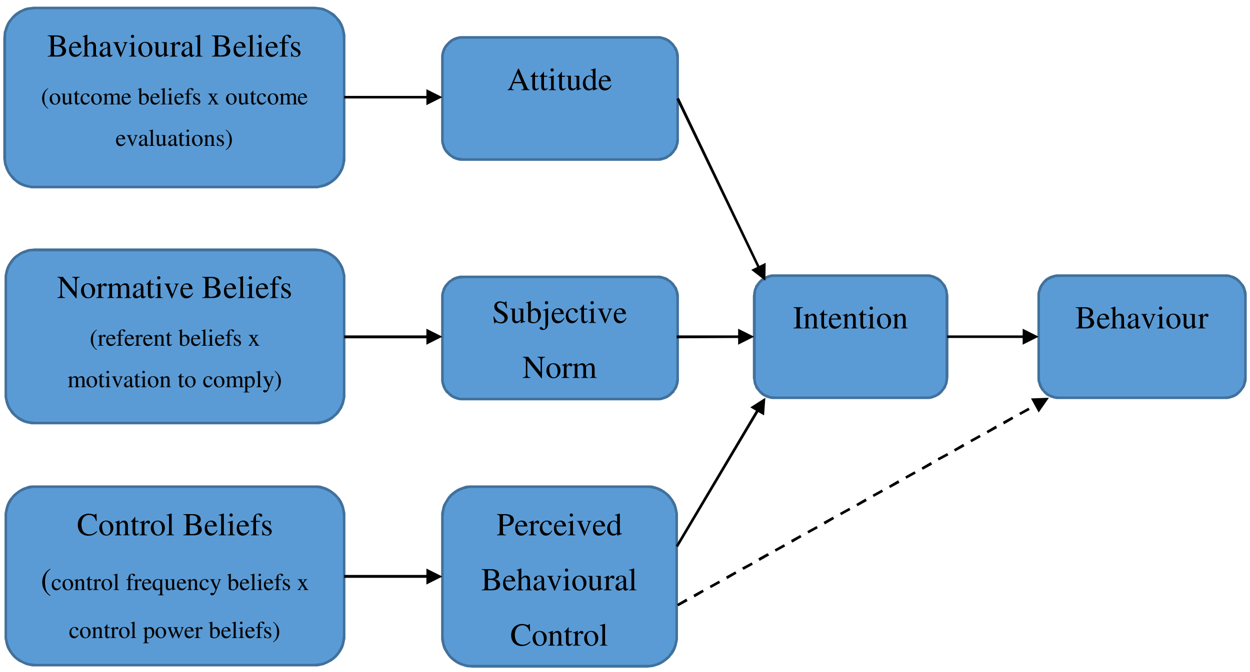

Figure 6-1: The Theory of Planned Behaviour (Ajzen, 1991)

When using the TPB to explain or predict behaviour, a prospective study design is recommended (Ajzen, 2011; McEachan et al., 2011) to reflect the theorised causal path between intention and adherence (i.e. behaviour). In other words, if behaviour is measured at the same time as other TPB constructs, in a cross-sectional investigation, this provides a measure of past or current behaviour, rather than future behaviour, and therefore does not replicate the causal associations of the model (McEachan et al., 2011). Thus, some temporal space should exist between the measurement of intention and behaviour. Additionally, Weinstein (2007) notes that that the behaviour itself can influence perceptions (e.g., beliefs, attitudes, self-efficacy). Therefore, if behaviour is measured at the same time point as other TPB variables, compared to prospectively, a cross-sectional investigation tends to overestimate effect sizes. Indeed, a number of TPB meta-analyses (Manning, 2009; Randall & Wolff, 1994; Topa & Moriano, 2010) have shown that the study design (cross-sectional or prospective) is a moderating factor in the intention-behaviour (I-B) relationship, with cross-sectional investigations displaying an inflated I-B relationship. Therefore, this current investigation will use a prospective design.

In considering the appropriate length of time between intention and behaviour, it is recognised that when participants are initially given an AFO they are advised to increase the number of hours the device is worn gradually, over a period of time, usually a few weeks. This will allow them to build up tolerance to wearing the device and also to reduce the likelihood of skin problems or excess pressure (Dorset County Hospital NHS Foundation Trust, 2015). Therefore, it may take up to one month for any new users to be using their AFO optimally, as prescribed. Consequently, this needs to be considered when deciding the appropriate period between measurement of intention and behaviour. However, at the same time, it is also necessary to take into account, if there is an excessive length of time between the measurement of intention and behaviour, other intervening events may result in changes to intention or PBC, thereby reducing the accuracy of prediction of behaviour (Ajzen, 1991). Indeed, McEachan et al. (2016) found that the length of time between measurement of intention and behaviour affected the strength of correlations between intentions and behaviour, with longer time intervals between measurement demonstrating lower correlations. Therefore, in the current investigation, one month is considered to be the optimal time gap between measurement of intention and behaviour, to ensure that all participants in the study should be using their AFO fully as recommended to enable optimal use, and minimise the likelihood of other factors, which could change intentions or PBC.

6.3.2 Belief-Based Measures

A, SN and PBC can be measured directly, by asking the participant about their overall perceptions of A, SN and PBC in relation to a behaviour. They can also be measured indirectly by questioning participants about the specific beliefs and outcome evaluations of those beliefs (Francis et al., 2004), and these are referred to as indirect (or belief-based) measures for A, SN and PBC. Indirect measures can be obtained from an elicitation study, conducted using participants from the same population, which the main TPB investigation aims to investigate (Ajzen, 2006), and the beliefs elicited are then used in the TPB questionnaire. As both direct and indirect measures are considered to measure the same construct, their scores are likely to be positively correlated (Francis et al., 2004).

Usually, when indirect measures of attitude are measured in a TPB questionnaire, the questionnaire asks the participant to rate the likelihood that a particular belief is true (e.g., "using an AFO as prescribed will enable safer walking"), and also to evaluate the desirability or undesirability of that outcome (e.g., "being able to walk safely is desirable or undesirable"). The belief score is then multiplied by the outcome evaluation and this is referred to as the expectancy-value model (Fishbein & Ajzen, 1975). Likewise, in order to assess subjective norms, a participant is asked to rate the normative belief strength (e.g., "How much would your family approve or disapprove of you using your AFO as recommended?") and the motivation to comply with that belief (e.g., "I am likely / unlikely to do what my family want me to do"). Finally, indirect measures of PBC are typically assessed by asking the participant to evaluate the control belief strength (e.g., "when using my AFO as recommended, I will come across obstacles in the environment"), and the control belief power (e.g., "obstacles in the environment will make using my AFO easier/ more difficult"). Inclusion of belief-based antecedents of A, SN and PBC in a TPB questionnaire is of value because they can provide knowledge in relation to understanding and explaining behaviour, and assist in identifying potential targets for behaviour change interventions (Ajzen, 2006; Downs & Hausenblas, 2005a).

6.3.3 Elicitation Study

Ajzen (1991) has recommended that prior to conducting a TPB study, the underlying beliefs should be elicited. This is of particular importance when applying the TPB to a new behaviour or a new population (Ajzen, 2006). The beliefs should be elicited from the same population for whom the questionnaire is intended, and these beliefs should be used to generate the items of the questionnaire in order to measure the TPB constructs. Chapter 5 detailed a beliefs elicitation study conducted on a representative sample of 13 participants who had been prescribed an AFO following a stroke. This ensured there was correspondence between the beliefs being measured in the elicitation investigation and the current prospective TPB questionnaire study. The elicitation study highlighted the behavioural, normative and control beliefs of a representative sample of the population under investigation, and, therefore, provides support to applying the TPB to understanding AFO use in people with stroke. Although the elicitation investigation offered some insights into the cognitive processes, which may influence intentions and behaviour, it does not provide information about which beliefs are associated with intentions and/or behaviour, and, therefore, which beliefs might provide specific targets in the design of an intervention designed to increase adherence to use of AFOs. Therefore, inclusion of these beliefs within the TPB questionnaire will allow the identification of beliefs, which are most strongly associated with intention and behaviour for this population.

6.4 Aims

There were three primary aims of this investigation. Initially, this investigation aimed to measure adherence to use of AFOs as recommended in people who had been prescribed an AFO following a stroke. Secondly, this investigation aimed to examine the utility of the Theory of Planned Behaviour (TPB) to predict intention and adherence to AFO use in people with stroke. In line with the tenets of the TPB, attitude, subjective norm and PBC were measured at Time 1(T1) and behaviour was measured one month later, at Time 2 (T2). The third aim of this investigation was to identify if the indirect belief-based measures were associated with their related, direct constructs of attitude, subjective norms, and perceptions of control.

The following hypotheses were tested:

1. Attitudes, subjective norms and PBC measured at T1 will predict intentions to use an AFO as recommended at T1
2. Intentions and PBC measured at T1 will predict actual use of an AFO as recommended, measured at T2
3. Behavioural beliefs will be significantly associated with attitudes; normative beliefs will be significantly associated with subjective norms; and control beliefs will be significantly associated with PBC.

The fourth and final aim of this investigation is to explore the individual beliefs associated with intention and behaviour. Knowledge of the specific individual beliefs which are related to intention and behaviour, will provide an understanding of the important beliefs that underpin intention to use an AFO, and actual use of an AFO, and consequently may enable these specific beliefs to be targeted in a future intervention to increase adherence to AFOs. Therefore, identification of the key beliefs, which influence a patient's intention and decision making to use an AFO, provides a theoretically informed evidence base, to design interventions, which aim to increase adherence to AFOs. As no previous investigations have explored relationships between beliefs about using AFOs, analysis of the associations between the specific beliefs, and intentions and behaviour was considered exploratory, and no specific hypotheses were set.

6.5 Method

6.5.1 Participants

Participants were 49 people[22] who had been prescribed an AFO because of a stroke, between 2014 and 2017, by NHS Lanarkshire. The same inclusion criteria were employed for the current investigation as the earlier elicitation investigation, described in Section 5.4.1. All individuals in Lanarkshire who had been prescribed an AFO following a stroke in the preceding three years were invited to participate. Three years of data were considered to provide an adequate sample size, given that, on average, two new orthotic referrals per week were seen for an AFO following stroke in Lanarkshire (R. Rooney, personal communication, March 2014), giving an expected sample size of 300. In order to identify participants meeting the inclusion criteria, data from two sources were combined: Participants provided with an AFO from NHS Lanarkshire were cross-referenced with the Lanarkshire Stroke Database. Participants appearing in both sources were identified as meeting the inclusion criteria. The demographic and clinical characteristics of the sample are seen in Table 6.1 below.

The characteristics of the sample were broadly comparable with participants recruited in the earlier elicitation study. The most notable difference between the samples was that the elicitation study did not did include younger stroke survivors (<50yrs). However, an overall similar mean age of participants in both investigations, and similar beliefs elicited across

[22] A power analysis showed that a minimum of 85 participants would be required to provide sufficient power (>0.8) to detect a medium effect size (Cohen, 1988) in a multiple regression equation with four TPB variables. It is therefore recognised that this study is underpowered, and this is given due consideration in the discussion.

different age ranges in the elicitation investigation, provided some reassurance that beliefs elicited would not have been different in a younger age group.

Table 6-1: Demographic and Clinical Characteristics of Sample (n=49)

Characteristics		N (%)	Mean (SD)	Range
Age			62.8 yrs. (13.9)	22-86yrs
Gender	Female	26 (53)		
	Male	23 (47)		
Marital Status	Married	29 (61.7)		
	Widowed	7 (14.9)		
	Single	5 (10.6)		
	Divorced	4 (8.5)		
	Living with partner	2 (4.3)		
Length of time since stroke			51.2 mths. (46.5)	1-230 mths.
Length of time since AFO prescribed			29.4 mths. (32.1)	1-122 mths.
AFO use (as recommended)*	Use as recommended	24 (52.2)		
	Did not use as recommended	14 (30.4)		
	Not aware of recommendations for use	8 (17.4)		
AFO use (no. of hours/wk)			72.2 hrs (35.4)	0-168 hrs
AFO (which side?)	Right	21 (45)		
	Left	26 (55)		

*Three participants did not report the appropriate category for this question.

6.5.2 Design

A prospective questionnaire design was used with the TPB constructs (attitudes, subjective norms, perceptions of control, underlying behavioural, normative and control beliefs, and intentions) measured at T1, and behaviour measured at T2, one month later. All respondents at T1, were sent a second questionnaire, one month later. Of the 49 T1 respondents, 42 (86%) responded at T2[23].

[23] A series of one-way between subjects ANOVAs and chi-squared tests was conducted to compare respondents and non-respondents' demographic and clinical characteristics and TPB variables (A, SN, PBC, and I), and no significant differences were found.

6.5.3 Procedure

A questionnaire pack was sent to a consecutive sample of 160 potential participants in March 2017, containing the following: a questionnaire (see Appendix 6.1) with an attached consent form, a participant information sheet (seen in Appendix 6.2), and a return addressed, postage paid envelope. Questionnaires were sent to 160 participants meeting the inclusion criteria, and of these, participants (31%) responded at T1. The response rates are consistent with previous studies with patient groups using a postal survey methodology (Gontkovsky et al., 2007; Hatcher et al., 2009; Sackett, Strauss, Richardson, Roseberg, & Haynes, 2000).

Participants filled in the questionnaires in their own homes, and assistance was allowed from carers or family members, although participants were reminded that answers should be their own. Participants were asked to return the questionnaire to the research team at the University of Strathclyde using the addressed envelope. The information sheet stated that the study was investigating how people with stroke use AFOs and the factors affecting use of AFOs. It also stated that participation would involve the completion of two questionnaires, one month apart, that participation was voluntary, that participants could withdraw from the study at any time, and that all information would be treated confidentially. Participants were encouraged to be honest in their responses to the questions. If no response was obtained within one month, another questionnaire was sent to the participant with a reminder letter. If no response was obtained within a month of the reminder, participants were contacted by phone to inquire if assistance might be required in filling the questionnaire.

Ethical approval was obtained from Newcastle and North Tyneside NRES Committee (REC reference: 14NE1002), (IRAS project ID: 146140), and was endorsed by the University of Strathclyde Ethics Committee (UEC14/24). The favourable opinion of the NRES committee and acknowledgement of having met conditions can be seen in Appendix 5.1.

6.5.4 Questionnaire Development

A questionnaire was constructed, which included both direct and indirect (belief-based) measures, following the guidelines of Ajzen (2006) and Francis et al. (2004). Indirect measures were obtained from the beliefs identified in the earlier elicitation investigation, detailed in Chapter 5. The beliefs were reviewed and refined in order to ensure the beliefs worked well within the questionnaire context, and were reflective of the theoretical underpinnings of the TPB. Two other researchers with experience in using the TPB (K. Russell and S.A. Rasmussen) reviewed the beliefs along with the main author, and via a process of discussion and reflection, consensus was reached regarding the wording of the beliefs. For example, the attitudinal beliefs: “helps me to be more confident” and “improves quality of walking”, were rephrased to “increases my confidence” and “makes my walking look more natural”. For normative beliefs, “acquaintances” was removed and replaced with “other, please specify”, allowing individuals to state any other referent groups to account for the possibility that such groups may not have been identified in the beliefs elicitation study. The control belief: “difficult to put on and off” was changed to “need help to put on and take off” as this was considered to provide more detail to the participant in understanding the control belief.

The resulting questionnaire was 13 pages long, and, on reflection, was felt to be too long for this specific participant group, many of whom were expected to be elderly and have co-morbidities, and may find it difficult to concentrate for a long period of time. Given the low response rate with a similar population in the first study, detailed in Chapter 3, there was also a concern that a longer questionnaire would provide a lower response rate in a smaller population, resulting in an under-powered study. Therefore, ways in which the length of the questionnaire could be reduced without damaging the validity of the output, were considered. It was not considered appropriate to compromise the accessibility of the questionnaire design by e.g. reducing font size. Therefore, other aspects of the questionnaire were reviewed to identify any unnecessary questions that might be eliminated.

Belief measures are traditionally scored by multiplication of belief strength (e.g., outcome beliefs, referent beliefs and control frequency beliefs) and evaluative measures (e.g., outcome evaluations, motivation to comply and control power beliefs), and this is termed the expectancy-value model (Fishbein & Ajzen, 1975). However, only when there is a wide variation in both belief strength and outcome evaluation can the multiplicative composite make a significant difference over and above the effects of the two separate measures (Ajzen & Fishbein, 2008). Therefore, removal of one aspect of the expectancy-value equation in the questionnaire, was considered a relevant and appropriate way of reducing the length of the questionnaire. Behavioural belief strengths, normative belief strengths and control power beliefs were retained in the questionnaire to reflect the measures which were expected to demonstrate the most variance, in line with recommendations of Fishbein and Ajzen (2010) and O'Sullivan, McGee, and Keegan (2008).

Following removal of these items, the final questionnaire was then reviewed by two experts in social psychology with experience in designing TPB questionnaires. The final questionnaire was eight pages long, with clear instructions and large font size in order to meet accessibility criteria. This was considered the most effective design in ensuring a reasonable response rate, whilst maintaining the necessary recommended measures.

6.5.5 Measures

6.5.5.1 Demographic and Clinical Measures

The questionnaire contained measures relating to the following demographic details: age, gender, and marital status. Participants were asked to detail length of time since stroke, perceived current health status, and perceived seriousness of stroke. The questionnaire also included the following questions in relation to the AFO: "what leg is your AFO made for?"; "when did you get your current AFO?", "do you use your AFO?", "how long have you used your AFO for in last month (hrs/ day and days/week)", and, "are you satisfied with your AFO?"

6.5.5.2 TPB Variables

TPB items included both direct measures (attitude, subjective norm and PBC) and indirect measures (behavioural, normative and attitudinal beliefs). Items were pseudo-randomised to minimise consistency biases (e.g. Ajzen, 2006; Podsakoff, MacKenzie, Lee, & Podsakoff, 2003). The response scales were reversed on some questions to prevent response set biases (e.g., Podsakoff et al., 2003). The direct and indirect measures of attitude, subjective norm and PBC were measured on a seven-point bipolar scale.

Attitude and Behavioural Beliefs

Attitude: A direct measure of attitude was determined by six items, which included both instrumental and affective aspects of attitude. The stem for this question was "For me, using my AFO in the next month would be…." with responses being: pleasant/ unpleasant, safe/ unsafe, easy/ difficult, harmful/ beneficial, comfortable/ uncomfortable, and good/ bad. Internal consistency of the attitude scale was assessed by calculating Cronbach's alpha coefficient (α=.57). In interpreting α, a measure of >.7 is considered to provide acceptable internal consistency (Nunnaly, 1978). Therefore, the attitude scale was considered to have a low level of internal consistency, and one item was removed (comfortable/ uncomfortable).

The mean of the remaining five attitude items[24] was used as the final measure of attitude in the data analysis. The Cronbach's alpha for these five items was α=.91 indicating high internal reliability.

Attitudinal beliefs: To measure attitudinal beliefs, participants were asked about the likelihood that using the AFO as recommended in the following month would have the following outcomes: increase my mobility, make walking look more natural, improve balance/ prevent falls, increase my confidence, support my foot or leg, help me to improve during rehab, make my leg feel heavy, make my leg swell, cause me pain or discomfort, make it difficult to find footwear that fits, make it difficult to use footwear that looks good or matches my clothing, limits my choice of clothing, limits the motion at my joints, and requires a lot of effort. Attitudinal belief measures were recoded prior to analysis to ensure that higher scores reflected positive evaluations of AFO use. The resulting beliefs were summed[25] to create an overall measure of indirect attitude (Ajzen, 2006).

Subjective Norm and Normative Beliefs

Subjective norms: Four items were used to assess the direct measure of subjective norm. Two items measured injunctive norms: "Most people important to me would want me to use an AFO in the next month" and "Most people important to me would approve of me using an AFO in the next month", with the response being strongly agree (1) to strongly disagree (7). Two items measured descriptive norms: "Most people who have an AFO are likely to use it in the next month with options ranging from very likely (1) to very unlikely (7) and "How many people after stroke do you think will use their AFO in the next month?", with possible responses varying between none of them (1) and all of them (7). The mean of the four items was used as the final measure for subjective norm. Cronbach's alpha for the subjective norms scale was α=.75.

Normative beliefs: Normative beliefs were assessed using the question: "How much do you think each of these groups will approve or disapprove of you using your AFO as

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[24] The mean for the direct measures of A, SN and PBC were calculated. This is because each individual measure of A, SN and PBC is considered to directly measure the theoretical construct. Therefore, a mean score provides a more accurate representation of the theoretical construct (Ajzen, 2006).

[25] Scores for indirect measures were behavioural, normative and control beliefs were summed to provide an overall measure of the attitudinal beliefs, as recommended by (Ajzen, 2006). This is because it is quite possible that people can hold a range of both positive and negative beliefs about a behaviour. The overall score will indicate if people have positive or negative beliefs about a behaviour. For the same reason, a measure of internal consistency, such as Cronbach's α, for belief-based measures, was not calculated, as an internal consistency measure was not considered appropriate (Ajzen, 2006).

recommended over the next month?" Participants were asked to respond to this in relation to five referent groups: family, friends, health professionals, other AFO users, and exercise professionals. Another option was given for participants to note any other normative group. Prior to analysis, normative belief measures were recoded so that higher scores represented increased approval by normative groups, and all normative beliefs were summed to create a total indirect normative belief score.

Perceived Behavioural Control and Control Beliefs

Perceived behavioural control: PBC was measured directly using three items. In line with findings from the moderator analysis conducted in Chapter 5, which demonstrated that self-efficacy measures had consistently higher correlations with intentions and behaviour than controllability or combined items (i.e., containing items which measure both self-efficacy and controllability), only self-efficacy questions were included. These items were: "I am confident that I can use my AFO in the next month", with responses ranging from true (1) to false (7), "I am confident in my ability to use my AFO in the next month", with responses varying between true (1) and false (7), and "If I wanted to, I could easily use my AFO in the next month" with answers varying from strongly agree (1) to strongly disagree (7). The mean of the three self-efficacy items was used to measure PBC in the data-analysis. Cronbach's alpha for the PBC (self-efficacy) scale was α=.81.

Control beliefs: Control beliefs were measured using the following question: "To what extent do you think each of these factors will make using your AFO as recommended easier or more difficult over the next month?" The factors were: needing help to put on and take off the AFO, obstacles in the environment (e.g., kerbs, slopes, weather), muscle weakness or tightness, lack of/ poor sensation in my leg, limited or poor hand function, being unwell (e.g., sickness), poor fit of AFO on my leg or foot, poor fit of the AFO with my shoes, the AFO causing pain or discomfort, feeling self-conscious, feeling low or tired, the weight of my AFO or footwear I have been advised to use with it, the bulk or size of my AFO, practice using my AFO, training to use my AFO, and the right angle/ tilt of my AFO. The responses ranged from: makes it easier to use my AFO (1) to makes it more difficult to use my AFO (7). In order to obtain a score for the total control beliefs, items were reverse scored to ensure that beliefs, which made AFO use easier were scored higher, and then all items were summed together.

Intention

Intention was measured by five items: "I intend to use my AFO in the next month" which was rated on a seven point bipolar scale from true (1) to false (7); "I am planning to use my AFO in the next month", also rated on a seven point bipolar scale from false (1) to true (7); "I want to use my AFO in the next month" with responses ranging from strongly agree (1) to strongly disagree (7); "How likely is it that you will use your AFO in the next month?" with options varying from very likely (1) to very unlikely (7); and "I will try to use my AFO in the next month" with choices ranging between strongly agree (1) and strongly disagree (7). Cronbach's alpha for the intention scale was α=.89.

Behaviour

When designing a TPB study, the behaviour of interest should be defined in terms of action, target, context and time. Therefore, in this investigation the behaviour was to use (action) the AFO (target) as recommended (context) in the last month (time). Behaviour was measured using two items "In the last month, did you use your AFO?", and "In the last month how often did you use your AFO?" with the following options; more often than recommended; about as often as recommended; less often than recommended; don't know- I was not told how often to use the AFO; and don't know-I can't remember. From these responses, a dichotomous score of AFO use as recommended was created by combining participants who did not use their AFO in the last month, with participants who used their AFOs either more than or less than recommended in the last month, to form a group that did not use their AFO as recommended. The context was "as recommended", but this was removed from the direct questions relating to A, SN, PBC and I in the questionnaire to reduce the words per sentence to ensure the questionnaire was more accessible. However, the participants were instructed at the beginning of each section of the questionnaire that they should answer the questions with respect to AFO use "as recommended".

6.6 Analyses

All questionnaire data were coded and entered into SPSS® Version 23. To address the first aim of this study, the adherence rate was calculated by dividing the number of participants using their AFO, as recommended in the last month, by the total number of participants who responded at T2. Then, correlations between the TPB variables and AFO use were measured using Pearson's correlation coefficient (*r*). This enabled the relationships between the TPB variables to be examined. In interpreting correlations, Cohen (1988) has suggested the following criteria for describing effect sizes: small≥ 0.10, medium≥ 0.3, and large≥ 0.5. Collinearity was checked by examining the correlation matrix, the tolerance, and the variation inflation factor (VIF). To address the second aim of this investigation, two regression analyses were conducted. In the first regression analysis, which tested hypothesis one, a linear multiple regression was carried out to identify predictors of intention to use AFOs. The adjusted R^2 was used as an overall estimate of the model fit, and standardised beta weights were examined to consider the effects of ATT, SN and PBC on intention to use an AFO as recommended. In the second analysis, which tested hypothesis two, a logistic regression was conducted to identify predictors of adherence to AFO use as recommended (behaviour). Goodness of fit of the logistic regression model was tested using the Homer-Lemeshow (H-L) test, a type of chi-squared statistic, in which the null hypothesis states that the model is a good fit, and, therefore, if $p>0.05$, the model is considered to fit the data well. Additionally, a descriptive measure of goodness of fit, R^2 as described by Nagelkerke (1991), was calculated, which is a variation of the R^2 statistic provided in linear regressions. To address the third aim, and hypothesis three of this investigation, correlations between the specific behavioural, normative and control beliefs and the direct TPB measures were calculated. Finally, correlations between the specific beliefs and intentions and behaviour were calculated to explore the relationships between the constructs, to identify beliefs which might be potentially targeted in an intervention. This is in line with TPB theory which focuses of the central role of intentions in influencing behaviour (Fishbein, von Haeften, & Appleyard, 2001). In addition, because establishment of a belief-behaviour relationship is considered an essential pre-cursor to targeting a behavioural belief in a behavioural intervention (Rhodes & Blanchard, 2007; Weinstein, 2007), the correlations between the individual beliefs and behaviour were also evaluated. Alpha was set at $\alpha = 0.05$ for all statistical tests.

6.7 Results

The results were initially assessed for normality using histograms, PP plots for the standardised residuals, and an examination of skewness and kurtosis. Intention was positively skewed with a significant Komogolov-Smirnov statistic ($p<0.000$), indicating a non-normal distribution. Therefore, this was log transformed to provide a more normal distribution, which corrected for skew, and was then used in the subsequent linear regression analysis.

6.7.1 Adherence to AFOs

Adherence was defined as use of AFOs as recommended. Of the 42 participants who completed the follow-up questionnaire, one month after the original questionnaire was sent, one person did not report if they used the AFO or not, and was excluded from the analysis. Four participants reported not knowing the recommendations for use. However, as they had provided the number of hours the AFO was used, described in Section 6.5.1, these participants were grouped into one of 2 groups: using AFOs as recommended (n=2) or not using AFOs as recommended (n=2). Therefore, in total, of the 41 remaining participants, 26 (63%) used their AFOs as recommended and 15 (37%) did not use their AFOs as recommended.

6.7.2 Correlations between TPB Constructs and AFO Adherence

Table 6.2 presents the mean and standard deviations of the TPB variables and the Pearson correlation coefficients between the direct and indirect TPB variables, measured at T1, and adherence behaviour measured at T2 (one month after the first questionnaire was sent). Pearson's correlation coefficients were used as despite the variables having a non–normal distribution, Pearson's correlation is fairly robust to non-normality excepting if a very high kurtosis or a very small sample size (e.g. <10) are present (Bishara & Hittner, 2012) . Therefore, as the reason for non-normality was a skewed distribution, and the minimum sample size was 41, Pearson's correlation was considered a robust method. Use of AFOs as recommended was strongly and positively associated with intention to adhere ($r=.58$, $p<.001$). Use of AFOs as recommended was also significantly, positively correlated with PBC ($r=.36$, $p=.02$) and attitudes ($r=.46$, $p<.01$), but was not significantly associated with subjective norms. Intentions to use the AFO as recommended were significantly and positively associated with attitude ($r=.72$, $p<.01$), subjective norms ($r=.50$, $p<.001$), and PBC ($r=.74$, $p<.001$). However, for the indirect measures, only the behavioural beliefs were significantly, positively associated the intention ($r=.32$, $p=.03$).

The correlations between the TPB variables were between -.06 and .81. Collinearity is considered to be a major concern if $r >.95$ between any of the independent variables (Paulson, 2007). Additionally collinearity statistics were within accepted limits (a tolerance level >.2 and a VIF<4; (Hair, Black, Babin, & Anderson, 2010). Therefore, multi-collinearity was not a concern.

Table 6-2: Pearson's Correlation Coefficients between TPB Variables and Adherence Behaviour (n=49)

		Mean	SD	1	2	3	4	5	6	7	8
1.	Adherence to AFO (Yes/ No)[a]	0.63	0.49	1.00	0.58**	0.46**	0.25	0.36*	0.19	-0.06	0.03
2.	Intention	5.64	1.72		1.00	0.72**	0.50**	0.74**	0.32*	0.14	0.07
3.	Attitude	5.37	1.69			1.00	0.62**	0.81**	0.65**	0.21	0.25
4.	Subjective Norm	5.75	1.31				1.00	0.73**	0.41**	0.22	0.25
5.	PBC	5.86	1.64					1.00	0.43**	0.18	0.15
6.	Behavioural beliefs	53.96	19.16						1.00	0.37*	0.27
7.	Normative beliefs	28.25	7.65							1.00	-0.08
8.	Control beliefs	50.04	23.78								1.00

**Correlation is significant at 0.01 level   *Correlation is significant at 0.05 level

[a] for correlations with adherence behaviour n= 41

6.7.3 Predicting Intention to Use of AFOs as Recommended

To test hypothesis 1, a regression analysis was conducted to test the efficacy of the TPB in predicting intention to use AFOs. Table 6.3 shows a multivariate linear regression analysis in which the dependent variable was intention and the independent variables were attitude, subjective norm and PBC. The regression model explained a significant proportion of the variance: 57% of the variance in intention to use an AFO as recommended was accounted for by the independent variables. The standardised regression coefficient indicated that attitude was the only significant predictor of intentions (β= -.45, t (49) =-2.64, p=.01).

Table 6-3: Multiple Regression Analysis of Behavioural Intentions towards AFO Use as Recommended (n=46)

Independent Variables	Unstandardized B	Std. Error	Standardised Beta	t	*p*
Attitude[a]	-0.08	0.03	-0.45	-2.64	0.01*
Subjective Norms	0.01	0.03	0.03	0.20	0.84
PBC	-0.07	0.03	-0.39	-2.00	0.05

(Adjusted) R^2 = 0.57 F =20.60 p=0.000   *p< 0.05

[a] Note Beta weights and t values are negative due to the reversed scoring and log transformation required to normalise the intention score.

6.7.4 Predicting Adherence to Use of AFOs as Recommended

To test hypothesis 2, a logistic regression analysis was carried out to examine if intention and PBC predicted adherence to use of AFOs as recommended. Table 6.4 shows the results from the analysis, with use of AFOs as recommended as the DV, and intention and PBC as the predictor variables. The model significantly predicted use of AFOs as recommended (χ^2= 15.11, df=2, p=.001). The model was considered a good fit (Homer and Lemeshow goodness of fit, x^2 = 1.345, p>.05), and accounted for 42.9% (Nagelkerke's R square=.43) of the variance in AFO use as recommended. The model successfully predicted 92% of people using AFOs as recommended and 60% of participants who did not use AFOs as recommended. Overall 80% of the predictions were accurate.

Table 6-4: Logistic Regression Analysis of AFO use as recommended (n=40)

Predictors	**β**	**SE**	**Wald Test**	***p***	**Odds Ratio**	***CI (lower)***	***CI (upper)***
Intention	1.11	.48	5.42	0.02*	3.07	1.19	7.88
PBC (self –efficacy)	-0.33	0.44	0.57	0.45	0.72	0.31	1.70

Nagelkerke's R square= 0.43   *p< 0.05

Intention was a significant predictor of AFO use as recommended, and the odds ratio value demonstrates that an increased score of intention by one unit, is associated with an increase in odds of using an AFO as recommended by a factor of three (95% CI, 1.19-7.88).

6.7.5 Beliefs Associated with Direct TPB Constructs, Intention and Behaviour

The associations between underlying behavioural beliefs and the respective direct TPB measure and intentions, all measured at T1, and behaviour measured at T2, were examined using Pearson's correlation coefficients. This enabled identification of the beliefs most strongly associated with direct attitude, SN, PBC, intention, and behaviour, and hence addressed the final two aims of this investigation. The results are seen in Table 6.5 below.

In line with hypothesis three, 12 out of the 13 behavioural beliefs were significantly associated with the direct measure of attitude (positive behavioural beliefs were positively associated and negative behavioural beliefs were negatively associated with a positive attitude towards AFO use): all normative groups identified as approving or disapproving of AFO use were significantly and positively associated with the direct subjective norm measure, and all control beliefs were significantly associated with the direct PBC measure (negative control beliefs were negatively associated, and positive control beliefs were positively associated with perceived control over AFO use). This demonstrated that the beliefs elicited in Chapter 5, were able to explain the cognitive foundations of attitude, subjective norms and PBC for people who had been prescribed an AFO following stroke.

Table 6-5: Associations between Underlying Beliefs and, Direct TPB constructs, Intentions and Behaviour

	Mean	SD	r (direct measure)	r (Intention)	r (Behaviour)
Behavioural Beliefs			*Attitude*		
Increase my mobility	5.89	1.65	0.62**	0.50**	0.52**
Make walking look more natural	4.24	2.28	0.34*	0.08	0.12
Improve balance/ prevent falls	5.59	1.96	0.46**	0.28	0.33*
Increase my confidence	4.58	2.14	0.42**	0.17	0.19
Support my leg or foot	6.38	1.15	0.37*	0.29	0.29
Help me to improve during rehabilitation	5.05	2.12	0.49**	0.32*	0.26
Make my leg feel heavy	5.05	2.23	-0.55**	-0.36*	-0.04
Make my leg swell	4.39	2.54	-0.31	-0.15	0.08
Cause me pain or discomfort	4.59	2.42	-0.64**	-0.33*	-0.20
Make it difficult to find footwear that fits	5.70	1.99	-0.36*	-0.06	-0.10
Make it difficult to use footwear that looks good	5.60	2.08	-0.40**	-0.16	-0.10
Limits my choice of clothing	4.90	2.37	-0.32*	-0.05	0.01
Limits the motion at my joints	4.88	2.20	-0.39*	-0.11	-0.13
Requires a lot of effort	4.95	2.13	-0.52**	-0.30*	-0.28
Normative Beliefs			*Subjective Norm*		
Family	6.47	1.26	0.55**	0.32*	0.31
Friends	6.24	1.21	0.56**	0.56**	0.32
Health Professionals	6.63	0.87	0.79**	0.20	0.31
Other Users	6.03	1.31	0.67**	0.11	0.03
Exercise Professionals	6.30	1.00	0.41*	0.25	0.38*
Control Beliefs			*Perceived Control*		
Needing help to take on or put off AFO	3.20	2.22	-0.43**	-0.13	-0.22
Obstacles in Environment	4.51	2.35	-0.50**	0.03	0.04
Muscle Weakness or tightness	4.51	2.30	-0.52**	-0.02	-0.16
Lack of/ poor sensation in leg	4.44	2.23	-0.64**	-0.05	-0.07
Limited/ poor hand function	5.06	2.27	-0.53**	-0.10	-0.04
Being unwell	4.06	2.09	-0.53**	0.01	-0.17
Poor fit of AFO on leg/ foot	5.08	2.20	0.62**	0.04	-0.01
Poor fit of AFO with shoe	5.21	2.17	-0.75**	-0.06	-0.11
AFO causing pain or discomfort	5.40	1.93	-0.66**	-0.10	-0.11
Feeling self-conscious	3.92	2.92	-0.32*	0.20	0.29
Feeling low/ tired	4.73	2.18	-0.73**	-0.05	-0.10
Weight of AFO or footwear	4.30	2.13	-0.66**	-0.18	-0.01
Bulk or Size	4.58	2.15	-0.75**	0.05	0.11
Practice in using AFO	4.85	2.02	0.39*	0.18	0.07
Experience with AFO	4.57	2.23	0.65**	0.10	0.24
Right angle/ tilt of AFO	4.30	2.12	0.64**	0.07	0.28

*Significant at 0.05 ** Significant at 0.01

Five attitudinal beliefs were significantly associated with behavioural intentions to use an AFO as recommended. The attitudinal beliefs positively associated with intention were: using my AFO as recommended in the next month will increase my mobility ($r=.50$, $p< .001$) and help me to improve during rehabilitation ($r=.32$, $p=.04$). The attitudinal beliefs negatively associated with intention were: using my AFO as recommended will be heavy ($r=-.55$, $p<0.01$), cause me pain or discomfort ($r=-.33$, $p=.03$), and requires a lot of effort ($r=-.30$, $p=.049$). Attitudinal beliefs significantly associated with behaviour were: the AFO increases my mobility ($r=.52$, $p =0.01$), and the AFO prevents falls/ aids balance ($r=.33$, $p=.045$). Analysis of normative beliefs showed that approval of family ($r=.32$, $p =.04$) and friends ($r=.56$, $p<.001$) was significantly and positively associated with intention to use the AFO as recommended. In relation to behaviour, approval of exercise professionals ($r=.33$, $p=.03$) was positively associated with actual AFO use as recommended. None of the perceived control beliefs were associated with intention or behaviour.

6.8 Discussion

This study investigated the utility of the TPB in predicting adherence to use of AFOs as recommended in people with stroke. This is the first study, to the author's knowledge, which has used a psychological model of behaviour to investigate adherence to using AFOs in a clinical population. A prospective design enabled adherence to the theoretical tenets of the TPB (Ajzen & Madden, 1986), and use of direct and indirect measures of A, SN and PBC provided insight into the psychosocial determinants affecting use of AFOs in people with stroke. This new knowledge may enable the design of interventions, which can increase adherence, and therefore potentially increase activities and participation among AFO users.

6.8.1 Adherence to use of AFOs as recommended

The adherence rate to use of AFOs as recommended, over a one-month period, was 63%. This compares favourably with previous investigations into adherence (Swinnen & Kerckhofs, 2015; Vinci & Gargiulo, 2008), and is similar to the adherence rate of 56% found in the ICF study (See Chapter 3). However, the resultant non-adherence rate of 37%, represents a sizable proportion of participants who are either not engaging or only partially engaging with orthotic management following a stroke. As highlighted in Chapter 3, non-adherence to AFO use as recommended is associated with poorer outcomes in physical and mental health. Therefore, this significant minority of people not adhering to AFO use as recommended is an important concern which highlights the need to understand the factors affecting adherence to use of AFOs, and the need for clinicians and researchers to consider appropriate ways and methods of increasing adherence.

6.8.2 The Utility of the TPB in predicting adherence to use of AFOs

In this investigation, the TPB was able to account for 57% variance in intentions and 43% variance in use of AFOs as recommended, which are both considered as large effect sizes in the social sciences (Cohen, 1988). The results of this study demonstrated that the TPB is an effective model in explaining the use of AFOs as recommended in the stroke population. As this is the first investigation, which has investigated adherence to AFOs in people with stroke using the TPB, there is no relevant literature to make direct comparisons with. However, comparisons can be made with the TPB meta-analyses investigating general social behaviours, and TPB investigations, which have investigated other adherence behaviours (Armitage & Conner, 2001; Godin & Kok, 1996). The variances explained in this study are somewhat higher than previous meta-analyses investigating the utility of the TPB in explaining behaviour. For example, Armitage and Conner (2001) found that attitudes, subjective norm and perceived behavioural control predicted a lower variance in intention (39%) and behaviour (27%) in a wide range of social behaviours. Similarly, Godin and Kok (1996) reported that the TPB explained a 41% variance in prediction of intention and a 34% variance for prediction of behaviour in a range of health behaviours.

In considering other TPB studies, which have investigated adherence behaviours in other clinical populations for which orthoses might be prescribed (e.g., adherence to: exercise (Gucciardi, 2016), diet (White et al., 2010), self-care (Sheppard et al., 2006)), the variance that was explained in this study, compares favourably. Additionally, the variance explained in this investigation was markedly higher than 32% variance in intentions and a 9% variance in behaviour found in the meta-analysis of Rich et al. (2015) which investigated the utility of the TPB in predicting adherence behaviours in chronic conditions. The high variance explained in the current investigation may be partially attributable to careful construction of the TPB questionnaire in this study, and adherence to the principle of compatibility: the latter factor was identified as an important moderator in the meta-analysis described in Chapter 4. It therefore highlights the importance of following guidelines in TPB questionnaire construction (Ajzen, 2006; Francis et al., 2004).

Another reason for this difference may be that Rich et al. (2015) did not include any studies which specifically investigated stroke as a chronic condition in their meta-analysis. Previous research has identified that the TPB may perform differently when applied to different health behaviours (Godin & Kok, 1996; McEachan et al., 2011; Rich et al., 2015). As no previous investigations have tested the efficacy of the TPB in understanding adherence to health behaviours in people with stroke, the efficacy of the TPB in explaining health behaviours in people with stroke is not known. In addition, as AFO use as recommended has not previously been investigated using the TPB as an explanatory model, it may be that the TPB is effective in explaining this particular type of adherence behaviour. For many patients, the ability to walk following a stroke is the primary goal in stroke rehabilitation (Bohannon, Andrews, & Smith, 1988; Dobkin, 2005; Swinnen et al., 2017b), and may therefore be a compelling motivation to use an AFO in rehabilitation (Momosaki et al., 2015), despite the physical challenges in doing so. Consequently, it is possible that the TPB captures the varying levels of beliefs about walking again, which could drive positive attitudes towards using an AFO found in the current study. Therefore, although Rich et al. (2015) suggested that the TPB may not be an appropriate model for predicting adherence behaviours in people with chronic conditions, the results of the current study suggest that the TPB is an effective model for predicting adherence to use of AFOs in people with stroke.

The current study found that attitude was the only predictor of intention to use an AFO as recommended, and intention was the only predictor of the actual behaviour: adherence to use of AFOs as recommended. Looking broadly across the TPB literature, it is clear that the determinants of intention and behaviour vary depending on the behaviour being investigated, the health condition, and a number of other variables such as methodological moderators (Armitage & Conner, 2001; Godin & Kok, 1996; McEachan et al., 2011). However, the findings of the current study are broadly in line with the findings of the meta-analysis in Chapter 5. This suggests that an overall positive attitude towards AFO use is the most important factor in influencing intention to use an AFO, and therefore any future intervention to increase adherence should focus on attempting to change attitudes. The current investigation gives some insights into possible beliefs which might be targeted in an intervention, and are discussed in 6.8.3, below.

Whilst PBC was not a predictor of intention ($t=-2.00$, $p=0.05$), the p-value was close to significance. Given that the current study was underpowered, it is possible that if this study was repeated with a larger sample size that PBC might then become a significant predictor of intention. However, it is acknowledged that in the current investigation, PBC and subjective norm did not predict intention. These findings do not refute the efficacy of the TPB model.

Indeed, perceived behavioural control is a proxy for actual control over a behaviour (Ajzen, 2011), and when perceived control and actual control diverge, PBC may be a poor predictor of behaviour. The non-significant effect of PBC on behaviour, therefore, suggests that adherence to use of AFOs as recommended may be more difficult for people with stroke than anticipated (i.e. PBC may not have been reflective of the actual control that participants had over the ability to use the AFO as recommended). This makes intuitive sense when one considers that use of an AFO following a stroke presents functional challenges for the user which are not only linked to loss of lower limb function, but also relate to other types of functional loss, which may not immediately come to mind when one considers walking with an AFO following a stroke. Stroke can also result in weakness or spasticity of the upper limb, perceptual and visual changes, sensory loss, effects of fatigue and loss of cognitive function (Stroke Association, 2018a). Therefore, someone prescribed an AFO following a stroke may have challenges donning and doffing the AFO due to poor upper limb function, may experience loss of balance and visual disturbances, which make it more challenging to navigate their surroundings; may have fatigue after standing or walking for a short period of time; may encounter difficulty with thinking, memory and concentration, all of which can contribute to a reduced control over their ability to use their AFO as recommended.

Subjective norm did not predict intention, and, given that subjective norm is usually regarded as a weaker predictor of intention, compared to attitude and PBC (Ajzen, 2011; Armitage & Conner, 2001; Godin & Kok, 1996; McEachan et al., 2011; Rich et al., 2015), this finding is not entirely surprising. Armitage and Conner (2001), in their TPB meta-analysis investigating multiple social behaviours, found that performance of the subjective norm component was dependent on efficacy of measurement, with single item measures of subjective norm resulting in weaker associations with intention. However, in this investigation, given that all measures of subjective norm were appropriately defined in relation to TACT, and a multiple item measure with four items was used to provide a score for subjective norm, it is unlikely that the lack of prediction of intention was caused by an ineffective measure of subjective norm. The finding that subjective norm was not a specific predictor of intention to use an AFO as recommended in people with stroke, was in agreement with the findings of the meta-analysis described in Chapter 5, which investigated health adherence behaviours in conditions for which orthoses might be prescribed. As there were no obvious limitations to the measurement of subjective norms in the current investigation, this may suggest that perceived support, or approval from others, has little influence on intention to use an AFO in people with stroke. This could be because the user interacts with the AFO in an intimate and personal way, so that decision making about AFO use is more likely to be influenced by personal beliefs rather than the beliefs about significant others' views regarding AFO use. Therefore, it suggests that interventions which aim to positively influence adherence to AFO use as recommended will be ineffective if they attempt to influence normative beliefs.

6.8.3 Identification of beliefs which can be targeted in a future intervention

Analysis of the correlations between individual beliefs and the direct TPB constructs, provided valuable information about the beliefs underpinning attitude, subjective norms and perceived control in people who had been prescribed as AFO following stroke. Significant correlations between the individual beliefs and their respective direct TPB constructs were seen, demonstrating that the indirect measures were well-constructed and direct constructs were reflective of the underlying beliefs. The results of this study also provided knowledge about the beliefs, which might be targeted in a behavioural change intervention. An intervention should be designed to affect beliefs which are strongly related to intention or behaviour (Fishbein et al., 2001).

As attitude was identified as the only direct predictor of intention, and intention was also shown to predict use of an AFO as recommended, any future intervention should therefore attempt to target the specific attitudinal beliefs which have been shown to be strongly correlated with intentions and or/ behaviour. Given that only one belief- "the AFO can improve mobility"- was associated with both intention and behaviour, this logically appears to be the most relevant belief to target. Increased mobility as a result of AFO use has been reported previously in the stroke population (Doğğan et al., 2011; Tyson & Kent, 2013; Tyson & Rodgerson, 2009). Use of targeted messages, based on theory, to address adherence to AFOs in stroke have not been described in the literature previously. Therefore, consideration for the way in which this advantage of increased or improved mobility is conveyed to people with stroke who have been prescribed an AFO as a persuasive message is warranted. Chapter 5 highlighted the benefits of increased mobility for participants in the elicitation study, but also linked increased mobility to increased social and functional activities. A future intervention might therefore specifically highlight the role that AFOs can play in increasing the ability to move around the home environment, and undertake functional activities such as cooking, or leisure activities such as gardening. An intervention might also emphasise the increased ability to mobilise outside of the home, and therefore increase opportunities to socialise with others.

Another positive attitudinal belief associated with AFO use as recommended was "the AFO improves balance and prevents falls." Several authors have reported beneficial effects of AFOs on balance in people with stroke (Doğğan et al., 2011; Tyson & Kent, 2013; Zissimopoulos et al., 2013). Stroke results in a range of sensory, motor and cognitive effects impacting on the musculoskeletal and neurological systems, which creates challenges to static and dynamic balance. An AFO may therefore offer increased stability and reduce fear of falling, as well as decreasing the risk of a fall, and potential injury as a result of a fall. In designing an information-based intervention around this advantage, the message might focus on the positive aspects of increased balance to persuade people with stroke to use their AFOs, such as increased stability during different activities, and increased ability to move around safely in different environments, which in turn could increase activity levels and participation.

Whilst the beliefs highlighted above might be the most obvious targets of an intervention, due to being significantly associated with behaviour, Fishbein et al. (2001) suggested that beliefs which had higher correlations with intention or behaviour, may be more resistant to change due to greater centrality of the belief to a person's wider belief system. He therefore suggested another strategy might be to attack a number of peripheral beliefs which might be more amenable to change. Therefore, some consideration is also given to the other beliefs, associated with intention, which might form part of a behaviour change intervention.

Another possible belief that was associated with a positive intention to use an AFO, and consequently, could be a target for an intervention, was improvement during rehabilitation. This behavioural belief was quite specific to use of the AFO over a limited period of time soon after stroke, when people are initially prescribed AFOs, rather than use of the AFO in the longer term. This was a particularly interesting finding as the majority of participants in this study (72%) had been prescribed an AFO more than one year previously, and it might therefore have been expected that improvement in rehabilitation may not have been as important as other beliefs to longer term users. However, this highlights that use of the AFO during rehabilitation is perceived as an important advantage for people who have been prescribed AFOs, and supports the use of AFO as a therapy tool in early rehabilitation. A future intervention might therefore emphasise one of the benefits of using an AFO as making gainful improvements during rehabilitation to people *prior* to being prescribed an AFO.

Three underlying beliefs were negatively associated with intentions towards using an AFO as recommended: pain/ discomfort; heaviness and effort of use. Pain and/or discomfort has been reported in the general orthotic literature (Fisher & McLellan, 1989; Phillips et al., 2011; Swinnen & Kerckhofs, 2015), although has not previously been reported as a concern in people with stroke. Pain or discomfort due to the AFO should not be considered a normal part of the experience of AFO use, and patients must be encouraged to report such concerns to their clinicians in order to enable them to be resolved. Heaviness or increased weight of an AFO has also been identified in the literature as a problem or disadvantage by AFO users (Phillips et al., 2011; Tyson & Thornton, 2001), and Doğğan et al. (2011) previously reported that 16% of participants in their study experienced difficulty in walking due to the weight of the AFO. Whilst advances in material science can undoubtedly enable the creation of more lightweight orthotic appliances, for example by using carbon-fibre in the orthotic design (Brehm et al., 2007), consideration should also be given to the fit of the AFO. Although no studies have identified a relationship between the fit and perceived weight of an AFO by a person wearing it, a well-fitting AFO enables the forces to be distributed over a wider area, thereby reducing pressure on the body interface (Bowers et al., 2009b), which could reduce the sensation of weight of the AFO. Therefore, whilst these concerns are practical and may require practical solutions, it is essential that patients are provided with information about what they can do if they experience pain or discomfort caused by an AFO, or feel that the orthosis is heavy. Patients should also be advised of realistic expectations of the orthosis: the AFO should be comfortable and fit well, and once donned, should reduce the physical effort required to walk. They should be reassured that they can discuss these concerns with a clinician who might help to address these problems, in a timely manner. The final belief negatively associated with intention to use an AFO; "the AFO requires a lot of effort to use", has not previously been identified in the literature and therefore was unexpected. Whilst AFOs will require some additional effort (e.g., in donning or doffing, or extra time taken for dressing), they should not be effortful to use. Indeed, AFOs should actually reduce the physical effort required in walking (Franceschini et al., 2003; Thijssen, Paulus, van Uden, Kooloos, & Hopman, 2007). Further investigation is required to understand what aspects of AFO use are deemed to require effort. However, a possible future intervention might inform patients of the reduced physical effort in walking that use of AFOs might provide.

In deciding the number of messages which might be used in targeting beliefs in a theory-based intervention, Fishbein and Ajzen (2010) note that it is only a small number of beliefs, i.e. those that come readily to mind, which influence the behaviour and this has implications for designing interventions which can affect behaviour. In addition, research has shown that the brain can accept only four new pieces of information at any one time (Cowan, 2001). Therefore, when designing a theory-based intervention that provides information to patients, a maximum number of four beliefs should be targeted. Given the possible cognitive challenges which may be seen in stroke survivors (Sun, Tan, & Yu, 2014), it may be more effective to target only two or three beliefs in a future intervention which aims to increase adherence. Whilst targeting of normative and control beliefs might also be considered in a future intervention, given that neither SN or PBC were strong predictors of intention, and the necessity to select two or three beliefs which can be targeted, there is a strong rationale for focusing on the specific attitudes which had significant correlations with intentions and behaviour, rather than beliefs associated with SN or PBC.

6.8.4 Strengths and Limitations

This study has demonstrated the utility of the TPB in understanding use of AFOs as recommended in people with stroke. Despite the methodological strengths of the study, and use of a theory-based approach to understand adherence, it is important to acknowledge some limitations, which should be considered when interpreting the results.

It is acknowledged that the number of participants who completed both time points in this study was small (n=41), and therefore the study was underpowered. It is important to recognise that the clinical population of people prescribed AFOs following stroke are a sub-population of the larger stroke population. To maximise the sample size, the whole population of participants within NHS Lanarkshire, people who had been prescribed an AFO following a stroke in the previous three years, was utilised.

This also had the advantage of ensuring the results could be generalised across the whole population. In order to maximise the response rate, participants were contacted at least three times in order to inform them about the study and follow-up phone calls were also made to participants to support completion of the second questionnaire, and offer assistance if required. In regression analysis ten participants per predictor variable (Harrell, 2001), is considered to be the an absolute minimum number of acceptable participants, and this was achieved. Therefore, whilst it is acknowledged that a large sample size would have provided more confidence in the statistical analysis and interpretation of results, additional effort in the recruitment process would not have significantly increased the sample size. Future investigations in this area should consider pooling participants across different health boards, in order to increase sample size, and allow subgroup analysis and investigation of other background variables, such as age, gender, and severity of condition, which are thought to influence intention and behaviour by influencing the underlying beliefs, and in turn attitudes, subjective norms and PBC (Fishbein & Ajzen, 2010). However, it should be recognised that despite the low power of the analyses, a number of significant effects were identified, which have valuable clinical implications. For example, the finding that attitude was a significant predictor of intention and intention was a significant predictor of behaviour, provides a clear direction in terms of intervention design to increase adherence to AFO use as recommended.

A self-report measure was used to quantify the behaviour under investigation. Self-report measures have been criticised, with an objective measure of adherence being considered as more accurate (Sabaté, 2003). Use of an objective measure of adherence was considered in this investigation (e.g., use of an activity or pressure monitor), but was not deemed to be feasible, as this would have required a new AFO to be manufactured for each participant, which incorporated the activity monitor. Financially, this was not a viable option. The meta-analysis described in Chapter 4, gave some support for using self-reported measures of adherence, as no significant difference was found between effect sizes for I-B and PBC-B using either self-reported or objective measures of behaviour. In addition, a clear definition of the adherence behaviour provided confidence that the self-reported measure was appropriate in this instance.

It is recognised that this investigation was carried out in one geographical area in Scotland and orthoses were provided by one health board, in Scotland, NHS Lanarkshire. Therefore, the applicability of these results to other populations in the UK or further afield remains unclear. Finally, the fit of the AFOs on participants was not assessed by a clinician due to the study design (i.e., use of postal questionnaire). Whilst this has advantages in allowing anonymous responses, and, therefore, may enable honest answers (Coolican, 2014), it is possible that the quality of fit and function may have affected the person's decision to use an AFO as recommended (Swinnen et al., 2017a). Nevertheless, these promising results should encourage other researchers to apply the TPB when investigating adherence behaviours to orthotic devices in different populations.

6.9 Conclusion

In conclusion, this investigation provides support for the use of the TPB as a theoretical framework when investigating use of AFOs as recommended in people following a stroke. This investigation is of value because it is the first such investigation, which uses a psychological theoretical framework to attempt to understand adherence to AFO use in people with stroke, and therefore advances knowledge by applying the TPB to a new behaviour, and health condition, which has not previously been explained by this model. As described previously, use of psychological theory to explain behaviour has been shown to provide better results in intervention studies compared to non-theory-based interventions (Michie & Abraham, 2004; Michie et al., 2018). Therefore, this study provides support for use of TPB theory in design and development of future interventions and offers a valuable preliminary strategy for the development of an intervention designed to increase adherence to use of AFOs in people with stroke, which may then increase activities and participation. More specifically, a future intervention could promote of positive attitudes and intentions towards AFO use, for people whom have been prescribed AFOs and offers opportunities to address non-adherence to AFOs in this patient group. The suggested intervention might direct attention on the benefits of increased mobility and improved balance in relation to wider activities that enable pursuit of patient interests, and increased opportunities for socialisation, as well as highlighting the role that AFOs play in stroke rehabilitation. Consideration should also be given to the timing of an intervention, which might be most effective prior to, or during, the rehabilitation process. In the final Chapter, the implications of these findings will be considered in the context of the other investigations conducted for this thesis. The final chapter will therefore detail the main outcomes of this work, and consider its' theoretical and clinical implications. It will also make recommendations for future research in order to further understand and increase adherence to use of AFOs in stroke and more generally to other orthotic devices.

Key Points from Chapter 6

1. This is the first study that has used a psychological theoretical framework to understand and explain adherence to AFOs in people with stroke. This investigation used the TPB to prospectively predict adherence to use of AFOs in participants following stroke.
2. In this investigation, 63% of people used their AFO as recommended.
3. The TPB was able to account for 57% variance in intentions and 43% variance in use of AFOs as recommended. The significant amount of variance accounted for suggests the TPB is a useful model for understanding adherence to AFOs in this patient group.
4. Attitude was the only significant predictor of intention, and intention was the only significant predictor of behaviour.
5. Attitudinal beliefs, normative beliefs and control beliefs were significantly correlated with the direct constructs, demonstrating that the beliefs measured provided a good understanding of the cognitive foundations of attitude, subjective norms and PBC.
6. Analysis of correlations between belief-based measures, intention, and behaviour have enabled the identification of beliefs, significantly associated with behaviour and/or intention, which might be targeted in a future intervention to increase adherence to AFO use. These include positive beliefs that AFOs can increase mobility, improve balance, and help a person to improve during rehabilitation; and also negative beliefs that AFOs may cause pain or discomfort, are heavy, and are effortful to use.

Next Steps

The relevance of the findings of this investigation will be considered in the context of the other investigations in this thesis.

Further steps to expand and develop this important research area will be considered.

Chapter 7 General Discussion

7.1 Overview of Chapter

AFOs are the most commonly used orthotic intervention (Whiteside, 2015), and are used to manage a wide range of mobility disabilities, including stroke, multiple sclerosis, arthritis, and trauma. However, poor adherence to orthotic intervention has been identified as a major concern (Swinnen & Kerckhofs, 2015; Vinci & Gargiulo, 2008). Adherence to AFOs should be viewed within the context of a society with a growing elderly population, an increasing understanding of the role of orthoses in maintaining independence in this population, and recognition of the economic benefits that orthotic intervention can provide (Hutton & Hurry, 2009).

Therefore, understanding the factors which affect optimal use of orthoses is an important and timely topic of investigation. Consequently, the main aims of this thesis were: to examine the prevalence of AFO use, to investigate the use of the ICF in understanding the outcomes for patients who use/don't use their AFO, and to test the efficacy of a theoretical model of behaviour in understanding adherence to AFO in people with stroke. In order to meet these aims, five core research questions were developed which this thesis aimed to answer. This final chapter reviews the findings in relation to these questions (see Section 2.9) and discusses the importance of the findings. It discusses several important theoretical and clinical implications of this work. The strengths and limitations of this work are recognised, and a reflection of the challenges of this work is detailed. Finally, this chapter recommends new avenues of research to further advance this work.

7.2 Findings in Relation to Key Research Questions

7.2.1 To what Extent do People, who have been Prescribed AFOs, Adhere to Use of AFOs as Recommended?

Two investigations measured adherence to AFOs, using the definition "use of the AFO as recommended". The first study, described in Chapter 3, investigated the level of adherence to use of AFOs as recommended, in 157 participants who had been prescribed an AFO by NHS Greater Glasgow and Clyde to manage a wide range of different health conditions. This investigation, found an adherence rate of 56%. In the second investigation within NHS Lanarkshire, which measured adherence to AFOs specifically in people with stroke (Chapter

6), a similar, although slightly higher rate of adherence to use of AFOs (63%) was obtained. Both investigations highlighted the significant problem with non-adherence to AFOs.

There were challenges in defining adherence to AFO use across a range of different conditions. For example, adherence could not be defined by a fixed number of hours that the AFO should be worn per day or week, as different instructions regarding wearing time are frequently given. The definition of adherence to orthoses has not previously been given due consideration in the literature (Swinnen & Kerckhofs, 2015; Vinci & Gargiulo, 2008). Therefore, in this investigation adherence to AFOs was defined as "use of the AFO as recommended" as this recognises the individual nature of wearing instructions which might be given to patients when prescribed an AFO, and also allows for adherence to be investigated across different conditions in which different recommendations may be made.

In order to classify people as adherent or non-adherent, using a self-reported measure of adherence, participants were required to know the recommendations for use. An unexpected finding of the first investigation (Chapter 3) was the number of participants (n=42, 27%) who were not aware of recommendations for use of their device. A possible reason for this, was that the orthotic service at the time of the study did not provide written instructions regarding use of the orthosis. This finding was passed onto NHS Greater Glasgow and Clyde who have since implemented the provision of written information which details advice regarding appropriate use of AFOs. A smaller group of participants in the investigation detailed in Chapter 6, also did not know recommendations for use (n=4, 10%) although written instructions were provided by NHS Lanarkshire about AFO use. In this instance, given that the clinicians in Lanarkshire advise patients who have been prescribed an AFO following stroke, to use their AFOs all or most of the day, the number of hours were used to classify those participants, who did not know recommendations for use, as adherent or non-adherent. Therefore, this enabled them to be included in the analysis. However, it does suggest that for some patients, even when given written and verbal instructions, they may not understand or retain information about AFO use. Given that many of the conditions for which as AFO is used, can also impact on cognitive abilities (e.g. stroke, traumatic brain injury, multiple sclerosis), health professionals need to mindful of this additional challenge for patients, when communicating with them. Thus, consideration should be given to providing a range of methods to convey information, and of the key messages about use that clinicians need to emphasise during orthotic appointments.

In the latter chapters, the focus of the investigation was participants who had been prescribed an AFO following a stroke. The rationale for investigating this condition was established in the first investigation, detailed in Chapter 3, which identified stroke as the most common reason for being prescribed an AFO (See 3.5.4). In addition, in Scotland, stroke is the most common cause of severe physical disability in adults and improving the treatment, and care of people with stroke is a current priority in healthcare (Scottish Government, 2014b).

Key conclusions: The adherence rate established in these investigations, using an appropriate definition of adherence, provides some insight into the scale of the challenge, and establishes a baseline against which adherence to AFOs in other settings can be compared. The rates of adherence in the two different investigations were similar, suggesting that non-adherence is a phenomenon across multiple conditions, including stroke, and given that these investigations were conducted in different health boards, highlights that the problem of adherence was not specific to one health board. The relatively low levels of adherence (56% and 63%) identified in the two studies, identify that non-adherence is a considerable challenge. Specifically, an opportunity exists to increase adherence to AFOs. The significant number of participants who did not adhere (44% and 37%) to using their AFO as recommended, may have experienced reduced health outcomes, and may not have achieved their full potential. Whilst it is important to enable each individual patient to achieve their optimal outcome, the high level of non-adherence suggests that successful interventions which address adherence could have a substantive impact. However, before an investigation of the factors affecting adherence could be justified, it was necessary to establish if increased adherence might lead to better health outcomes.

7.2.2 Do People who Adhere to Use of AFOs as Recommended have Reduced Levels of Impairment, Activity Limitation and Participation Restriction, Compared to People who do Not Use AFOs as Recommended?

Chapter 3, detailed a cross-sectional questionnaire survey, conducted with 157 participants who had been prescribed an AFO by NHS Greater Glasgow and Clyde. The ICF (WHO, 2001) was used as a framework to investigate differences in impairment, activity limitation and participation restriction in people using AFOs as recommended and people not using AFOs as recommended. This study found that people who adhered to AFO use as recommended, demonstrated significantly lower levels of impairment, as measured by higher energy levels, and lower levels of activity limitation, as measured by physical functioning. In addition, people who adhered to AFO use as recommended reported significantly lower levels of anxiety, compared to participants who did not use their AFOs as recommended. These differences were not explained by clinical or demographic variables. It is acknowledged that this was a cross-sectional investigation, and therefore adherence to the AFO as recommended and the outcomes of impairment, activity limitation, participation restriction, anxiety and depression were measured simultaneously. Therefore, the associations found between adherence to use of AFOs as recommended and the outcomes do not imply causation i.e. it is not possible to determine if the outcomes were determined by orthotic use, or indeed if, orthotic use was determined by the outcomes.

Nevertheless, this study was the first study to explicitly use the ICF to identify appropriate outcomes to investigate use of AFOs to manage mobility disability. The vast majority of previous authors (e.g. Brehm et al., 2007; Carse et al., 2014; de Wit et al., 2004; Ferreira et al., 2013; Franceschini et al., 2003; Mojica et al., 1988; Tyson et al., 2013) investigating the efficacy of orthotic interventions have focused on objective measures of gait which can be measured in a laboratory. These studies provide a specific measure of the value of an AFO in a controlled environment. Thus, whilst objective measures of gait are useful for researchers and clinicians, they do not offer information about the impact of an intervention on a person's day-to-day life. Use of the ICF offers a framework for the identification of different constructs of impairment, activity limitation and participation restriction, which are more reflective of the overall experience of functioning of the person with disability. Therefore, it is important to move beyond just measuring the effects of AFOs on gait, and use a range of outcomes to provide a holistic understanding of the impact of orthotic use in daily life. In addition, use of the ICF framework provides a more structured approach to selection of outcome measures which enables easier comparison across investigations, and therefore may enable different orthotic treatments, with different patient groups, to be more easily evaluated. This should therefore encourage other researchers to use the ICF to enable an appropriate choice of outcome measures in relation to orthotic intervention.

These findings have important clinical implications. Whilst different variables of the AFO, such as material choice, fit, and alignment, have been highlighted as important to improving function (Malas, 2011), no previous investigations have demonstrated the relationship between optimal adherence and reduced levels impairment or activity limitation in people with mobility disability. Given that increased adherence to AFO use was found to be associated with reduced impairment and decreased activity limitation, this study demonstrated that there is potential to increase functioning and activities in people using

AFOs, by increasing adherence to AFOs. This is supported in the rehabilitation literature. For example, Geidl, Semrau, and Pfeifer (2014) identified personal modifiable factors of physical activity such as attitudes, skills and beliefs, which might be addressed by behavioural therapies to promote physical activity behaviour within the context of the ICF for people with chronic diseases. Additionally, Dixon et al. (2008) proposed an integrated model which incorporated the TPB into the ICF. They were able to demonstrate that control beliefs mediated the relationship between impairment and activity limitation. A number of other investigations have highlighted the possibility to reduce impairment and activity limitations by using behaviour change techniques to change cognitions (Bonetti & Johnston, 2008; Dixon, Johnston, Elliott, & Hannaford, 2012; Quinn et al., 2012). This therefore highlights an opportunity to reduce activity limitation and participation restriction in locomotor disability by design of interventions which modify the underlying beliefs about a behaviour.

Key conclusions: This study makes an original contribution to new knowledge in three ways. Firstly, this research establishes that AFO use as recommended was associated with decreased levels of impairment and activity limitation, and provides support for the need to better understand factors affecting adherence to AFOs. Secondly, it demonstrates that the ICF can be used as a framework to enable identification of outcomes relevant to an orthotic intervention, that are more aligned with the patient experience, compared to gait laboratory investigations. Finally, this investigation highlights the possibility of potentially improving health outcomes, by increasing adherence to AFOs. Using the ICF as a framework, it can be seen that personal factors which can be modified would be appropriate targets of an intervention, to increase adherence. Therefore, this offers a novel approach for researchers and clinicians to potentially increase functional outcomes of orthotic intervention, and optimise orthotic management, by considering ways in which adherence might be increased. These findings thus provided justification of the need to gain a better understanding of the factors which affect adherence to AFOs, so that interventions can be can be designed, which target modifiable factors that may increase adherence to AFOs.

7.2.3 Is the Theory of Planned Behaviour (TPB) a Useful Model for Understanding Adherence to Health Behaviours in Conditions for which Orthoses may be Prescribed?

Using theoretical approaches in order to understand adherence behaviour is important, because, interventions are more likely to be successful in changing behaviour when they target theory-based determinants of that behaviour (Ajzen, 2011; Davis et al., 2015; Michie et al., 2018; Michie & Johnston, 2012). However, none of the previous research of adherence to orthoses has attempted to use a theoretical approach to understanding adherence to AFOs as a behaviour.

In order to better understand adherence to use of orthoses, a range of different health behaviour models were considered, as detailed earlier in this thesis, in Table 4.1. The TRA/TPB Ajzen (1991) was considered to be the most appropriate theoretical model, for several reasons. Firstly, the TPB has previously explained more variance in behaviour than a range of other behavioural theories (Ajzen, 2014; Armitage & Conner, 2001; Giguere, Beggs, & Sirios, 2019; Taylor et al., 2006). Secondly, the parsimonious nature of the TPB, and, therefore, its application across a wide range of different behaviours and conditions (McEachan, Conner, Taylor, & Lawton, 2011), makes it particularly relevant when considering the range of conditions which might be seen in orthotic interventions. The small number of constructs included within the TPB, supports its use in applied settings. Thirdly, the TPB is one of the most utilised and written about theories of behaviour (Ajzen, 2011), and with clear guidelines for constructing a TPB questionnaire being available (Ajzen, 2006; Francis et al., 2004), is one of the most accessible psychological behavioural theories for a researcher, with a limited background in psychology, compared with other theories. Finally, and perhaps most importantly, when one considers the behaviour of AFO use, it is clear that the behaviour under investigation is truly a rational or reasoned decision-making process: a person has to go through a number of steps to put the AFO on in order to use it, which involve both thinking and physical action. This involves donning a sock or interface first, ensuring the correct location of the AFO on the leg, tightening and securing the straps, and finally applying the footwear over the AFO. Even though putting an AFO on, using it and taking it off, will become easier with practice, it can never become completely habitual.

Despite these strong arguments for using the TPB in this thesis, the TPB has been heavily criticised by several authors (see Sniehotta, Presseau, & Araújo-Soares, 2014), and some of the criticisms of the theory are worth further consideration. The TPB is often viewed as a static model and it has argued that it does not account for the effects of behaviour on cognitions, and future behaviour. However, Ajzen (2014) has countered that such arguments demonstrate a lack of understanding of the TPB as it was originally described: the original diagram which depicted the TPB clearly shows feedback loops which demonstrate the possible effects of behaviour on intentions, attitudes, subjective norms and perceived control, which in turn can affect future behaviour (Fishbein & Ajzen, 1975). Authors have highlighted a problem with the sufficiency assumption of the theory (Conner & Armitage, 1998;

Sniehotta, Scholz, & Schwarzer, 2005), in which the constructs are considered to fully explain intention and behaviour, and have highlighted the intention-behaviour gap, with a number of additional variables being suggested: such as anticipated regret (e.g. Sandberg & Conner, 2008), habit strength (e.g. Albarracin, Johnson, Fishbein, & Muellerleile, 2001; De Bruijn et al., 2007), and various socio-demographic measures (e.g. Sniehotta et al., 2013), which could improve the explanatory power of the TPB. Ajzen (2011) contends that the gap between intention and behaviour can be at least partially explained due to random measurement error, and has also highlighted there is scope to add additional variables to the model provided that they meet specific criteria: the proposed variable should be behaviour specific, it should be a potential causal factor of both intentions and behaviour, it should be conceptually independent of the other TPB variables, and should consistently improve predictions of intentions and behaviour (Fishbein & Ajzen, 2010).

Sniehotta et al. (2014) has also argued that the TPB is of little value because it does not provide specific guidance on behaviour change techniques. Indeed, it is true that the TPB does provide not advice on changing behaviour and this is acknowledged by Ajzen (2014), who has stated that the TPB was not intended as a theory of behaviour change, rather as a theory which can be used to understand and predict behaviour. However, whilst the TPB is not able to ascertain the most effective method of changing behaviour, the TPB does allow identification of possible targets of an intervention, and therefore can be used as a framework to devise a behaviour change intervention. The TPB has additionally been criticised (e.g. Hardeman et al., 2002; Sniehotta et al., 2014) because the majority of publications, based on the TPB, have reported correlational and/ or cross-sectional investigations, rather than experimental studies. However, this cannot be viewed as a criticism of the model itself, rather it is a criticism of researchers who use the model. Indeed, a recent meta-analysis by Steinmetz, Knappstein, Ajzen, Schmidt, and Kabst (2016) identified 82 studies investigating the efficacy of the TPB as a model for behaviour change. They found a significant mean effect size of 0.5 for behaviour change, and concluded that the TPB was a useful model when applied to behaviour change interventions.

A further criticism of the TPB is that the TPB does not account for the effect of emotions or non-conscious processes on behaviour (Conner & Armitage, 1998). However, Ajzen (2011) argues that affect and emotions can be considered to influence the underlying behavioural, normative and control beliefs. In addition, affective mood can influence which beliefs are easily accessed by memory. Furthermore, Ajzen (2011, 2014) argues that the TPB does not assume that the beliefs underpinning the TPB are rational, logical or representative of reality, rather that intentions are formed by the attitudes, subjective norms and perceive behavioural control, which in turn are influenced by their underlying beliefs, irrespective of how accurate or unbiased they are. It is in this way that the behaviour is considered to be planned or reasoned.

In summary, the TPB, is not only one of the most popular behavioural theories used to study health behaviours, it is also one of the most widely critiqued theoretical models. Other theories which have been used to understand adherence to other health behaviours, such as the Health Belief Model (Rosenstock, 1974) or the Common Sense model of Illness Representations (Leventhal, Brissette, & Leventhal, 2003), were also considered as potential models to investigate adherence to orthoses. However meta-analyses of the efficacy of these models in predicting health adherence behaviours in people with health conditions (Brandes & Mullan, 2014; DiMatteo, Haskard, & Williams, 2007) have explained less variance that similar TPB meta-analyses (Rich, Brandes, Mullan, & Hagger, 2015). Furthermore, the behaviour of orthotic use is a planned or rational behaviour, which never becomes truly habitual. The process of donning the AFO is part of planning to use the orthotic device, which requires some thought, and physical action, and conscious effort. Therefore, the TPB appears to offer the most effective theory of behaviour for understanding orthotic use.

Consequently, Chapter 4 detailed a meta-analysis of investigations using the TRA/ TPB to explain adherence to a range of health behaviours in conditions, which might give rise to an orthotic intervention. Twenty-three articles were identified meeting the inclusion criteria, and a random effects meta-analysis was used to calculate correlations between the components of the TPB, using a weighted mean effect size, r. All of the weighted mean correlations between the TPB variables were statistically significant. Meta-analytic path analysis showed that the TPB accounted for 28.3% of the variance in intentions and 14% of the variance in adherence behaviours (a moderate to large sized effect) (Cohen, 1992). The percentage of variance explained by the TPB, in the current investigation, which examined adherence behaviours, was less than when the TPB was used to investigate other general health and social behaviours (Armitage & Conner, 2001; McEachan et al., 2011). However, given that 14% of the variance accounted for in behaviour is regarded as a moderate to large sized effect in the social sciences, and 28% of the variance accounted for in intention is regarded as a large sized effect (Cohen, 1992), this suggests that overall the TPB is a useful model for explaining adherence to health behaviours in conditions where orthoses may be utilised.

Attitudes and PBC[26] were significant predictors of intention, and intention was a significant predictor of behaviour. Intention was shown to mediate the effects of attitude and PBC on behaviour in line with the TPB. Although subjective norm was not shown to be a predictor of intention, this finding does not necessarily refute the TPB. Indeed, previous meta-analyses have shown subjective norm to be a weaker predictor of intention, compared to attitude and PBC (Armitage & Conner, 2001; Godin & Kok, 1996). In addition, Ajzen (1991) notes that the relative importance of the TPB constructs of attitude, subjective norm, and PBC are expected to vary in different behaviours and situations.

A meta-analysis in methodological terms is considered to provide the strongest level of evidence (Borenstein et al., 2009; Harbour & Miller, 2001; Murad, Asi, Alsawas, & Alahdab, 2016). However, meta-analyses have also historically been criticised as 'garbage-in, garbage out' research (Eysenck, 1978; Sharpe, 1997), meaning that if poor quality data is included in the analyses, the results are likely to be flawed. For this reason, grey or unpublished literature was excluded, as although it is recognised that peer-reviewed publications do not offer a perfect method of quality control, the peer-review process proposes some merit to the methodological aspects of an investigation. In addition, inclusion of grey literature is likely to result in increased bias in the selection process, as it would be very difficult to identify all unpublished TPB/TRA investigations. In general, the findings of the meta-analysis provide some weight to Ajzen's (2014) argument that investigations of the TPB, which have low correlations and variances, are often presented as inefficiencies in the TPB model, when methodological flaws are a more likely source of poor results. For example, in the current meta-analysis, fewer than half of the studies adhered to the principle of compatibility, as detailed by Ajzen (2006) and Francis et al. (2004). In the current meta-analysis, adherence to compatibility was shown to be an important moderator, with higher correlations between intention and behaviour seen in studies, which used compatible measures. Therefore, ensuring compatibility across the measures was considered an important concept for design of the next phase of the research.

Key conclusions: Although many meta-analyses of TPB investigations have been conducted in relation to health behaviours previously (Cooke et al., 2016; Godin & Kok, 1996; McEachan et al., 2011; Topa & Moriano, 2010), and a few have also focused specifically on adherence health behaviours (Husebo et al., 2013; Rich et al., 2015), this investigation adds

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[26] PBC was conceptualised as self-efficacy. The term PBC is used to reflect the language of the TPB model, and is in keeping with the rest of the thesis.

to the general TPB literature because it focuses on adherence behaviours in specific conditions for which orthoses might be utilised. In addition, this research demonstrated use of meta-analytic techniques to review health adherence literature across a range of relevant conditions, to understand how a theory might perform when applied to a behaviour which has not previously been investigated. The application of a theoretical approach to understand adherence behaviours is not new. However, no previous researchers have used a specific theoretical model, such as the TPB to understand adherence to lower limb orthoses. This meta-analysis therefore also adds to the orthotic literature, because it demonstrates the utility of a psychological model of behaviour to predict adherence health behaviours in conditions which may give rise to an orthotic intervention, and, by extension, offers support for using the TPB to investigate adherence to AFOs.

7.2.4. What are the Underlying Behavioural, Normative and Control Beliefs affecting Use of AFOs in People with Stroke?

The identification of beliefs about a given behaviour is a key step in designing a TPB questionnaire to test the efficacy of the TPB (Ajzen, 2006; Fishbein & Ajzen, 2010). Knowledge of the beliefs underpinning a behaviour, also provides information about the cognitive foundations of one's behaviour, and therefore enables the identification of likely targets of an intervention in order to change behaviour (Conner & Sparks, 2005). Identification of these beliefs is of critical importance when investigating a new behaviour or health conditions which have not previously been investigated (Downs & Hausenblas, 2005a). However, the majority of TPB investigations, tend to bypass the beliefs elicitation phase, and only use the direct TPB constructs; or, if beliefs are utilised, they are obtained from investigations where the population do not share the same demographic or clinical characteristics. This practice therefore means that the principle of compatibility cannot be met (Ajzen, 1991), and the underlying beliefs used may not be reflective of the cognitive foundations underpinning the behaviour. Therefore, the third study of this PhD, detailed in Chapter 5, was a beliefs elicitation study, which examined the underlying beliefs affecting adherence to use of AFOs in people with stroke. Thirteen participants who had previously been prescribed or given an AFO, following a stroke by NHS Lanarkshire took part in a structured interview, in which they were asked about the advantages and disadvantages of AFO use, people who approved or disapproved of AFO use, and factors which made AFO use easier or more difficult.

Six advantages and eight disadvantages of AFO use were highlighted by participants. The most commonly stated advantages were ‘increased mobility’ and ‘supports the position of the leg or foot’, both highlighted by nine out of 13 participants. These advantages are consistent with previous research, which has identified positive aspects of AFO use (Bowers et al., 2009b; Bulley et al., 2011; Swinnen et al., 2017a; Tyson & Rodgerson, 2009). The most common disadvantage detailed was ‘discomfort’, cited by eight participants, followed by ‘problems with footwear size’ and ‘problems with footwear style’ detailed by five participants. Discomfort has been reported as a potential determinant of adherence to AFOs by a number of authors (Phillips et al., 2011; Vinci & Gargiulo, 2008). However, the high number of participants who reported discomfort was surprising, and is a concern. The clinical implications of high numbers of participants reporting discomfort are considered in more depth in Section 7.5. Problems with footwear size and style have been reported in the orthotic literature (Phillips et al., 2011; van Netten et al., 2012; Williams et al., 2007; Williams et al., 2010), but have not previously been identified in the stroke population. This may be because clinicians are so focused on the major functional losses seen in stroke, and the efficacy of the orthotic intervention, that the footwear, which accommodates the AFO, becomes an afterthought.

The majority of normative beliefs expressed were in support of using an AFO, with ‘family’ (n=10) and ‘health professionals’ (n=9) being the most frequent normative referents. However, only three participants specifically identified orthotists as normative referents, who would approve of AFO use. This finding was surprising and disappointing, given that participants were recruited via the orthotic service. This suggests a low level of recognition of the role of the orthotist by participants, and requires further investigation to explore how orthotists might promote their role more effectively. Three normative referent groups who disapproved of AFO use were identified: ‘family’, ‘acquaintances’, and ‘exercise professionals’, although, altogether, only three participants identified normative groups who might disapprove of AFO use. This is a positive finding which suggests general support in the community for use of AFOs.

Many more barriers to AFO use were identified compared to enabling factors. Thirteen factors which made AFO use more difficult and three factors which made AFO use easier were identified. The main difficulties highlighted by participants were: ‘obstacles in the environment’ (n=5), ‘needing help to put the AFO on and off’ (n=4), ‘the AFO causing pain or discomfort’ (n=4), and ‘low mood or tiredness’ (n=4). Obstacles in the environment, have not previously been identified as a barrier to AFO use in the literature. This can be explained by the laboratory settings used for the majority of AFO investigations, in which participants are usually asked to walk on a flat surface in a gait laboratory without having to deal with the obstacles frequently incurred in real-life settings. Identification of low mood or tiredness as a barrier to using an AFO as recommended, is also an important finding which highlights the relationship between psychological measures and adherence. In addition, this finding supports the outcomes of study one which identified lower levels of psychological distress, as measured by anxiety, in people using their AFOs as recommended. Evidence of this relationship between AFO use and reduced anxiety is important for a number of reasons. Firstly, it highlights the need for greater awareness of a person's mental well-being and the potential impact that this might have on successful fitting of an AFO and subsequent rehabilitation; and, consequently, highlights the need to include psychological measures as a potential variable, which might influence outcomes of AFO use. Additionally, whilst it is acknowledged that the relationship between adherence and anxiety is not one of cause and effect, there are possibilities to increase adherence to orthoses by interventions designed to reduce anxiety, or alternatively, to reduce anxiety by facilitating adherence to AFOs. Only three factors which made AFO use easier were identified by participants, and these were: 'practice in using AFO': 'having had experience in using the AFO'; and 'use of wedges'. This suggests that, in general, participants had low levels of perceived control about using an AFO.

Key Conclusions: In summary, participants tended to have a mixture of both positive and negative beliefs about AFO use. Participants had a similar number of positive and negative attitudes towards AFO use, whereas normative beliefs were mostly positive. However, far fewer enabling factors were identified when compared to barriers to AFO use. These results also highlight the complexities and contradictions involved in the decision-making processes by patients about use of AFOs, and suggests that participants will still use AFOs even when they hold some negative beliefs, or have negative experiences of using an AFO.

As the first study to identify beliefs relating to AFO use in people with stroke using the TPB, this investigation provides unique insights into the experience of people who have been prescribed AFOs following stroke. It also establishes a point of reference against which future investigations into adherence can be compared. Whilst the orthotic literature encompasses several previous investigations into adherence to orthoses (Basaran, Benlidayi, Yiğitoğlu, Gökçen, & Guzel, 2016; Phillips et al., 2011; Sangiorgio et al., 2016; Swinnen et al., 2017a; Vinci & Gargiulo, 2008), none of these investigations have considered adherence as a health behaviour. The use of a psychological framework to elicit the beliefs which underpin adherence to AFOs, is important because it has helped to identify potentially modifiable beliefs which could be potential targets of a future intervention, to increase adherence to AFOs in people with stroke. Specifically, the significance of using a theoretical approach to identify determinants of adherence, is, that interventions which are designed with a theoretical grounding, are more likely to be successful (Craig et al., 2013; Medical Research Council, 2008). However, before interventions based on theory can be designed, more evidence is required to identify the specific underlying beliefs are related to behavioural intentions and behaviour, and, consider if these beliefs could potentially be manipulated in an intervention.

7.2.5 Can the Theory of Planned Behaviour (TPB) Predict Intention and Adherence to Use of AFOs in People with Stroke?

The final study in this thesis investigated the efficacy of the TPB as a model for explaining adherence to AFOs in people with stroke. A prospective questionnaire design was used, which measured the TPB constructs of A, SN, PBC, Intention as well as the underlying beliefs were measured at Time 1, and then behaviour (adherence to AFO as recommended), was recorded one month later, at Time 2. Participants were 49 people who had been prescribed an AFO following a stroke by NHS Lanarkshire between 2014 and 2017, with 42 participants responding to the follow-up questionnaire. The design of the questionnaire incorporated key findings from the meta-analysis conducted in Chapter 4, such as use of SE as the measure for PBC, and adherence to the principle of compatibility. In addition, the beliefs elicited in the previous study, and detailed in Chapter 5, were incorporated into the questionnaire to enable relationships between the underlying beliefs with intention and behaviour to be explored. Finally, use of a prospective design ensured that the causal associations underling TPB theory (Godin & Kok, 1996) were respected.

The regression model indicated that the TPB explained 57% of the variance in intention to use an AFO as recommended, with attitude being the only significant predictor of intentions. The logistic regression model which predicted behaviour, explained 43% of the variance in behaviour, with intention being the sole determinant of AFO use as recommended. The model successfully predicted 92% of people using AFOs as recommended and 60% of participants who did not use AFOs as recommended. Overall 80% of the predictions were accurate. The model was considered a good fit, as evidenced by the significance test of the overall model, significance test of individual predictors, and the goodness of fit statistics. The odds ratio value demonstrated that an increased score of intention by one unit, was associated by a three-fold increase in the odds of using an AFO as recommended. Overall this suggests that the TPB is an effective model to understand and predict adherence to use of AFOs as recommended, and highlights that increasing intention to use an AFO would be likely to increased AFO use as recommended.

Attitude was the only significant predictor of intention, and intention was the only predictor of AFO use. Whilst PBC was not a predictor of intention ($t=-2.00$, $p=0.05$), the p-value was close to significance, and given the low power in this investigation, it might be expected that with more participants, PBC might also become a significant predictor of intention. This point, although somewhat hypothetical, is worthy of comment, as, if PBC had predicted intention, the results of the TPB study would align with the findings of the meta-analysis, detailed in Chapter 4, in terms of the significant predictors of intention and behaviour. Subjective norm was not a predictor of intention, and this is considered in further detail in Section 7.4 below. Additionally, PBC was not a predictor of behaviour, indicating that there may be some divergence between perceived control and actual behavioural control of the behaviour. In other words, participants may have found actual use of the AFO more challenging than anticipated. However, overall, the findings of this study therefore provided support for the TPB, as a model for understanding adherence to AFOs in people with stroke. This is also discussed further in Section 7.4.

As attitude was identified as the only direct predictor of intention, and intention was the only predictor of AFO use, specific behavioural beliefs, which were strongly correlated with intentions and or/ behaviour were identified as the most effective targets of a successful future intervention. These beliefs were: the AFO can improve mobility, the AFO improves balance and prevents falls, the AFO helps improvement in rehabilitation, the AFO causes pain or discomfort, the AFO is heavy, and the AFO is effortful to use. These beliefs could form the basis of a future theory-based intervention which aims to increase adherence to AFOs in people with stroke and the development of a potential intervention based on some of these beliefs is considered in more detail in Section 7.7.

Key Conclusions: This is the first investigation, which has used the TPB to predict and explain adherence to AFOs in people with stroke. However, it is also provides a unique perspective to enable an understanding of adherence to orthoses, because it is the first investigation, which has used psychological theory, specifically the TPB, to explain adherence to lower limb orthoses in any population. Furthermore, analysis of the relationship between beliefs, their direct constructs, and intention and behaviour has provided detailed insight into the cognitive foundations, which underlie adherence to AFOs. Attitude was the only predictor of intention and intention was the only predictor of behaviour. Therefore, this knowledge will enable the design of a future intervention, which aims to increase adherence to AFOs, by targeting the significant underlying attitudinal beliefs. In addition, this study provides evidence of the efficacy of TPB as a theoretical model for investigating other health behaviours, and specifically adherence behaviours.

7.3 Use of a Mixed Methods Approach to Understand Adherence

This thesis used a mixed methods approach to understand adherence to use of AFOs as recommended. Mixed methods refers to combining qualitative and quantitative techniques, methods or approaches into a single study or set of related studies (Johnson & Onwuegbuzie, 2004). The first study was a quantitative survey designed to investigate the prevalence of AFO use as recommended and to explore differences in impairment, activity limitation and participation restriction in people using AFOs as recommended. The second study described in Chapter 4, used meta-analytic techniques to quantitatively synthesise the literature describing investigations which have used the TPB to predict adherence to a range of health behaviours. A mixed methods sequential design (Creswell & Clark, 2017) was then used for the following two investigations. Firstly, a qualitative elicitation investigation was used to identify the beliefs underpinning AFO use in the stroke population. Then, these beliefs were used in a prospective quantitative questionnaire study, which tested the efficacy of the TPB as a model for predicting AFO use. The qualitative elicitation study was considered an essential component of the research design, as it ensured that the beliefs being analysed in the final study were relevant to the population being investigated (Downs & Hausenblas, 2005; Francis et al., 2004). The value of using a mixed methods approach is to enable the integration of both qualitative and quantitative data to provide a more complete view of the phenomenon being investigated (Creswell & Clark, 2017). Specifically, the qualitative elicitation investigation allowed insights into the specific underlying beliefs, which might be targeted in a future intervention, and therefore enabled a more detailed understanding of the Theory of Planned Behaviour applied to adherence to orthoses. In this thesis, use of a mixed methods approach, offered important insights, and enabled a richer understanding of the patient perspective, which quantitative methods on their own would not allow. It also ensured that the findings and recommendations for possible interventions were grounded in participants' own experiences.

7.4 Theoretical Implications of the Research

There are a number of important theoretical implications arising from this work. As highlighted previously, a theory-based approach to understanding adherence is essential in order to understand the processes of behaviour change and therefore design successful interventions (Michie et al., 2018). Overall the findings of the TPB study have demonstrated that the TPB is an effective model at predicting and explaining use of AFOs as recommended. It found that attitudes were the only predictor of intention and intention was the only predictor of behaviour. The findings suggest that people with positive attitudinal beliefs towards AFO use are more likely to have positive intentions towards AFO use, and that people with positive intentions are more likely to use AFOs as recommended.

However, the model did not perform exactly as described by Ajzen (1991). Subjective norm did not predict intention. Subjective norm has usually been identified as the weaker predictor of intention in the TPB model (Ajzen, 2011; Armitage & Conner, 2001; McEachan et al., 2011; Rich et al., 2015). Therefore, this finding was not entirely unexpected. However, the behaviour under investigation, was adherence to the AFO *as prescribed* i.e. the patient was specifically advised to use the AFO by a health professional. Therefore, the role of the health professional in advising the participant was central to the behaviour. As such, subjective norm might have been expected to be a significant predictor. This finding, that subjective norm was not a significant predictor of intention to adhere to a *recommended* health behaviour, was also seen in the TPB meta-analysis, detailed in Chapter 4. However, this contrasted with the meta-analysis of Rich et al. (2015), which found that subjective norm was a significant predictor of adherence behaviours in chronic illnesses. There could be a number of reasons for this effect. Differences in characteristics of both samples may have caused this effect. For example, the meta-analysis in Chapter 4, included participants with both chronic and rehabilitative conditions. In addition, the TPB investigation in Chapter 6 included both participants with chronic stroke and those who had experienced a recent stroke. It may be that normative influences on adherence behaviour are greater in participants who have chronic conditions, compared to participants with short term rehabilitative conditions, and normative influences, by significant others, on a person's adherence behaviour may increase over time. Additionally, there are a number of different conceptualisations of social norms such as personal, descriptive and injunctive norms (Cialdini, Kallgren, & Reno, 1991), self-identity and social identity (Terry, Hogg, & White, 1999), and moral norms (Godin, Conner, & Sheeran, 2006), which have demonstrated additional variance in intentions, above the TPB constructs. Therefore, it may be that the measurement of subjective norm, used in Chapter 6 did not accurately capture the social influence of the health professional in influencing adherence to the AFO. The lack of predictive power of subjective norm may be related to the changing dynamic of the patient-clinician relationship, with a shift away from a paternalistic relationship where the medical professional is the dominant partner, towards the patient being recognised as an equal partner in managing their own health care, and a shared decision-making model (Elwyn et al., 2010; Kaba & Sooriakumaran, 2007). It may be that normative influences of health professionals on a patient's behaviour haves reduced over the last 30 years, as patient-centred care, and respect for patient autonomy has become the dominant paradigm. Further research is required to investigate if this is the case. An alternative explanation for the reduced impact of subjective norms on intentions to use an AFO could be that, because the user interacts with the AFO in an intimate and personal way, their decision making about AFO use is more likely to be influenced by personal beliefs rather than normative beliefs. Therefore, further exploration of the role of normative influences is required to understand why subjective norms were not significant predictors of intention to adhere to an AFO as recommended.

Another difference between the findings of the investigation detailed in Chapter 6, and the theoretical model, was that PBC did not predict intention or behaviour. With regards to the prediction of intention, given the low power of this investigation, and the p-value ($p=0.05$) of the regression coefficient being so close to significance, it is possible that, with an increased number of participants, PBC would have become a significant predictor of intention. However, the non-significant effect of PBC on behaviour requires further reflection. Indeed, this effect was supported by the results of the meta-analysis described in Chapter 4. In the TPB investigation detailed in Chapter 6, PBC was conceptualised as self-efficacy, based on the findings of the earlier meta-analysis, in Chapter 4, which demonstrated that SE provided the strongest correlations with intentions and behaviour. This has been supported elsewhere in the literature (e.g. Armitage & Conner, 2001; McEachan et al., 2016). Therefore, it is unlikely that the insignificant effect of PBC on behaviour, was due to the way that PBC was operationalised. Thus, this suggests that adherence to health behaviours may actually be more difficult than initially considered by patients (i.e., PBC may not have been reflective of the actual control that participants perceived over the ability to perform adherence behaviours).

The results of the TPB study, detailed in Chapter 6, were broadly in line with findings of the meta-analysis detailed in Chapter 4, albeit with greater levels of variance explained. One potential reason for a greater variance being explained in the TPB study, compared to the meta-analysis, may have been careful questionnaire design and construction, which ensured adherence to the compatibility principle specified by Ajzen (2006). In addition, the path analysis conducted as part of the meta-analytic investigation in Chapter 4, may have explained less variance in intention and behaviour due to methodological limitations in the design of studies included in the meta-analysis. For example, some papers included in the meta-analyses did not report correlations for all constructs and did not adhere to the principle of compatibility across measures. Inclusion of the results of these articles may have reduced the reported effect-sizes in the meta-analysis, and reduced the amount of variance explained. In order to improve the standard of research in this area, there needs to be a recommended minimum level of data included in research articles (e.g., the correlation matrix between the TPB constructs might be considered a minimum requirement), which should also be supported by journal editors and publishers. Alternatively, authors could make this information available as an on-line resource.

The findings of the moderator analysis have important theoretical implications for others who have an interest in the TPB. Firstly, for TPB studies, which investigated adherence behaviours, self-efficacy demonstrated significantly higher correlations with both intentions and behaviour. This is in agreement with a number of other meta-analyses (Armitage & Conner, 2001; Downs & Hausenblas, 2005b; Notani, 1998), which, taken together, suggest that SE is be a more effective predictor of BI and behaviour, and is the most effective conceptualisation of PBC when investigating adherence behaviours in this population. Secondly, this meta-analysis identified that adherence to the principle of compatibility is an important moderator. The findings of the investigation, detailed in Chapter 4 are in line with the few previous meta-analyses (Kim & Hunter, 1993; Starfelt Sutton & White, 2016), which have investigated the principle of compatibility, and found that studies adhering to the principle of compatibility across measures demonstrate higher correlations between the TPB constructs. Therefore, the principle of compatibility might be considered as an important moderator in future TPB meta-analyses. This also highlights the need for researchers who apply the TPB in their work, to describe the adherence behaviour clearly in relation to target, action, context and time, and to highlight if there is compatibility across different constructs with reference to TACT. Finally, there was no significant difference between the magnitude of correlations, when using objective or self-reported measures of behaviour. This provided some confidence that self-reported measures may offer a reasonable alternative to objective measures. There will continue to be some situations where objective measures of adherence are not viable, and, providing that recognised biases can be adequately controlled, self-reported measures may provide results, which are not significantly different from objective measures of behaviour.

7.5 Clinical and Treatment Implications of the Research

Non-adherence to orthoses is an important challenge which can potentially impact on physical and mental health outcomes of patients (O'Brien, 2010). Adherence rates to use of AFOs as recommended as reported in the ICF study, detailed in Chapter 3 (56%), and in Study 4, which was described in Chapter 6 (63%), were broadly comparable, and highlight that adherence to use of AFOs, both in the wider orthotic population and specifically in people with stroke, is a significant concern.

The effects of stroke reach beyond the individual, to family, friends and wider society (Lutz et al., 2011). AFOs are a low cost and accessible technology, which can increase mobility and function in people with stroke. Consequently, an understanding of why people may not adhere to use of AFOs is essential when prescribing orthoses in stroke rehabilitation. In this thesis, the TPB has been used to identify beliefs, which influence a patient's decision to use an AFO. These underlying belief structures have the potential to be modified, and, therefore, could be targeted in a future intervention, which aims to increase adherence to AFOs. Such a theory-based approach has been shown to be more successful than non-theoretical approaches (Davis et al., 2015; Michie & Abraham, 2004; Michie & Johnston, 2012). Further research is required to corroborate these findings using a larger sample, ideally investigating beliefs of participants about AFO use across different areas in Scotland. This is important, in order to identify if there are any differences in beliefs in different geographical settings, and to order to ensure that any intervention designed will be relevant beyond the region where the research was conducted, However, these findings offer potential to design a theoretically informed intervention, which attempts to increase adherence to use of AFOs as recommended by targeting the attitudinal beliefs of individuals. In Section 7.7, possible methods of a behaviour change intervention to increase adherence to AFO use are considered. Therefore, this knowledge opens up possibilities of optimising AFO interventions by increasing adherence, which could potentially reduce impairment, and increase activities and participation of people who been prescribed AFOs. This may in turn reduce the burden of stroke and its deficits, on stroke survivors, and their families and ensure that orthotic services can be delivered more effectively and efficiently, with positive implications for the NHS and wider society.

The results also have clinical implications for researchers investigating effects of AFOs. The first study used the ICF as a framework to define outcome measures, and demonstrated that use of AFOs as recommended is associated with decreased impairment and activity limitation. This suggests the need for researchers to consider measuring not only the effects of the AFO on temporal-spatial, kinetic or kinematic outcomes, but to consider measuring the wider impact of the AFO on one's daily activities and levels of participation. Another important finding of this investigation was that AFO use as recommended was associated with lower levels of anxiety. To date, the relationship between psychological well-being and orthotic intervention has been given limited attention in the literature (Bulley et al., 2014; Guest et al., 1997; Vinci & Gargiulo, 2008), and this finding supports the importance of further research to understand the relationship between orthotic intervention and psychological well-being/ distress. Specifically, the role that psychological interventions, which aim to increase well-being, might have on influencing orthotic use and uptake should be investigated. Also for clinicians these findings are important, because they remind the clinician to view the person that is being fitted with an orthotic device holistically, and consider the effect the orthosis has beyond its impact on gait. Consideration of routine use of outcome measures, which are feasible in the clinical environment, and are linked to the ICF constructs of body function and structure, activity and participation, would do much to build the general evidence base for use of AFOs.

The TPB investigations, detailed in Chapters 5 and 6, also have important implications for the orthotic clinician. The orthotist has a valuable role to play in delivering positive messages about the orthosis, and what the orthosis might enable the participant to do, and also in counteracting the negative beliefs, which might reduce adherence or discourage a patient from using an AFO at all. Fishbein et al. (2001) explain that it is more likely to be challenging to change a descriptive belief, based on a person's direct personal experience, compared to changing an informational belief, based on knowledge provided by an outside source. Therefore, it is likely that people who have never previously used an AFO may be more amenable to changing their beliefs about AFO use, than someone who has previously experienced using an AFO and had a negative experience. This highlights the important responsibility on the orthotist to ensure that they achieve the optimal fitting and prescription on the first attempt and the patient has a positive experience, and therefore will develop positive beliefs about AFO use, based on their experience. Whilst orthotists have the opportunity to influence beliefs of participants by directly influencing a patient's personal experience, a surprising finding of the elicitation study was that orthotists were not recognised as an important normative group by the majority of participants. This could be because patients may only see the orthotist a few times in their rehabilitation, yet may see other AHPs, such as physiotherapists on a more regular basis whilst using their AFO. However, this highlights that orthotists have an important role to play in promoting their own professional role to patients. In addition, the use of clear, visible name badges with professional titles (Kapur, 2016) may help to increase awareness of the orthotist's role among patients and the general public.

Attitudinal beliefs were shown to be significant predictors of intention to adhere to AFO use in the TPB study. In addition, the meta-analysis which investigated health adherence behaviours in conditions for which AFOs might be prescribed, also found that attitude was the most important predictor of intention. This has important implications for clinicians, who have the opportunity to shape attitudinal beliefs, especially in the earlier stages of rehabilitation, prior to patients developing beliefs based on their direct experience. The information that clinicians provide to patients with stroke, about the advantages of AFO use are important. Clinicians should focus on the beliefs which were found to be strongly associated with intention or behaviour. Based on the findings of the beliefs analysis in Chapter 6, orthotists and other health professionals should highlight the advantages that AFO use can provide: such as increased mobility for the patient, the wider effects of increased mobility on participating in other activities, and increased opportunities for socialising with others. In addition, clinicians can emphasise increased safety provided by the AFO for the user, with the resultant reduced likelihood of falls. Heath professionals can also stress the role that AFOs can play in the rehabilitation process, such as helping the patient to achieve important milestones in rehabilitation, possibly, more quickly than without using the AFO. Whilst orthotists are the health professionals with the greatest knowledge about orthoses and their benefits, they were viewed as a less important normative group by participants in the elicitation study. Therefore, all AHPs have a vital role in being able highlight these important benefits of AFO use. It is important that clinicians do not disregard the potential disadvantages of AFO use for the patient, and they should be able to offer advice which might prevent disadvantages from becoming a problem. For example, patients should be informed that discomfort or pain should not be expected when using an AFO, and if this is experienced, they should attend for a review, rather than persevering with an uncomfortable device. Given that discomfort or pain when using an AFO is a sign that there is a potential problem with the fit, the high number of participants (8/13) who identified discomfort or pain as a disadvantage of AFO use, in the beliefs elicitation investigation, was concerning. This finding should be a challenge for all orthotists, to ensure that the fit and comfort of AFOs are satisfactory before the device is delivered to the patient, and a reminder of the need to offer subsequent reviews to ensure that these problems do not arise.

Given that negative experiences or difficulties with the orthosis, may lead to the formation of negative beliefs (e.g., that the AFO will cause pain or discomfort or the AFO is too heavy), the patient should be able to see an orthotist in timely manner to discuss any worries or concerns they may have. The orthotist may then be able to swiftly resolve such issues. Therefore, ease of access to an orthotist, without having to wait several weeks for adjustments, is important in addressing patient concerns and potentially preventing negative beliefs from forming. However, whilst orthotists are the health professionals best placed to deliver such advice, given current workforce levels (ISD Scotland, 2018a; Scottish Orthotic Services Review Group, 2005), access to a timely appointment may be challenging for patients. Hence, more investment in human resource is recommended to enable appropriate access to services when required. In the interim, there may be scope for orthotists to prioritise appointments for patients who have recently been prescribed their orthoses, so that the likelihood of patients forming negative beliefs is reduced.

For the multidisciplinary team, who work with people with stroke, there are also important implications. Firstly, clinicians should consider that patients requiring orthotic intervention may already be required to adhere to a range of additional health behaviours related to that specific condition. For example, a patient following stroke may be required to undertake several health behaviours on a daily basis, such as taking oral medication, performing exercises which address the lower and upper limb weakness, eating an appropriate diet, and attending therapeutic appointments, as well as being asked to wear an AFO to assist in walking. An overview of the adherence regimes being recommended, may be helpful in allowing health professionals to better understand some of the challenges and assist in advising the patient in such a way that the adherence behaviours complement each other, or can even act as a trigger to perform other health behaviours. Additionally, consideration of ways to prevent a patient from becoming overwhelmed by the health behaviours they are expected to perform, may assist in enabling adherence behaviours. This thesis also highlights the need for psychological input into the stroke rehabilitation team. The psychologist may be able to provide psychological support for people who have mental health difficulties such as anxiety and depression, and explore barriers in adherence to therapy or orthotic management. They might also help the team to develop individually tailored interventions which support the patient to obtain the optimal results for their rehabilitation.

7.6 Strengths and Limitations of the Thesis

The strengths and limitations of each investigation have been detailed throughout the relevant chapters. However, when considered together, the overall strengths and limitations of this thesis warrant further discussion, detailed below.

7.6.1 Strengths

7.6.1.1 Use of a Theoretical Approach to Understand Adherence to AFOs

This thesis is the first body of work which has applied psychological theory to understanding adherence to AFOs. The application of theory to understanding adherence is important because it is known that theory-based interventions are more likely to deliver successful behaviour change than non-theory-based interventions (Michie et al., 2018; Michie et al., 2005). The TPB was the focus of the meta-analysis in Chapter 4, and investigated the efficacy of the TPB model in explaining adherence to health behaviours in conditions for which orthoses might be applied. Then, an elicitation beliefs investigation, guided by the TPB enabled the behavioural, normative and control beliefs influencing use of the AFO to be identified in Chapter 5. In Chapter 6, these beliefs were then used in the development of a TPB questionnaire, which was used to test the efficacy of the TPB as a model for predicting use of AFOs in people with stroke. This demonstrated that the TPB is a valid model to use in this population, and also enabled specific beliefs to be identified which could be targets in a theory-based intervention to increase adherence. Thus, the primary strength of this thesis is use of a cross-disciplinary approach, using psychological theory, to generate new knowledge about adherence to orthotic devices. This paves the way to applying this model to understanding adherence to other orthotic devices and assistive technologies across other populations.

7.6.1.2 Elicitation of Beliefs

Although a beliefs elicitation investigation is considered an important stage in the design of a TPB questionnaire (Ajzen, 2006), this step of the research process is frequently bypassed by other researchers (Downs & Hausenblas, 2005b). Researchers often 'import' beliefs obtained from other investigations, from similar group of participants, in place of an elicitation beliefs investigation (Curtis et al., 2010). However, this may result in beliefs being used in the questionnaire, which are not relevant or appropriate to the population under investigation. Therefore, an overall strength of this thesis was conduction of an elicitation investigation, using participants who met the same inclusion criteria as those who took part in the prospective questionnaire study. The characteristics of the participants in the elicitation investigation, and the follow-up prospective TPB investigation, were very similar. The only difference identified was that in the elicitation investigation, no participants below the age of 50 were recruited. Between 10-15% of people with stroke are thought to be young adults[27] (Smajlović, 2015), and this was in line with the prospective TPB study, in which seven participants (14%) were less than 50 years old. Despite this difference, between the elicitation study and follow-up TPB investigation, the mean ages of both groups of participants were similar, and the beliefs extracted in the elicitation investigation were not particular to one specific age group, giving some confidence that different beliefs would not be elicited if some participants from a younger age group had been recruited.

7.6.1.3 Design of Prospective TPB Questionnaire

A notable strength of this thesis was the design of the TPB investigation, which addressed a number of important issues. Firstly, use of a prospective design was essential to ensure that the theoretical causal pathway between intention and adherence was replicated in the measures (Ajzen & Madden, 1986). Therefore, if behaviour is measured at the same time as other TPB constructs, what is actually being measured is past or current behaviour (McEachan et al., 2011). Consequently, the TPB constructs, of intention, attitude, subjective norm and PBC were measured at Time 1, and adherence to use of AFOs as recommended was measured one month later at Time 2. This enabled a temporal sequence between the

[27] Smajlović (2015) notes that the definition of young adults is somewhat arbitrary but can be considered to be less than 45 or 50 years.

predictors and adherence to be established, which was reflective of the theoretical model. Secondly, the questionnaire and participant information sheet were designed to ensure that potential participants were not inadvertently excluded from the research process due to disabilities associated with stroke, such as aphasia, cognitive difficulties or upper limb dysfunction. Ease of accessibility of the participant information sheet and the questionnaire aimed to ensure that participants recruited were reflective of the general research population, and would maximise the potential sample from participants might be recruited. Finally, inclusion of the underlying beliefs in the questionnaire enabled particular beliefs to be identified (those associated with intention and/or behaviour) which can be used to design a theoretically informed intervention, which aims to increase adherence to AFOs in people with stroke.

7.6.5.4 Inclusion of Participants who did Not Use their Orthoses

A key strength of this thesis was the inclusion of participants who had been prescribed orthoses but did not use them. This group of participants have important insights into the reasons for non-adherence, and inclusion of this patient group is necessary to understand the full range of beliefs held by all people who have been prescribed AFOs. Targeting of these individuals was considered in the design phase of all three investigations, and careful phrasing and wording in the questionnaire and participant information sheets, informed these participants that they had a valuable contribution to make. Non-users (n=29, 26.1%) were included in the first investigation, described in Chapter 3, which examined differences in impairment, activity, limitation and participation between people who used their AFOs as recommended and those who did not. Non-users were also specifically targeted in the beliefs elicitation investigation (n=2, 15.4%), described in Chapter 5, and also participated in the prospective TPB investigation (n=8, 17.4%), which tested the efficacy of the TPB model. Non-adherent patients are an important group to recruit because they are likely to be an under-reported group in studies into adherence (Lieber, Helcer, & Shemesh, 2015). Furthermore, the design of interventions based on beliefs of participants who are adherent may lead to interventions which are less likely to be successful in non-adherent patients (Shemesh et al., 2017). Therefore, the inclusion of participants who did not use AFOs as recommended across all studies, ensured that the results were reflective across the whole population of participants with differing levels of adherence and therefore enhances knowledge of the phenomenon of adherence to AFOs.

7.6.2 Limitations

7.6.2.1 Low Response Rates

Response rates for both surveys conducted in this thesis, and detailed in Chapters 3 and 6, were low. The reasons for these low levels and future ways of improving the response rate are considered below. The first study, described in Chapter 3, which aimed to identify differences in impairment, activity limitation and participation restriction in participants using AFOs as recommended and those not using AFOs as recommended, had a response rate of 17%. Although the percentage of participants who responded was low, the number of participants (n=157) was considered a large sample size in an orthotic investigation, compared with other investigations into adherence to orthotic devices (Swinnen et al., 2017a; Vinci & Gargiulo, 2008). Unfortunately, it was not possible to send non-responders a second questionnaire due to the prohibitive cost of resending the questionnaires to all participants. In future investigations, use of appropriate coding on the initial questionnaire would allow identification of non-responders to enable them to be targeted with a follow-up questionnaire. In addition, a follow-up questionnaire would require increased resource to target non-responders in order to provide the opportunity for an improved response rate.

The TPB questionnaire study, described in Chapter 6, had a response rate of 31%. Following on from the experience of the first investigation, described above, a high percentage of non-responders was anticipated, and funding was obtained to enable resending of questionnaires. Also use of coding and consent forms allowed the identification of non-responders, and enabled questionnaires to be resent to non-responders only. In addition, efforts made to maximise the sample size included follow-up phone conversations with participants and their families, and assistance offered in filling in questionnaires. Although the response rate was increased, compared to the first study, the sample size is still considered lower than ideal for a postal survey (Asch, Jedrziewski, & Christakis, 1997; Morton, Bandara, Robinson, & Carr, 2012). Phone conversations with potential participants provided a greater appreciation of the difficulties for participants and their carers in completing a relatively straightforward questionnaire. The low response rate appeared to be reflective of the challenges that stroke survivors and their families had in coping with daily life, with a significant mobility disability, and the difficulty in finding time to complete the questionnaire. Efforts were made to reduce the burden on participants by reducing the length of the questionnaire, and taking steps to reduce the cognitive effort required, by ensuring the questionnaire and participant information sheet were accessible. An additional step to reduce the burden on research participants in a similar future project, might include offering the option of an interviewer administered survey, although this would have significant cost implications.

The main concern with a low response rate in any survey is in the risk of potential bias due to differences between responders and non-responders (Morton et al., 2012). In a future prospective questionnaire survey, a possible method of increasing participation might be to provide a financial incentive to participants who complete the questionnaire, either at one or both time points. However, the ethical implications of this decision, including possible coercion, compromised decision making by participants, or a skewed data pool (Grady, 2005) would require careful consideration. Another approach could be to accept a lower response rate but to request basic demographic and clinical information about all respondents as part of the research design, to enable a comparison of the characteristics of responders and non-responders. This would enable potential bias to be explored and the results could be interpreted in light of any potential bias.

7.6.2.2 Use of Self-reported Measure of Adherence

It is recognised that a self-reported measure of adherence was used, and this is acknowledged as a limitation of the studies conducted as part of this thesis. The possibility of measuring AFO use objectively by use of pressure, temperature or activity monitors was considered in the design phase of this project. However, any monitor would require to be embedded in the orthosis during the manufacture stage, and this was not feasible primarily due to the financial cost of manufacturing and fitting customised orthoses with a monitor for each participant. In addition, there is also the possibility that the presence of a monitor to measure adherence may, in itself, alter participant behaviour. Therefore, whilst it is known that self-reported measures of adherence can provide inflated estimates of the behaviour, due to accuracy of recall, self-presentational or response biases (Podsakoff et al., 2003), self-reported measures may be an acceptable alternative, provided that steps are taken to reduce these biases. In the investigations conducted as part of this thesis, such steps were taken. These included careful and appropriate wording of the questionnaires, encouragement of an honest response in filling in the questionnaires, and also, professionals directly involved in care were not able to access patient-identifiable data. Additionally, the results of the moderator analysis conducted as part of meta-analytic review, demonstrated no significant difference in correlations between the TPB variables and behaviour when objective or self-reported measures of behaviour were measured. This therefore provided some support for the use of self-reported measures of behaviour. A future TPB research investigation, which is dependent on self-reported measures, might seek to validate these by using a monitor to measure adherence objectively in a smaller sub-sample of participants. This would enable a comparison of self-reported and objective measures in this small sub-sample, and could provide additional reassurance of the acceptability of a self-reported measure of adherence in the larger sample.

In addition, another limitation of the subjective measure of adherence was that the definition, "use of the AFO as recommended" was potentially open to interpretation by participants. The phrasing used was designed to capture many of the complexities of adherence, including the time the AFO was used, but also encompass use of an appropriate interface, donning the AFO correctly, an appropriate choice of footwear, and follow-up care and maintenance of the orthosis. However, the participants may have focused on specific aspects of use of the AFO as recommended, when answering the questionnaire, without recognising the multiple aspects of adherence identified by the researcher.

7.6.2.3 Insufficient Information included in Papers used in Meta-analytic Review

One of the limitations of the meta-analysis described in Chapter 4, was in relation to limited data provided in the investigations included in the meta-analyses which resulted in their exclusion from some of the moderator analyses. This reduced the power of the moderator analyses, and was a likely reason why heterogeneity was only partially explained. Therefore, when using the TPB to investigate adherence behaviours to manage health conditions, the following recommendations are made: a clear definition of adherence should be provided with reference to the target, action, context and time, an explicit description of the measurement of adherence should be included, inclusion of details regarding operationalisation of attitude, subjective norm and PBC measures is necessary, and reporting should consider variables for specific health conditions independently if possible. Despite efforts to obtain such materials from authors, many people reported that the data had not been measured or was no longer available. It is recognised that a tension exists between authors being able to meet word count requirements for publication, and inclusion of detailed descriptions of constructs or variables, which might be included in future meta-analyses. In such instances, authors could consider making such data freely data available on-line, for further analyses by others.

7.6.2.4 Lack of Control of Orthotic Factors affecting Adherence

A general limitation of this thesis was that the research designs, used in different investigations, did not enable the fit or the function of the orthosis to be evaluated. It is possible that an inadequate fit or function of the AFO could have affected adherence (Malas, 2011; Vinci & Gargiulo, 2008) by influencing the beliefs of the individual. However, if people develop negative beliefs because of direct experiences of, for example, pain or discomfort caused by the AFO, rather than attempting to change the underlying beliefs of participants, the appropriate intervention would be to address inadequacies in fit or function of the AFO. A future investigation might also seek to provide a quantitative assessment of fit and function of the AFO, by an orthotist, not directly involved in patient care, who could provide an objective assessment of fit or function.

Despite these limitations this investigation provides evidence that the TPB is an effective model at explaining AFO use as recommended in the stroke population. Furthermore, the strengths of this thesis highlighted in Section 7.6.1 above, should encourage other researchers to use the TPB across other orthotic interventions and health conditions, and to investigate other adherence health behaviours in the stroke population.

7.6.2.5 Limitations of Multiple Comparisons in Statistical Analysis

In Chapter 3, in the ICF study, multiple comparisons of the cross-sectional data were carried out. Efforts were made to ensure that only relevant comparisons were made between specific outcomes relevant to the ICF framework, which were specified a priori. Multiple comparisons were necessary as the ICF framework aims to provide a holistic view of functioning and disability, and includes a number of components which are measured using a range of different outcomes. This was further compounded by an unexpected finding of a large number of participants (27%), who did not know recommendations for AFO use. It was decided to include this group in comparing the outcomes of impairment, activity limitation, participation restrictions and measures of psychological distress, because this group might contribute valuable information about outcomes related to a previously undocumented group of participants, further increasing the number of comparisons which were made.

It is acknowledged that there are limitations when several multiple comparisons are made simultaneously, because this can increase the likelihood of a Type 1 error (i.e. if an excessive number of comparisons are made, there is a risk there is that any significant effects found are due to chance.) Bonferroni corrections or similar are recommended in such instances (Abdi, 2007). However, there are challenges in conducting corrections for multiple comparisons, in that the nature of the correction is highly conservative, and, as the chance of a Type 1 error decreases, the likelihood of a Type 2 error (i.e. not finding a significant result, when one actually exists) increases, and thus, potentially useful findings may be overlooked (Streiner, 2015). To prevent this problem, Schulz and Grimes (2005) recommend limiting the number of outcomes used in comparisons. However, this is not feasible when complex interventions (e.g. such as use of AFOs) are being investigated, using a framework such as the ICF which has a number of outcomes. Therefore, use of such corrections, and appropriate interpretation of such results, may be necessary in future similar investigations.

7.7 Areas of Further Research

There are several areas of further research that are suggested to complement and advance the investigations described here. It has been acknowledged that the sample size in the TPB investigation was small, and therefore it would be important to attempt to replicate this investigation using a larger sample of participants with stroke, by recruiting participants across several health boards in Scotland, or elsewhere in the UK. Despite this limitation, it is worth noting that, significant results were obtained in line with the TPB theory. This investigation has been conducted on participants with stroke, and, therefore, it is not known if similar findings might be found in people with other conditions for which AFOs are prescribed. Given that people are prescribed AFOs for a wide number of different conditions, and they present with a varied range of functional problems, affecting both physical and mental well-being to a different degree, it is possible that the TPB may perform differently across these conditions. Consequently, conducting such an investigation across other patient groups would be of value in understanding wider applications of the TPB to understanding adherence to orthoses.

Replicating these investigations using objective measures of adherence would be of value. In order to measure adherence to AFOs a temperature, pressure monitor could be applied to the inside surface of the device, or an activity monitor could be attached to the orthosis. Due to the increased costs and practical considerations associated with such an investigation, it might be more feasible to conduct objective measures with a smaller subsample of the population. A potential difficulty when measuring adherence objectively, is that when participants know that their behaviour is being measured, they may subsequently modify their behaviour, therefore artificially inflating their adherence rate. To manage this, an element of deception might be required in recording the adherence measure. For example, the participant could be informed that the monitor is measuring stress or strain in the material, rather than adherence, in order to prevent the participant altering their adherence behaviour. However, this might be ethically problematic. Using an authorised deception approach, where the participant is informed that there is an element of deception which will be revealed after the data has been collected (Jarl, 2018), could offer an acceptable solution.

Particular thought was given to the definition of adherence in this thesis (use of AFO as recommended), in order to accommodate a range of different conditions and prescription options. However, the lack of clarity and evidence for correct dosage of AFOs was apparent and remains a significant gap in the AFO literature. Whilst the definition used in this thesis allowed alignment with clinician recommendations for use, and also accommodated for different recommendations provided for different patients, it is recognised that recommendations for orthotic use may vary depending on the knowledge and experience of the orthotist and other members of the AHP team. Therefore, further research is required to evaluate outcomes of different use patterns in order to identify optimal wearing times and create guidelines for appropriate use dependent on functional losses of the patient.

The investigation has highlighted some possible beliefs about AFO use, which could be used as targets in a future intervention to increase adherence. Six potential attitudinal beliefs, which were associated with intention and/or behaviour, were identified. Beliefs which are related to a patient's direct experience may be the most challenging beliefs to change (Fishbein et al., 2001). Therefore, it may be quite difficult to affect beliefs linked to personal experience such as the AFO is heavy, and the AFO causes discomfort or pain. Hence, a likely intervention might focus on the belief that "the AFO improves my mobility" and could emphasise the value that increased mobility can bring, when using an AFO, by highlighting the ability to return to enjoyable physical activities such as cooking and gardening, as well as the ability to move around in the community and socialise with others. In the same way, an intervention to increase adherence to AFOs might emphasise the belief "the AFO improves balance and prevents falls", by highlighting not only, the advantage of increased stability and prevention of falls but also, the wider benefits of improved balance whilst performing different activities and socialising.

Whilst the TPB offers the possibility to identify specific beliefs which might be targeted in an intervention, it does not suggest how these cognitions might actually be changed (Hardeman et al., 2002). A wide range of methods for implementing behaviour change interventions are available (e.g., goal setting, action planning, motivation interviewing, increasing skills, persuasion), and have shown some success in facilitating behaviour change (Michie & Abraham, 2004; Michie & Johnston, 2012; Steinmetz et al., 2016). However, it is not known which method, or combination of methods, is likely to be most successful in changing attitudes towards AFO use in people who have been prescribed AFOs following a stroke. In reviewing the literature in this area, Steinmetz et al. (2016) established that increasing skills was the most successful individual behaviour change method for changing attitudes in a meta-analysis of behaviour change interventions based on the TPB. However, this finding was limited by the small number of studies (k=8) included in the moderator analysis and the use of more than one behaviour change method in a number of investigations included the meta-analysis. Consequently, further work is consequently required to identify the most effective behaviour change techniques in this population. A possible strategy would involve a review of successful behaviour change techniques used in the literature, followed by design of an intervention in collaboration with stroke survivors and clinicians, pilot testing and refinement of the behaviour change intervention, before the efficacy of the intervention is investigated.

7.8 Reflections on Challenges Faced

The process of completing this thesis, has afforded numerous opportunities for reflection, and the author wishes to share with the reader, a few reflections on the significant challenges faced. A major difficulty faced was in accessing and recruiting participants. In the first investigation, detailed in Chapter 3, there was a delay in over one year before gaining access to participants, despite ethical approval having been obtained, and a prior agreement to allow contact with participants. The reasons for the delay were unclear, but ultimately the issue was resolved by perseverance, continued persistent requests to allow access, and sustained communication. In the TPB investigations, detailed in Chapters 5 and 6, although the consultants and orthotists in NHS Lanarkshire were very supportive of the project, the requirement by the NHS board to have the support from the Scottish Stroke Research Network, meant that without successful funding from specific organisations, recruitment could not begin. This problem was finally overcome with an agreement that the Chest Heart and Stroke Scotland (CHSS) would support the project, but with no allocated funding. On reflection, success in recruiting participants was related to building and maintaining personal relationships with collaborators, and negotiating and communicating with gatekeepers of services who enabled access to the data.

Another challenge was maintaining an up to date meta-analytic review, over a period of eight years, due to part-time study, which resulted in several major searches to update the literature. The greater length of time over which a literature review requires updated inevitably increases the risk that another research group will win the race to publication. Indeed, a systematic review (Rich et al., 2015), similar to one already conducted by the author was published, in the interim. Whilst this was frustrating, this enabled a more focused and relevant meta-analysis to be designed, which strengthened the overall narrative of the thesis. A valuable lesson learned from this process was that some aspects of research are out with the researcher's control. However, even when other research teams are working on a similar topic, their research can be used as an opportunity to modify and strengthen one's own work. On reflection, it would also have been useful to have sought advice from a librarian at an earlier stage of the process to enable a more effective search strategy to be devised, and reduce the amount of time utilised in searching the literature.

The greatest challenge has been in finding sufficient time to devote to this work, whilst working full-time as a teaching fellow. The demands of a teaching role mean that there several times in the academic calendar when all efforts had to be focused on teaching commitments. This caused difficulty in building momentum and maintaining progress, and an inability to meet self-imposed deadlines, which led to constant dissatisfaction with the process. This challenge was never truly resolved and remained a constant theme throughout. Perseverance and determination were key factors in completing this work, and a true appreciation of the luxury of immersing oneself in research and writing has been gained.

7.9 Concluding Remarks

AFOs are used to manage hemiplegic gait, and improve the biomechanical deficits caused by stroke (Bowers et al., 2009b; Tyson et al., 2013). However, the positive effects of AFOs following stroke are dependent on people using their AFOs as recommended. To date, adherence to AFOs has received scant attention in the literature. This thesis has addressed this important gap in current knowledge. Firstly, in Chapters 3 and 6, adherence was shown to be a significant concern for people with a range of different conditions, including stroke. This thesis also demonstrated that AFO use as recommended is associated with reduced impairment, activity limitation and psychological distress, and highlights the need for researchers and clinicians to look at a broader range of outcome measures, when measuring effects of orthoses. One of the overarching aims of this thesis was to apply psychological theory to understand and explain use of AFOs in people with stroke. This thesis has demonstrated that the TPB is an appropriate model for explaining AFO use as recommended in people with stroke. This thesis therefore highlights the value of using a theoretical approach to understand AFO use, and offers some insights into potential targets of future interventions, which might increase adherence.

This thesis has also highlighted some future avenues for further research. It provides the basis and supports the rationale to apply the TPB to other orthotic interventions and health conditions, to gain a more rounded understanding of the value of TPB theory when applied to orthotic use more broadly. Additionally, stronger evidence for the appropriate wearing recommendations is required, and this will ultimately strengthen any future research into adherence and indeed into interventions, which aim to increase adherence. Finally, this research offers the potential to develop a theory-based intervention, which aims to target attitudinal beliefs that people with stroke may hold about use of AFOs which could increase intention to use an AFO, and actual AFO use of the AFO as recommended, with potential to reduce impairment, and increase activities and societal participation.

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Appendix 3.1 Ankle-foot Orthosis (AFO) and Health Questionnaire

This survey is being carried out to investigate peoples' experiences of using their ankle–foot orthosis (AFO/splint/brace), and their general health. As someone who has been prescribed, currently has, or has previously had an AFO we would greatly appreciate your help with this survey. Even if you no longer use your AFO, we would like you to complete this questionnaire. It should not take long to complete (most of the questions require a response by ticking a box, or by giving one or two word answers). The questionnaire can be completed by you or with the assistance of a carer. Please answer as honestly as possible. Your answers will be treated confidentially and used for research purposes only.

SECTION 1: Basic background information

Q1.1 Are you:

Male ☐

Female ☐

Q1.2 How old are you?

……………… Years old

Q1.3 Where do you live? *Please indicate postcode (e.g.* G75 9; *including first number of second part of the post code)*

………………………………………….

Q1.4 What condition do you have that required an AFO to be recommended for you?

Stroke ☐

Cerebral Palsy ☐

Multiple Sclerosis ☐

Poliomyelitis ☐

Spinal Cord Injury ☐

Spina Bifida ☐

Charcot- Marie Tooth Disease ☐

Osteoarthritis ☐

Nerve injury ☐

Bone injury ☐

Muscle/Tendon injury ☐

Don't know ☐

Other ☐ Please Describe……………………………………………………

Q1.5 How would you rate the seriousness of this condition? *Please tick ONE option*

Extremely serious ☐

Fairly serious ☐

Not very serious ☐

Not at all serious ☐

Q1.6 When were you diagnosed with this condition? *If you are not sure please give your best guess*

Month ………………………… Year …………………………

Q1.7 Do you have any other health conditions?

Yes ☐ ***If yes, please tick the appropriate boxes***

No ☐ ***If no, please go to SECTION 2***

Asthma ☐

Coronary Heart disease ☐

Cancer ☐

High blood Pressure ☐

Stroke ☐

Musculo-skeletal problems ☐

Kidney disease ☐

Digestive problems ☐

Genito-Urinary problems ☐

Epilepsy ☐

Depression ☐

Visual Problems ☐

Hearing problems ☐

Other ☐ Please Describe…………………………………………….

Q1.8 How would you rate the seriousness of this/these other condition(s)? *Please tick ONE option*

Extremely serious ☐

Fairly serious ☐

Not very serious ☐

Not at all serious ☐

SECTION 2: About Your Ankle-Foot Orthosis / Splint / Brace

Q2.1 Which leg is your AFO made for?

Right leg ☐ ***Fill in Section 2A***

Left leg ☐ ***Fill in Section 2B***

Both legs ☐ ***Fill in Sections 2A AND Section 2B***

SECTION 2A: Your AFO – right side

Q2A.1 When did you first get an AFO for your right leg? *If you are not sure please give your best guess*

Month ………………………… Year …………………………

Q2A.2 When did you get the current AFO for your right leg? *If you are not sure please give your best guess*

Month ………………………… Year …………………………

Q2A.3 Who fitted the current AFO for your right leg? *Please tick ONE option*

- Orthotist ☐
- Physiotherapist ☐
- Occupational Therapist ☐
- Doctor ☐
- Other ☐
- Don't know ☐

Q2A.4 Were you given a reason for why you needed your most recent AFO for your right leg?

- Yes ☐ ***If yes, please go to Q2A.5***
- No ☐ ***If no, please go to Q2A.6***
- Don't know ☐ ***If you don't know, please go to Q2A.6***

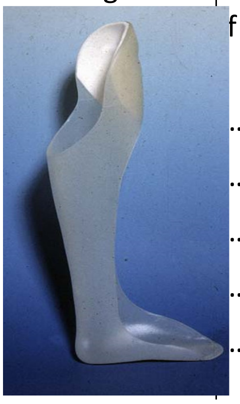
Q2A.5 Did the explanation make sense to you?

- Yes – fully ☐
- Yes – partly ☐
- No, not at all ☐

Q2A.6 Before being given your most recent AFO for your right leg were you given one to try out, or test?

- Yes ☐
- No ☐
- Don't know ☐

Q2A.7 **What type of AFO is your current one for the right leg?** *Please tick ONE option*

☐ A rigid AFO - e.g.	☐ A flexible AFO – e.g.	☐ An AFO with joints - e.g.	☐ A ground reaction AFO - e.g.	☐ Other	☐ Don't know
				f other, please describe …………………… …………………… …………………… …………………… ……………………	

Q2A.8 **Is the current AFO for your right leg made specifically for you (e.g. from a cast or a computerised scan of your leg)?**

Yes ☐

No ☐

Don't know ☐

Q2A.9 **How satisfied are you with the current AFO for your right leg?**

Very satisfied ☐

Satisfied ☐

Dissatisfied ☐ ***Please state why……………………………………………***

Very dissatisfied ☐ ***Please state why……………………………………………***

Q2A.10 **Can you put it on and take it off yourself?:** *Please tick ONE option*

Yes, and it is easy ☐

Yes, but it takes a lot of effort ☐

No, I need help ☐

Don't know, I haven't tried ☐

SECTION 2B: Your AFO-left side

Q2B.1 **When did you first get an AFO for your left leg?** *If you are not sure please give your best guess*

Month ……………………… Year ………………………

2B.2 **When did you get the current AFO for your left leg?** *If you are not sure please give your best guess*

Month ……………………… Year ………………………

Q2B.3 Who fitted the current AFO for your left leg? *Please tick ONE option*

Orthotist	☐
Physiotherapist	☐
Occupational Therapist	☐
Doctor	☐
Other	☐
Don’t know	☐

Q2B.5 Did the explanation make sense to you?

Yes – fully	☐
Yes – partly	☐
No, not at all	☐

Q2B.4 Were you given a reason for why you needed your most recent AFO for your left leg?

Yes	☐	***If yes, please go to Q2B.5***
No	☐	***If no, please go to Q2B.6***
Don’t know	☐	***If you don’t know, please go to Q2B.6***

Q2B.6 Before being given the most recent AFO for your left leg, were you given one to try out, or test?

Yes	☐
No	☐
Don’t know	☐

Q2B.7 What type of AFO is the current one for your left leg? *Please tick ONE option*

☐ A rigid AFO - e.g.	☐ A flexible AFO – e.g.	☐ An AFO with joints - e.g.	☐ A ground reaction AFO - e.g.	☐ Other	☐ Don’t know
				If other, please describe …………………… …………………… …………………… …………………… ……………………	

Q2B.8 **Is the current AFO for your left leg made specifically for you (e.g. from a cast or a computerised scan of your leg)?**

Yes ☐
No ☐
Don't know ☐

Q2B.9 How satisfied are you with the current AFO for your left side?

Very satisfied ☐
Satisfied ☐
Dissatisfied ☐ ***Please state why…………………………………………***
Very dissatisfied ☐ ***Please state why…………………………………………***

Q2B.10 **Can you put it on and take it off yourself?:** *Please tick ONE option*

Yes, and it is easy ☐
Yes, but it takes a lot of effort ☐
No, I need help ☐
Don't know, I haven't tried ☐

SECTION 3: How do you use your Ankle-Foot Orthosis / Splint / Brace?

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. We would like to ask you a few questions from about how you use your orthosis**.**

Q3.1. **Do you use your AFO(s)?**

Yes ☐ ***If yes, please go to Q3.2***
No ☐ ***If no, please go to SECTION 4***

Q3.2 **Approximately, how many hours a day do you use it/them?** **……………** Hours per day

Q3.3 **Approximately, how days per week do you use it/them?** **…………….** Days per week

Q3.4 **Did you receive any training to use your orthosis/orthoses?**

Yes ☐
No ☐

Q3.5 Do you use your AFO(s): *Please tick ONE option*

More often than recommended ☐
About as often as recommended ☐
Less often than recommended ☐
Don't know – I have not been told how often to use it ☐
Don't know – I can't remember how often I was told to use it ☐

Q3.6 Does/ do your AFO(s) stop you from doing anything?

Yes ☐ ***If yes, please detail...***

No ☐

Q3.7 What is the longest distance you can walk without the AFO(s)? ....(metres or km)

Q3.8 What is the longest distance you can walk with the AFO(s) ....(metres or km)

Q3.9 To what extent do you use your AFO(s) for the following activities? *Tick ONE box for EACH activity*

		Rarely or not at all	A little	Moderately	Quite a bit	Most or all of the time
(a)	For walking inside the home	☐	☐	☐	☐	☐
(b)	For walking outdoors	☐	☐	☐	☐	☐
(c)	For long walks outside	☐	☐	☐	☐	☐
(d)	For sitting in a chair	☐	☐	☐	☐	☐
(e)	For sporting activities	☐	☐	☐	☐	☐
(f)	Other (please specify ………… ……………………………………………)	☐	☐	☐	☐	☐

SECTION 4: Your Health & Well-Being

The following section asks about your health and well-being. Please tick the boxes that are most appropriate to indicate your response.

Q4.1 **In general, would you say your health is:** *Please tick ONE option*

- Excellent ☐
- Very good ☐
- Good ☐
- Fair ☐
- Poor ☐

Q4.2 **<u>Compared to one year ago</u>, how would you rate your health in general <u>now:</u>** *Please tick ONE option*

- Much better now than one year ago ☐
- Somewhat better now than one year ago ☐
- About the same ☐
- Somewhat worse now than one year ago ☐
- Much worse now than one year ago ☐

Q4.3 **Listed below are some activities you might do during a typical day. Does <u>your health now limit you</u> in these activities? If so, how much?** *Please tick ONE box for EACH activity*

		A lot	A little	Not at all
(a)	**Vigorous activities**, such as running, lifting heavy objects, participating in strenuous sports	☐	☐	☐
(b)	**Moderate activities**, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	☐	☐	☐
(c)	Lifting or carrying groceries	☐	☐	☐
(d)	Climbing **several** flights of stairs	☐	☐	☐
(e)	Climbing **one** flight of stairs	☐	☐	☐
(f)	Bending, kneeling, or stooping	☐	☐	☐
(g)	Walking **more than a mile**	☐	☐	☐
(h)	Walking **several blocks** (about half a mile [or 800 metres])	☐	☐	☐
(i)	Walking **one block** (about ¼ to ⅛ of a mile [or 200 to 400 metres])	☐	☐	☐
(j)	Bathing or dressing yourself	☐	☐	☐

Q4.4 **During the <u>past 4 weeks</u>, have you had any of the following problems with your work or other regular daily activities <u>as a result of your physical health</u>?** *Please tick ONE box for EACH activity*

		Yes	No
(a)	Cut down the amount of time you spent on work or other activities?	☐	☐
(b)	**Accomplished less** than you would like?	☐	☐
(c)	Were limited in the **kind** of work or other activities?	☐	☐
(d)	Had **difficulty** performing the work or other activities? (for example, it took extra effort)	☐	☐

Q4.5 **During the <u>past 4 weeks</u>, have you had any of the following problems with your work or other regular daily activities <u>as a result of any emotional problems</u> (such as feeling depressed or anxious)?** *Please tick ONE box for EACH activity*

		Yes	No
(a)	Cut down the **amount of time** you spent on work or other activities?	☐	☐
(b)	**Accomplished less** than you would like?	☐	☐
(c)	Didn't do the work or other activities as **carefully** as usual?	☐	☐

Q4.6 **During the <u>past 4 weeks</u>, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbours or groups?** *Please tick ONE option*

Not at all ☐
Slightly ☐
Moderately ☐
Quite a bit ☐
Extremely ☐

Q4.7 **How much <u>bodily</u> pain have you had during the <u>past 4 weeks</u>?** *Please tick ONE option*

None ☐
Very mild ☐
Mild ☐
Moderate ☐
Severe ☐
Very severe ☐

Q4.8 **During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?** ***Please tick ONE option***

- Not at all ☐
- A little bit ☐
- Moderately ☐
- Quite a bit ☐
- Extremely ☐

Q4.9 **These questions are about how you feel and how things have been with you during the last 4 weeks. For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks…** *(Tick ONE box on EACH line)*

		All of the time	Most of the time	A good bit of the time	Some of the time	A little bit of the time	None of the time
(a)	Did you feel full of pep?	☐	☐	☐	☐	☐	☐
(b)	Have you been a very nervous person?	☐	☐	☐	☐	☐	☐
(c)	Have you felt so down in the dumps that nothing could cheer you up?	☐	☐	☐	☐	☐	☐
(d)	Have you felt calm and peaceful?	☐	☐	☐	☐	☐	☐
(e)	Did you have a lot of energy?	☐	☐	☐	☐	☐	☐
(f)	Have you felt downhearted and blue?	☐	☐	☐	☐	☐	☐
(g)	Did you feel worn out?	☐	☐	☐	☐	☐	☐
(h)	Have you been a happy person?	☐	☐	☐	☐	☐	☐
(i)	Did you feel tired?	☐	☐	☐	☐	☐	☐

Q4.10 **During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives, etc.)**? *Please tick ONE option*

- All of the time ☐
- Most of the time ☐
- Some of the time ☐
- A little bit of the time ☐
- None of the time ☐

Q4-.11 How true or false is <u>each</u> of the following statements for you? *(Tick ONE box on EACH line)*

		Definitely true	Mostly true	Don't know	Mostly false	Definitely false
(a)	I seem to get sick a little easier than other people	☐	☐	☐	☐	☐
(b)	I am as healthy as anybody I know	☐	☐	☐	☐	☐
(c)	I expect my health to get worse	☐	☐	☐	☐	☐
(d)	My health is excellent	☐	☐	☐	☐	☐

Read each of the following sentences and tick the box that best describes how you have been feeling during the LAST WEEK.

Q4.13 I feel tense or 'wound up':
- Most of the time ☐
- A lot of the time ☐
- From time to time / occasionally ☐
- Not at all ☐

Q4.14 I still enjoy the things I used to enjoy:
- Definitely as much ☐
- Not quite as much ☐
- Only a little ☐
- Hardly at all ☐

Q4.15 I get a sort of frightened feeling as if something awful is about to happen:
- Very definitely and quite badly ☐
- Yes, but not too badly ☐
- A little, but it doesn't worry me ☐
- Not at all ☐

Q4.16 I can laugh and see the funny side of things:
- As much as I always could ☐
- Not quite so much now ☐
- Definitely not so much now ☐
- Not at all ☐

Q4.17 Worrying thoughts go through my mind:
- A great deal of the time ☐
- A lot of the time ☐
- From time to time but not often ☐
- Only occasional ☐

Q4.18 I feel cheerful:
- Not at all ☐
- Not often ☐
- Sometimes ☐
- Most of the time ☐

Q4.19 I can sit at ease and feel relaxed:
- Definitely ☐
- Usually ☐
- Not often ☐
- Not at all ☐

Q4.20 I feel as if I am slowed down:
- Nearly all the time ☐
- Very often ☐
- Sometimes ☐
- Not at all ☐

Q4.21 I get a sort of frightened feeling like "butterflies" in the stomach
- Not at all ☐
- Occasionally ☐
- Quite often ☐
- Very often ☐

Q4.22 I have lost interest in my appearance:
- Definitely ☐
- I don't take as much care as I should ☐
- I may not take quite as much care ☐
- I take just as much care ☐

Q4.23 I feel restless as if I have been on the move:
- Very much indeed ☐
- Quite a lot ☐
- Not very much ☐
- Not at all ☐

Q4.24 I look forward with enjoyment to things:
- As much as I ever did ☐
- Rather less than I used to ☐
- Definitely less than I used to ☐
- Hardly at all ☐

Q4.25 I get sudden feelings of panic:
- Very often indeed ☐
- Quite often ☐
- Not very often ☐
- Not at all ☐

Q3.26 I can enjoy a good book or radio/TV programme
- Often ☐
- Sometimes ☐
- Not often ☐
- Very seldom ☐

Appendix 3.2: Participant Information Sheet for ICF Study (Chapter 3)

National Centre for Prosthetics and Orthotics and
School of Psychological Sciences and Health,
University of Strathclyde,
131 St. James Road,
Glasgow
G4 OLS

An investigation into the relationship between the use of ankle-foot orthoses and quality of life and psychological well-being

Information Sheet

We would like to invite you to take part in a research study. Before you decide you need to understand why the research is being done and what it would involve for you. Please take time to read the following information carefully. Talk to others about the study if you wish. Ask us if there is anything that is not clear or if you would like more information. We need to recruit a total of 200 participants for this study.

Who is conducting the research?

The research is being carried out by Christine McMonagle, a teaching fellow at the National Centre for Prosthetics and Orthotics at the University of Strathclyde. She is also a doctoral student in the School of Psychological Sciences and Health.

Christine can be contacted at the following address:

National Centre for Prosthetics and Orthotics,

University of Strathclyde,

131 St. James Road,

Glasgow G4 0LS

Tel: 0141 5483525

e-mail: christine.mcmonagle@strath.ac.uk

Other investigators are Dr Susan Rasmussen and Dr Mark Elliot at the School of Psychological Sciences and Health at the University of Strathclyde.

What is the purpose of the study?

The aim of this investigation is to investigate if a relationship exists between use of ankle-foot orthoses (splints/braces or callipers) and a person's quality of life and psychological well-being

Why have I been invited?

You have been invited to take part in this study as you have previously been given an ankle-foot orthosis (splint, brace, or calliper) to assist you in walking. Even if you do not use your ankle-foot orthosis (splint, brace, calliper) you can still participate in this questionnaire. You may have been provided with an ankle-foot orthosis for any condition.

Do I have to take part?

It is up to you to decide. We will describe the study in this information sheet, which we will then give to you. You will be asked to sign a consent form to show you have agreed to take part. You are free to withdraw at any time, without giving reason. This would not affect the standard of care you receive or your future treatment.

What does taking part involve?

You will be asked to fill in a questionnaire asking about the use of your ankle-foot orthosis (splint, brace, or calliper), and about aspects of your health and well-being. This should take approximately 20 minutes of your time. You will then be asked to return the questionnaire in the pre-paid envelope supplied.

You should be able to provide consent to take part in this study. This means you should understand the information provided about the study, what is being asked of you, and freely volunteer to take part. If you are not able to fill in the questionnaire yourself, but still want to participate, it may be filled in with the assistance of a career, family member or guardian on your behalf, but you still must give your own consent.

This questionnaire asks you about your feelings and emotions. After filling in the questionnaire, you may have an increased awareness of your feelings. If you have an increased awareness of feeling a bit low or depressed you are advised to contact a member of the research team, whose details are given below. You can also seek help from "Breathing Space", a free and confidential phone line service for any individual who is experiencing low mood and depression or in need of someone to talk to. They can be contacted at: 0800 838587

What happens to the information?

Your identity and personal information will be completely confidential. The information obtained will remain confidential and stored within a locked filing cabinet. The information will be kept for 5 years, and over this time this information may be further analysed. The data are held in accordance with the Data Protection Act, which means that we keep it safely and cannot reveal it to other people, without your permission.

What are the possible benefits of taking part?

It is hoped that by taking part in this research, you will be providing valuable information regarding the use of ankle-foot orthoses and their effect on quality of life and sense of well-being. While there is no guarantee that this study will help you directly, it is hoped that this study will inform future studies that will increase our understanding of the experience of using an ankle-foot orthosis.

Who has reviewed the study?

This study has been reviewed by the NHS West of Scotland Research Ethics Committee.

If you have any further questions?

We will give you a copy of the information sheet. If you would like more information about the study and wish to speak to someone **not** closely linked to the study, please contact:

Secretary of the University Ethics Committee
University of Strathclyde,
RKES,
50 George Street,
Glasgow,
G1 1QE

e-mail: ethics@strath.ac.uk

Tel: 0141 548 3707

Research Team Contacts:

Christine McMonagle,
National Centre for Prosthetics and Orthotics,
University of Strathclyde,
131 St. James Road,
Glasgow G4 0LS

Tel: 0141 5483525

christine.mcmonagle@strath.ac.uk

Susan Rasmussen,
School of Psychological Sciences and Health,
University of Strathclyde,
Graham Hills building,
40 George Street,
Glasgow G1 1QE

Tel: 0141 5482575

s.a.rasmussen@strath.ac.uk

If you have a complaint about any aspect of the study?

If you are unhappy about any aspect of the study and wish to make a complaint, please contact the researcher in the first instance but the normal NHS complaint mechanisms is also available to you.

Thank-you for your time and co-operation

Appendix 3.3 Ethical Approval for ICF Study (Chapter 3)

WoSRES
West of Scotland Research Ethics Service

NHS
Greater Glasgow and Clyde

West of Scotland REC 4
Ground Floor, Tennent Building
Western Infirmary
38 Church Street
Glasgow
G11 6NT
www.nhsggc.org.uk

Miss Christine McMonagle
Lecturer
University of Strathclyde
NCPO, University of Strathclyde
Curran Building
131 St. James' Road
Glasgow
G4 0LS

Date	24 May 2011
Direct line	0141-211-1722
Fax	0141-211-1847
e-mail	evelyn.jackson@ggc.scot.nhs.uk

Dear Miss McMonagle

Study title:	**Use and Usefulness of ankle-foot orthoses(AFOs): An investigation into the relationship between AFO use and quality of life and psychological well being**
REC reference:	**11/AL/0263**

The Research Ethics Committee reviewed the above application at the meeting held on 17 May 2011.

Ethical opinion

Professor Chris Robertson submitted written comments.

The Committee thank you for attending the meeting and the following was discussed:

You informed the Committee that individual patients will have different recommended wearing times depending on what activities they usually wear the ankle-foot orthoses for.

The Committee asked why participants were told to contact their GP if they feel low or depressed during the completion of the questionnaire and you explained that the questionnaire was piloted and then reviewed by University of Strathclyde and that they had suggested that this be added.

The members of the Committee present gave a favourable ethical opinion of the above research on the basis described in the application form, protocol and supporting documentation, subject to the conditions specified below.

Ethical review of research sites

NHS Sites

The favourable opinion applies to all NHS sites taking part in the study, subject to management permission being obtained from the NHS/HSC R&D office prior to the start of the study (see "Conditions of the favourable opinion" below).

Delivering better health
www.nhsggc.org.uk

Conditions of the favourable opinion

The favourable opinion is subject to the following conditions being met prior to the start of the study.

Management permission or approval must be obtained from each host organisation prior to the start of the study at the site concerned.

Management permission ("R&D approval") should be sought from all NHS organisations involved in the study in accordance with NHS research governance arrangements.

Guidance on applying for NHS permission for research is available in the Integrated Research Application System or at http://www.rdforum.nhs.uk.

Where a NHS organisation's role in the study is limited to identifying and referring potential participants to research sites ("participant identification centre"), guidance should be sought from the R&D office on the information it requires to give permission for this activity.

For non-NHS sites, site management permission should be obtained in accordance with the procedures of the relevant host organisation.

Sponsors are not required to notify the Committee of approvals from host organisations

Other Conditions Specified by the Committee

1. The Committee decided that only the postcode sector should be collected.

2. In the Information Sheet:
   (a) In the section headed "If you any further questions", the Secretary to the Research Ethics Committee is not an appropriate contact to discuss the study with potential participants. This contact should be someone who knows about the study and the subject, but is not involved in the study.
   (b) It is suggested that the participant should contact their GP should they feel a bit low or depressed. The Committee suggested that a member of the research team would be a more appropriate contact in the first instance.
   (c) Add the number of participants in the study.
   (d) As you have indicated in QA43 of the application form that further future analysis may be performed, this should be stated in the Information Sheet.

3. A Consent Form need not be sent out with the questionnaire as consent is implied when the participant completes the questionnaire. A Consent Form will be required for the 2nd phase of the study, but a section must be added to record the name of the person taking the consent.

4. As you plan to follow-up people who have returned a completed questionnaire the Committee suggested that a Subject ID No. be put on the questionnaires before they are sent out.

It is responsibility of the sponsor to ensure that all the conditions are complied with before the start of the study or its initiation at a particular site (as applicable).

You should notify the REC in writing once all conditions have been met (except for site approvals from host organisations) and provide copies of any revised documentation with updated version numbers. Confirmation should also be provided to host organisations together with relevant documentation

Approved documents

The documents reviewed and approved at the meeting were:

Document	Version	Date
Covering Letter	Version 1	21 April 2011
Investigator CV	Version 1	18 April 2011
Other: Supervisor CV	-	20 April 2011
Participant Consent Form	Version 1	19 April 2011
Participant Information Sheet	Version 1a	18 April 2011
Participant Information Sheet	Version 1b	18 April 2011
Protocol	Version 1	18 April 2011
Questionnaire: AFO & Health Questionnaire	Non-Validated	-
REC application	Version 1	18 April 2011

Membership of the Committee

The members of the Ethics Committee who were present at the meeting are listed on the attached sheet.

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees (July 2001) and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

After ethical review

Now that you have completed the application process please visit the National Research Ethics Service website > After Review

You are invited to give your view of the service that you have received from the National Research Ethics Service and the application procedure. If you wish to make your views known please use the feedback form available on the website.

The attached document "After ethical review – guidance for researchers" gives detailed guidance on reporting requirements for studies with a favourable opinion, including:

- Notifying substantial amendments
- Adding new sites and investigators
- Progress and safety reports
- Notifying the end of the study

The NRES website also provides guidance on these topics, which is updated in the light of changes in reporting requirements or procedures.

We would also like to inform you that we consult regularly with stakeholders to improve our service. If you would like to join our Reference Group please email referencegroup@nres.npsa.nhs.uk.

11/AL/0263	Please quote this number on all correspondence

With the Committee's best wishes for the success of this project.

Yours sincerely

Evelyn Jackson

for Dr Sue Langridge
Chair

Enclosures: List of names and professions of members who were present at the meeting and those who submitted comments
"After ethical review – guidance for researchers"

Copy to: Ms Lynda Frew
Mr Graeme Piper, R&D Office, Tennent Building, Western Infirmary

Appendix 4.1: Forrest Plots of Correlations between TPB Constructs

Intention- Behaviour Correlation

Study name	Correlation	Lower limit	Upper limit	Z-Value	p-Value
Carroll (2003)	0.723	0.412	0.883	3.768	0.000
Chapman (1995)	0.490	0.164	0.719	2.837	0.005
Costa (2012)	0.173	0.090	0.252	4.075	0.000
De Weert (1990)	0.517	0.453	0.575	13.481	0.000
Didarloo (2012)	0.341	0.245	0.430	6.636	0.000
Fai (2017)	0.291	0.114	0.450	3.171	0.002
Gatt (2008)	0.400	0.221	0.553	4.172	0.000
Gucciardi (2007)	0.336	0.211	0.451	5.047	0.000
Gucciardi (2016)	0.360	0.244	0.465	5.799	0.000
Guenette (2016)	0.281	0.220	0.340	8.653	0.000
Johnson (2016)	0.130	-0.079	0.328	1.220	0.222
Kagee (2006)	0.180	-0.148	0.472	1.077	0.282
Levy (2008)	0.387	0.226	0.527	4.497	0.000
McNeely (2012)	0.107	-0.171	0.369	0.752	0.452
Niven	0.182	-0.004	0.355	1.920	0.055
Shankar (2007)	0.610	0.409	0.755	5.063	0.000
White (2010)	0.320	0.141	0.479	3.431	0.001
White (2012)	0.536	0.394	0.653	6.446	0.000
	0.349	0.278	0.416	9.050	0.000

Correlation and 95% CI

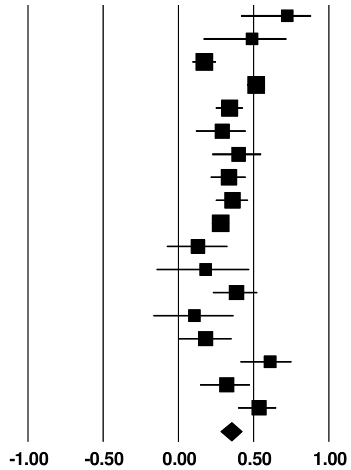


Figure A.4.1: Forest plots of correlations between intention and adherence behaviour

PBC-Behaviour Correlation

Study name	Correlation	Lower limit	Upper limit	Z-Value	p-Value
Bains and Powell (2007)	0.320	0.009	0.574	2.017	0.044
Carroll (2003)	0.335	-0.126	0.677	1.437	0.151
Costa (2012)	0.118	0.029	0.204	2.603	0.009
Didarloo (2012)	0.338	0.242	0.427	6.573	0.000
Fai (2017)	0.360	0.189	0.510	3.989	0.000
Gatt (2008)	0.540	0.384	0.666	5.950	0.000
Gucciardi (2007)	0.157	-0.028	0.332	1.663	0.096
Gucciardi (2016)	0.065	-0.073	0.200	0.924	0.355
Johnson (2016)	0.153	-0.057	0.350	1.429	0.153
Guenette (2016)	0.367	0.309	0.422	11.536	0.000
Kagee (2006)	0.364	0.050	0.612	2.257	0.024
Kleier (2014)	0.182	0.057	0.301	2.851	0.004
Levy (2008)	0.457	0.303	0.587	5.359	0.000
McNeely (2012)	0.090	-0.188	0.354	0.632	0.528
Niven	0.030	-0.194	0.252	0.263	0.793
Shankar (2007)	0.185	-0.057	0.407	1.500	0.134
White (2010)	0.270	0.087	0.435	2.864	0.004
White (2012)	0.424	0.265	0.561	4.895	0.000
	0.268	0.195	0.338	6.955	0.000

Correlation and 95% CI

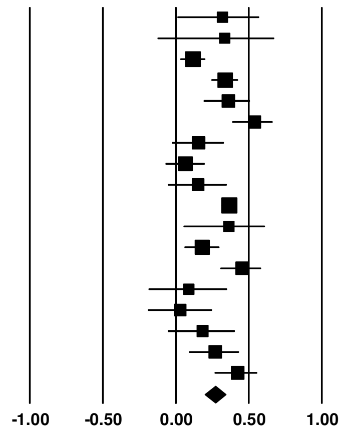


Figure A4.2: Forest plot of correlations between PBC and behaviour

Attitude- Intention Correlation

Study name	Correlation	Lower limit	Upper limit	Z-Value	p-Value
Carroll (2003)	0.682	0.343	0.864	3.434	0.001
Costa (2013)	-0.284	-0.413	-0.143	-3.874	0.000
De Weert (1990)	0.400	0.328	0.467	9.981	0.000
Didarloo (2012)	0.514	0.433	0.587	10.614	0.000
Fai (2017)	0.447	0.287	0.582	5.090	0.000
Gatt (2008)	0.360	0.176	0.520	3.712	0.000
Gucciardi (2007)	0.345	0.102	0.549	2.740	0.006
Gucciardi (2016)	0.480	0.339	0.600	6.031	0.000
Guenette (2016)	0.452	0.398	0.502	14.600	0.000
Johnson (2016)	0.398	0.224	0.546	4.287	0.000
Kagee (2006)	0.323	0.004	0.583	1.982	0.047
Levy (2008)	0.390	0.171	0.573	3.371	0.001
McGuckin (2012)	0.328	0.106	0.519	2.850	0.004
Niven (2012)	0.098	-0.116	0.304	0.896	0.370
Shankar (2007)	0.430	0.183	0.626	3.284	0.001
Sheppard	0.485	0.261	0.659	3.962	0.000
Trafimow	0.070	-0.352	0.469	0.314	0.754
White (2010)	0.370	0.226	0.498	4.820	0.000
White (2012)	0.390	0.220	0.537	4.280	0.000
	0.359	0.269	0.443	7.338	0.000

Correlation and 95% CI

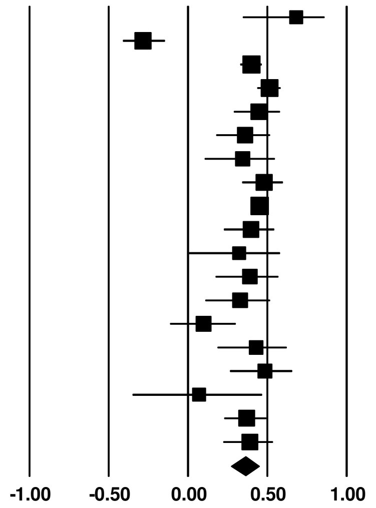


Figure A.4.3: Forrest plot for correlations between attitude and intention to adhere

Subjective Norm-Intention Correlation

Study name	Correlation	Lower limit	Upper limit	Z-Value	p-Value
Carroll (2003)	0.353	-0.106	0.688	1.521	0.128
Costa (2012)	-0.635	-0.715	-0.538	-9.947	0.000
De Weert	0.383	0.310	0.452	9.507	0.000
Didarloo (2012)	0.467	0.381	0.545	9.457	0.000
Fai (2017)	0.334	0.161	0.487	3.676	0.000
Gatt (2008)	0.240	0.046	0.417	2.411	0.016
Gucciardi (2007)	0.339	0.095	0.544	2.688	0.007
Gucciardi (2016)	0.300	0.139	0.446	3.570	0.000
Johnson (2016)	0.198	0.010	0.372	2.058	0.040
Kagee (2006)	0.327	0.008	0.585	2.008	0.045
McGuckin (2012)	0.615	0.448	0.740	5.998	0.000
Niven (2012)	0.178	-0.035	0.376	1.639	0.101
Shankar (2007)	0.180	-0.092	0.427	1.300	0.194
Sheppard (2006)	0.185	-0.324	0.611	0.700	0.484
Trafimow (1998)	0.090	-0.335	0.484	0.404	0.687
White (2010)	0.530	0.407	0.634	7.324	0.000
White (2012)	0.600	0.471	0.704	7.465	0.000
	0.286	0.111	0.444	3.154	0.002

Correlation and 95% CI

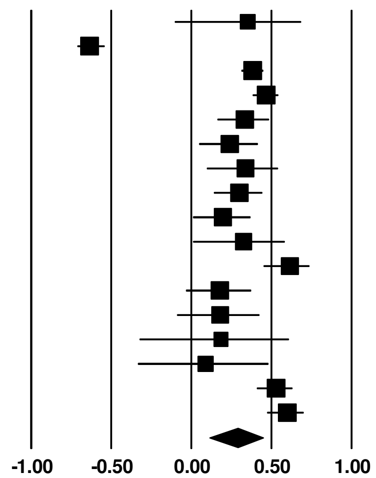


Figure A4.4: Forrest plot for correlations between subjective norm and intention to adhere

PBC-Intention Correlation

Study name	Correlation	Lower limit	Upper limit	Z-Value	p-Value
Carroll (2003)	0.474	0.040	0.758	2.124	0.034
Costa (2012)	0.479	0.357	0.585	6.921	0.000
Didarloo (2012)	0.559	0.483	0.627	11.795	0.000
Fai (2017)	0.480	0.325	0.610	5.535	0.000
Gatt (2008)	0.670	0.545	0.766	7.985	0.000
Gucciardi (2007)	0.413	0.180	0.602	3.345	0.001
Gucciardi (2016)	0.410	0.260	0.541	5.024	0.000
Guenette	0.772	0.744	0.797	30.724	0.000
Johnson (2016)	0.306	0.121	0.471	3.183	0.001
Kagee (2006)	0.680	0.460	0.821	4.905	0.000
Levy (2008)	0.270	0.037	0.475	2.266	0.023
McGuckin (2012)	0.501	0.308	0.655	4.640	0.000
Niven (2012)	0.265	0.103	0.414	3.156	0.002
Shankar (2007)	0.315	0.096	0.505	2.785	0.005
Sheppard (2006)	0.160	-0.060	0.365	1.428	0.153
Trafimow (1998)	0.500	0.238	0.694	3.507	0.000
White (2010)	0.350	0.205	0.480	4.535	0.000
White (2012)	0.790	0.712	0.849	11.589	0.000
	0.490	0.366	0.598	6.863	0.000

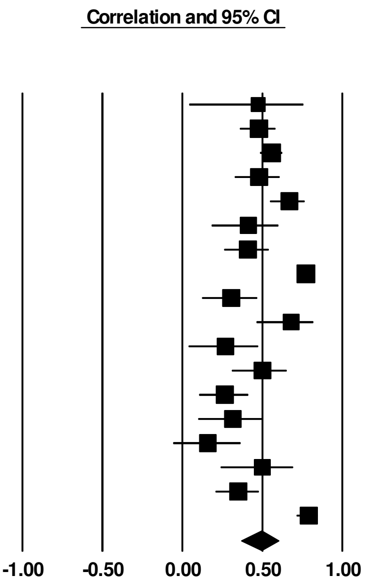


Figure A4.5: Forrest plot for correlations between PBC and intention to adhere

Attitude-Subjective Norm Correlation

Study name	Correlation	Lower limit	Upper limit	Z-Value	p-Value
Bains and Powell (2006)	0.410	0.113	0.640	2.650	0.008
Carroll (2003)	0.335	-0.126	0.677	1.437	0.151
Costa (2013)	0.386	0.254	0.504	5.401	0.000
Didarloo (2012)	0.508	0.426	0.582	10.462	0.000
Fai (2017)	0.330	0.156	0.484	3.628	0.000
Gucciardi (2007)	0.574	0.377	0.722	4.977	0.000
Gucciardi (2016)	0.280	0.144	0.405	3.965	0.000
Johnson (2016)	0.554	0.406	0.673	6.352	0.000
Kagee (2006)	-0.060	-0.373	0.265	-0.355	0.722
McGuckin (2012)	0.185	-0.049	0.400	1.555	0.120
Niven (2012)	0.136	-0.078	0.338	1.247	0.212
Shankar (2007)	0.150	-0.123	0.402	1.079	0.280
White (2010)	0.250	0.097	0.391	3.170	0.002
White (2012)	0.350	0.175	0.504	3.798	0.000
	0.336	0.246	0.419	7.007	0.000

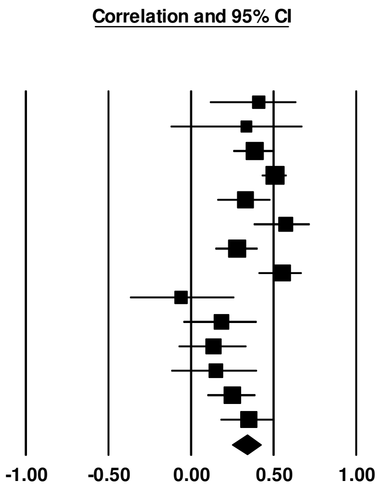


Figure A4.6: Forrest plot for correlations between attitude and subjective norm

Attitude-PBC Correlation

Study name	Correlation	Lower limit	Upper limit	Z-Value	p-Value
Bains and Powell (2007)	0.320	0.009	0.574	2.017	0.044
Carroll (2003)	0.481	0.049	0.761	2.162	0.031
Costa (2013)	0.206	0.061	0.342	2.773	0.006
Didarloo (2012)	0.498	0.415	0.573	10.212	0.000
Fai (2017)	0.159	-0.025	0.332	1.697	0.090
Gucciardi (2007)	0.436	0.207	0.620	3.559	0.000
Gucciardi (2016)	0.340	0.209	0.459	4.881	0.000
Guenette (2016)	0.552	0.505	0.596	18.617	0.000
Johnson (2016)	0.544	0.397	0.663	6.321	0.000
Kagee (2006)	0.070	-0.255	0.381	0.415	0.678
Kleier (2014)	0.319	0.127	0.488	3.188	0.001
Levy (2008)	0.040	-0.197	0.272	0.328	0.743
McGuckin (2012)	0.108	-0.125	0.330	0.907	0.364
Niven (2012)	0.145	-0.028	0.308	1.646	0.100
Shankar (2007)	0.575	0.395	0.712	5.417	0.000
White (2010)	0.220	0.066	0.364	2.775	0.006
White (2012)	0.390	0.220	0.537	4.299	0.000
	0.332	0.234	0.423	6.347	0.000

Correlation and 95% CI

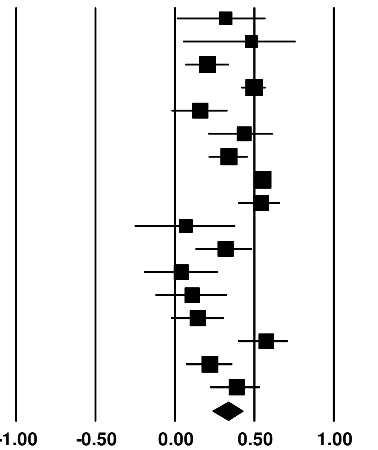


Figure A4.7: Forrest plot for correlations between attitude and PBC

Subjective Norm-PBC Correlation

Study name	Correlation	Lower limit	Upper limit	Z-Value	p-Value
Bains and Carroll (2006)	0.830	0.699	0.907	7.227	0.000
Carroll (2003)	0.267	-0.199	0.635	1.128	0.259
Costa (2012)	0.183	0.037	0.321	2.455	0.014
Didarloo (2012)	0.498	0.415	0.573	10.212	0.000
Gucciardi (2007)	0.413	0.180	0.602	3.345	0.001
Gucciardi (2016)	0.220	0.054	0.374	2.579	0.010
Johnson (2016)	0.635	0.503	0.738	7.496	0.000
Kagee (2006)	0.320	0.000	0.580	1.962	0.050
McGuckin (2012)	0.673	0.524	0.782	6.829	0.000
Niven (2012)	0.345	0.184	0.488	4.069	0.000
Shankar (2007)	0.035	-0.202	0.269	0.286	0.775
White (2010)	0.400	0.260	0.524	5.257	0.000
White (2012)	0.632	0.511	0.729	8.056	0.000
	0.449	0.326	0.557	6.539	0.000

Correlation and 95% CI

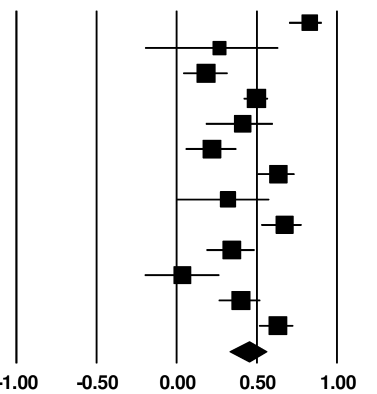


Figure A4.8: Forrest plot for correlations between subjective norm and PBC

Attitude- Behaviour Correlation

Study name	Correlation	Lower limit	Upper limit	Z-Value	p-Value
Bains and Powell (2007)	0.530	0.262	0.722	3.590	0.000
Carroll (2003)	0.741	0.444	0.891	3.928	0.000
Chapman (1995)	0.480	0.151	0.713	2.767	0.006
Costa (2013)	0.081	-0.012	0.173	1.709	0.087
Didarloo (2012)	0.257	0.157	0.352	4.911	0.000
Fai (2017)	0.060	-0.124	0.240	0.636	0.525
Gatt (2008)	0.120	-0.078	0.309	1.188	0.235
Gucciardi (2007)	0.221	0.034	0.393	2.311	0.021
Gucciardi (2016)	0.260	0.128	0.383	3.787	0.000
Guenette (2016)	0.270	0.208	0.330	8.297	0.000
Johnson (2016)	0.235	0.026	0.424	2.198	0.028
Kleier (2014)	0.021	-0.107	0.149	0.324	0.746
Kagee (2006)	0.010	-0.311	0.329	0.059	0.953
Levy (2008)	0.250	0.076	0.409	2.794	0.005
Niven (201	0.205	0.020	0.377	2.172	0.030
Shankar (2007)	0.360	0.102	0.573	2.692	0.007
White (2010)	0.210	0.055	0.355	2.645	0.008
White (2012)	0.255	0.072	0.421	2.710	0.007
	0.221	0.159	0.282	6.800	0.000

Correlation and 95% CI

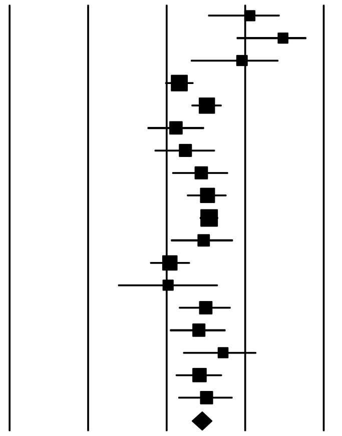


Figure A4.9: Forrest plot for correlations between attitude and adherence behaviour

Subjective Norm-Behaviour Correlation

Study name	Correlation	Lower limit	Upper limit	Z-Value	p-Value
Carroll (2003)	0.437	-0.007	0.737	1.932	0.053
Chapman (1995)	0.720	0.491	0.856	4.803	0.000
Costa (2012)	0.109	0.023	0.194	2.472	0.013
Didarloo (2012)	0.239	0.138	0.335	4.553	0.000
Fai (2017)	0.257	0.078	0.420	2.782	0.005
Gatt (2008)	0.060	-0.138	0.253	0.592	0.554
Gucciardi (2007)	0.274	0.095	0.436	2.958	0.003
Gucciardi (2016)	0.155	0.018	0.287	2.210	0.027
Johnson (2016)	0.085	-0.126	0.287	0.787	0.431
Kagee (2006)	0.153	-0.175	0.451	0.912	0.362
McNeeley (2012)	-0.026	-0.297	0.249	-0.182	0.856
Niven (2012)	0.118	-0.069	0.297	1.237	0.216
Shankar (2007)	0.120	-0.153	0.376	0.861	0.389
White (2010)	0.260	0.108	0.400	3.302	0.001
White (2012)	0.210	0.032	0.375	2.306	0.021
	0.192	0.125	0.257	5.532	0.000

Correlation and 95% CI

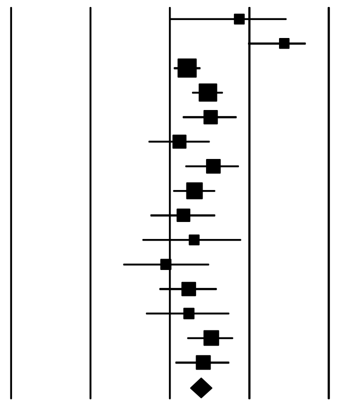


Figure A4.10: Forrest plot for correlations between subjective norm and adherence behaviour

Appendix 5.1: Ethical Approval for Studies 3 and 4 (Chapters 5 and 6)

Letter re-issued to clarify the Additional Conditions specified by the REC

NHS

Health Research Authority

NRES Committee North East - Newcastle & North Tyneside 1

Room 002
TEDCO Business Centre
Rolling Mill Road
Jarrow
NE32 4BW

Tel: 0191 428 3565

2 June 2014 Re-issued 4 June 2014

Miss Christine McMonagle
Teaching Fellow
University of Strathclyde
NCPO, Department of Biomedical Engineering
University of Strathclyde
Curran Building
131 St. James Road
G4 0LS

Dear Miss McMonagle

Study title:	**Application of the Theory of Planned Behaviour (TPB) to Investigate Adherence to Ankle-foot Orthoses (AFOs) in Patients with Stroke**
REC reference:	**14/NE/1002**
IRAS project ID:	**146140**

The Proportionate Review Sub-committee of the NRES Committee North East - Newcastle & North Tyneside 1 reviewed the above application on 28 May 2014.

We plan to publish your research summary wording for the above study on the NRES website, together with your contact details, unless you expressly withhold permission to do so. Publication will be no earlier than three months from the date of this favourable opinion letter. Should you wish to provide a substitute contact point, require further information, or wish to make a request to postpone publication, please contact the REC Manager Ms Gillian Mayer, nrescommittee.northeast-newcastleandnorthtyneside1@nhs.net

Ethical opinion

On behalf of the Committee, the Sub-Committee gave a **Favourable** ethical opinion of the above research on the basis described in the application form, protocol and supporting documentation, subjective to the conditions specified below

Conditions of the favourable opinion

The favourable opinion is subject to the following conditions being met prior to the start of the study.

Additional conditions specified by the REC

The consent forms to revise the statement regarding withdrawal (point 2) to be more precise:

A Research Ethics Committee established by the Health Research Authority

Letter re-issued to clarify the Additional Conditions specified by the REC

The section - 'I understand that my participation is voluntary. I know that I am free to withdraw from the study at any time. I know that I do not have to give a reason. There are not any consequences for me if I withdraw'.

To be replaced by:

' I understand that my participation is voluntary. I am free to withdraw from the study at any time without giving reasons and this will not affect my future clinical care in any way'.

You should notify the REC in writing once all conditions have been met (except for site approvals from host organisations) and provide copies of any revised documentation with updated version numbers. The REC will acknowledge receipt and provide a final list of the approved documentation for the study, which can be made available to host organisations to facilitate their permission for the study. Failure to provide the final versions to the REC may cause delay in obtaining permissions.

Management permission or approval must be obtained from each host organisation prior to the start of the study at the site concerned.

Management permission ("R&D approval") should be sought from all NHS organisations involved in the study in accordance with NHS research governance arrangements.

Guidance on applying for NHS permission for research is available in the Integrated Research Application System or at http://www.rdforum.nhs.uk.

Where a NHS organisation's role in the study is limited to identifying and referring potential participants to research sites ("participant identification centre"), guidance should be sought from the R&D office on the information it requires to give permission for this activity.

For non-NHS sites, site management permission should be obtained in accordance with the procedures of the relevant host organisation.

Sponsors are not required to notify the Committee of approvals from host organisations.

Registration of Clinical Trials

All clinical trials (defined as the first four categories on the IRAS filter page) must be registered on a publically accessible database within 6 weeks of recruitment of the first participant (for medical device studies, within the timeline determined by the current registration and publication trees).

There is no requirement to separately notify the REC but you should do so at the earliest opportunity e.g. when submitting an amendment. We will audit the registration details as part of the annual progress reporting process.

To ensure transparency in research, we strongly recommend that all research is registered but for non-clinical trials this is not currently mandatory.

If a sponsor wishes to contest the need for registration they should contact Catherine Blewett (catherineblewett@nhs.net), the HRA does not, however, expect exceptions to be made. Guidance on where to register is provided within IRAS.

It is the responsibility of the sponsor to ensure that all the conditions are complied with before the start of the study or its initiation at a particular site (as applicable).

Letter re-issued to clarify the Additional Conditions specified by the REC

Summary of discussion at the meeting

The Sub-Committee raised the following issues and as chief investigator you responded accordingly as follows:

Concern was expressed that the telephone call scheduled as a reminder two hours before the clinic appointment might cause unwarranted interference - these participants will be disabled with considerable transport issues and under stress. It was queried if it would be possible the telephone call could be made the day before the clinic appointment.

You clarified that in Section A26, the telephone call intended specifically for interviews conducted in the patient's home. Therefore these participants would not be getting transport to a clinic. A telephone call two hours prior to the visit was designed to remind participants of the visit and was felt to be a reasonable amount of time to give participants a reminder of the intended visit to their home. You noted that if the Committee considered that contact would be beneficial on the previous day, you would be happy to change this.

Participant Information Sheet: Confirmation was requested if the interviews will be audio recorded and if so, this should be stated in the information sheet together with information about transcription and disposal of audio-recordings.

You informed that you had not planned to audio-record the interviews. The reason for this was noted in Section A13 of the REC form: "It is not intended to record the interviews as the interview is highly structured, and there is no requirement for in-depth thematic analysis of the data". However you stated you would be happy to follow this process if the ethics committee believe this to be necessary.

It was also noted that contact for participants if they want to complain is currently the University Research Ethics office and a more appropriate independent organisation should be considered (similar to the Participant Liaison Service).

You informed that an appropriate similar organisation in Scotland called Patient Advice and Support Service has been identified. They are contactable through a local citizen's advice bureau. Contact details of all Citizens' Advice Bureaus in Lanarkshire have been provided in the information sheet.

The information sheet should also note that Newcastle and North Tyneside 1 Proportionate Review Sub Committee has reviewed the study.

You provided a revised information sheet accordingly.

The consent form needs to include the following a statement for permission to audio-record the interviews and also the mandatory paragraph as indicated on the HRA/NRES website (as appropriate to this study) - 'I understand that relevant sections of my medical notes and/or data collected during the study may be looked at by individuals from regulatory authorities or from the NHS Trust, where it is relevant to my taking part in this research. I give permission for these individuals to have access to this information'.

You provided a revised consent form to include the mandatory paragraph as requested however, as previously noted, you have no plans to audio-record the interviews.

GP Letter – It was unclear why the GPs need to be informed of the study and the Committee suggested they are not informed for study 1 (interviews) and study 2 (questionnaire) and reference to this to be removed from the information sheet and consent form.

Letter re-issued to clarify the Additional Conditions specified by the REC

You agreed that the GPs do not need to be informed and provided a revised information sheet and consent form accordingly.

Members were generally satisfied with the responses given to the issues raised and the revised documentation. However it was noted that point 2 of the consent forms could be improved by revision of the wording in the statement regarding withdrawal, to be more precise, to read 'I am free to withdraw from the study at any time without giving reasons and this will not affect my future clinical care in any way' (and remove the statement 'there will not be any consequences for me if I withdraw).

Ethical review of research sites

The favourable opinion applies to all NHS sites taking part in the study, subject to management permission being obtained from the NHS/HSC R&D office prior to the start of the study (see "Conditions of the favourable opinion").

Approved documents

The documents reviewed and approved were:

Document	*Version*	*Date*
Covering letter on headed paper [Christine McMonagle]		19 May 2014
Evidence of Sponsor insurance or indemnity (non NHS Sponsors only) [Insurance Documentation 1]	Professional Indemnity	15 July 2013
Interview schedules or topic guides for participants [Interview Schedule part 1]		07 May 2014
Letter from sponsor [Letter of Insurance]	Helen Baigrie	09 April 2014
Non-validated questionnaire [Questionnaire Time 2]	1	28 April 2014
Non-validated questionnaire [Part 1]		08 May 2014
Other [Insurance Documentation 3]	Employers' Liability	11 July 2013
Other [Scottish Stroke Research Network Letter of Support]	1 (Claire McFarlane)	19 March 2014
Other [Insurance Documentation 2]	Clinical Trials Coverage	08 July 2013
Participant consent form [Consent form Part 1]	2	28 May 2014
Participant consent form [Consent form Part 2]	2	28 May 2014
Participant information sheet (PIS) [TPB Study Part 1 PIS]	3	28 May 2014
Participant information sheet (PIS) [TPB study Part 2 PIS]	3	28 May 2014
Response (email)		28 May 2014
REC Application Form [REC_Form_19052014]		19 May 2014
Research protocol or project proposal		08 May 2014
Summary CV for Chief Investigator (CI) [CV Christine McMonagle]		
Summary CV for supervisor (student research) [Dr. Susan Rasmussen CV]	1	08 May 2014
Summary CV for supervisor (student research) [Mark Elliott]		20 May 2014

Membership of the Committee

The members of the Sub-Committee who took part in the review are listed on the attached sheet.

Letter re-issued to clarify the Additional Conditions specified by the REC

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

After ethical review

Reporting requirements

The attached document "After ethical review – guidance for researchers" gives detailed guidance on reporting requirements for studies with a favourable opinion, including:

- Notifying substantial amendments
- Adding new sites and investigators
- Notification of serious breaches of the protocol
- Progress and safety reports
- Notifying the end of the study

The HRA website also provides guidance on these topics, which is updated in the light of changes in reporting requirements or procedures.

Feedback

You are invited to give your view of the service that you have received from the National Research Ethics Service and the application procedure. If you wish to make your views known please use the feedback form available on the HRA website http://www.hra.nhs.uk/about-the-hra/governance/quality-assurance/

We are pleased to welcome researchers and R & D staff at our NRES committee members' training days – see details at http://www.hra.nhs.uk/hra-training/

With the Committee's best wishes for the success of this project.

14/NE/1002	**Please quote this number on all correspondence**

Yours sincerely
PP

G. Moyes

Professor Philip Preshaw
Chair

E-mail: nrescommittee.northeast-newcastleandnorthtyneside1@nhs.net

Enclosures:	*List of names and professions of members who took part in the review*
	'After ethical review – guidance for researchers'
Copy to:	*Ms Helen Baigrie – Contracts Manager, University of Strathclyde*
	Mr Raymond Hamill – R&D Dept, NHS Lanarkshire

Letter re-issued to clarify the Additional Conditions specified by the REC

NRES Committee North East - Newcastle & North Tyneside 1

Attendance at PRS Sub-Committee of the REC meeting on 28 May 2014 (by Correspondence)

Committee Members:

Name	*Profession*	*Present*	*Notes*
Dr Mike Bone (Vice Chair)	Consultant Physician	Yes	
Dr Etta Evans	Senior Lecturer in Psychology	Yes	
Professor Philip Preshaw (Chair)	Professor of Periodontology & Consultant in Prerestorative Dentistry	Yes	

Also in attendance:

Name	*Position (or reason for attending)*
Ms Gillian Mayer	REC Manager

Appendix 5.2 Participant Information Sheet for Beliefs Elicitation Study (Chapter 5)

Title of the study: Beliefs affecting use of Ankle–foot Orthoses (splints) in People with Stroke

Purpose of the Study

The **research team** wishes to **investigate use** of **ankle-foot orthoses (AFOs or leg splints).** The research team is **interested** in people with **stroke**. The research team **want to know how people think** about their AFOs (splints).

This **information** will **help health professionals**. Health professionals will be able to **understand why people** may **not use** their **AFOs** (splints).

The researchers will **interview** you. The researchers **want** to **know** your **thoughts** about **using** an **AFO** (leg splint). A **researcher** will **visit** you.

Invitation

A **research team** is **inviting** you to **take part** in a **research** study. **Before** you **decide** to take part, you **need** to **understand why** the research is being done. You also **need** to **know what** the researchers are **asking you** to do. A **research nurse** will **go through** the **information** sheet with you. This should take **15 minutes**.

The **information sheet tells you** about the study. It **describes what** the researchers are **asking** you to **do**. You **can talk to others** about the study. You can **ask the research nurse** if there is anything you do **not understand**. You can also ask for **more information**.

The **interview** will **take place** on the **ward** or at **home**. The interview should take about

Christine McMonagle is the **main researcher**. Christine is an **orthotist** who works at the University of Strathclyde. This **research** is part of a **PhD**. Christine studies her PhD in the **School of Psychological Sciences and Health**.

Christine can be **contacted** at the following **address**:

Christine McMonagle
NCPO, Department of Biomedical Engineering
University of Strathclyde
131 St. James Road
Glasgow G4 0LS
Tel: 0141 5483525
e-mail: christine.mcmonagle@strath.ac.uk

Other investigators are **Dr Susan Rasmussen** and **Dr Mark Elliott** at the School of Psychological Sciences and Health at the University of Strathclyde.

Do I have to take part?

It is **your decision** to take part. The information sheet **describes** the study. We will **give** this **sheet** to **you**. You will **have time** to **think** about **taking part**. You will be able to **ask questions** about the study.

You will be **asked** to **sign** a **consent form**. This shows you have **agreed** to **take part.** You **can withdraw** at any time. You do **not need** to give a **reason**. You can ask to **withdraw** your **information**. Withdrawal **does not affect** your **care** or your future treatment.

Why have I been invited?

You have been invited to take part because:

- You have had a **stroke**
- You have been **prescribed an AFO** (splint) to help your standing or walking
- You are **over 18 years old**
- You are **able** to **share** your **beliefs** about using the AFO (splint).

Even if you **do not use** your **AFO** you can still **take part**.

What will I do in the study?

You will take part in an **interview**. The interview will take **half an hour**.

If you are in **hospital**, the **researcher** will **visit** you on the ward. The **interview** will **take place** on the **ward**.

If you are at **home**, the **researcher** will **visit** you. The interview will take place in **your home**. The researcher will **ask questions** about you and your AFO (splint). Then the researcher will ask about **your thoughts** about **using AFOs**.

The interview will take place during the **daytime**. The interview can take place at a **time** that **suits you**. The interviews will happen between **July** and **August 2014**. You will **not** receive **any payment** for taking part.

Are there any risks in taking part?

The **researcher** will **ask** your **thoughts** about **using** an **AFO** (splint). This may make you **feel** more **tired**. The interview should only last half an hour. We hope the interview will **not** be **too tiring**.

If you **begin** to **feel tired**, you should **tell** the **researcher**. The researcher will give you **a break**. There are **no other risks** involved in this study.

Are there any benefits?

The researchers **cannot promise** any **direct benefits** to you. However the researchers hope to **understand** what **people** with **stroke think** about **using** their **AFOs** (splints).

This **knowledge can help** health professionals. **Health professionals** may be able to **understand** why **people** with **stroke** may **want to use AFOs** or **not**. The **information** you give may help professionals to **design interventions**. The interventions may allow **best use** of **AFOs** (splints).

What happens to the information in the study?

Your **confidentiality** will be **protected**. The researchers will **remove** your **name** from the **data** collected. Your name will be **replaced** with a **code**. Only the **researchers** will have **access** to your information.

Your **contact details** will be **stored** in a separate **secure** location. The **researcher** will store the data in a **secure** locked **filing cabinet**.
The cabinet is in the researcher's **office.** The office is **locked** when empty.

The researcher will also **store** the information **electronically**. This will be stored on a University **server**. Access to the server is **password protected**.

The **information** you **give** may be **used** in a **follow -up study**. The follow -up study is a **questionnaire**. You **do not need** to **take part** in the **follow-up** study. **If** you would **like** to take part, **let** the **researcher or** research **nurse know**.

The researchers **may use** some of your **quotes** in a future **publication**. The researchers will **anonymise** your quotes. You will **not** be **identifiable** from these quotes.

The **researchers** will **send** a **summary** document to you with **findings** of this **study**. The researchers can make a more **detailed report** of the final results available to you **on request**. We also **intend** to **publish** our **results** in a peer reviewed academic **journal**.

Four years after the study is **completed**, **all confidential information** will be safely **destroyed**.

The **University of Strathclyde** is **registered** with the **Information Commissioner's Office**. The Commissioners office implements the **Data Protection Act 1998.** All **personal data** on participants will be processed in **accordance** with the Data Protection Act 1998.

Please **ask** if you have any **questions** about how the **data** is **handled**.

Who has reviewed this study?

An **independent group** of people **look** at all **research** in the **NHS**. The group is called a **Research Ethics Committee**. The Ethics Committee **protect your interests**. **Newcastle** and **North Tyneside** 1 **Proportionate Review Sub Committee** has **reviewed** and **approved** this study.

What happens next?

If you are **happy** to **take part** in this study please **let** the **research nurse know.** The research nurse will then **pass** on your **contact details** to the main **researcher.** The researcher will then **call** you to **arrange** a **time** for the **interview** to take place. The time should be **convenient** to you.

You **may** need **more time** to decide, You can **take** this **sheet away** with you. **Talk** to **others** if you wish. You have **1 week** to **decide**. If **you decide** to take part you should **call** the **researcher** on **0141 548 3525**. You can **arrange** a suitable **time** for the **interview**. **Before** you take part you should to **sign** a **consent form**.

If you **do not** want to be **involved**, we **thank you** for **reading** this information sheet.

Questions?

*If you have **any questions** you should **ask** to **speak** to the **researchers**. The researchers will try to **answer** your questions. Their **contact details** are below.*

Chief Investigator Contact Details:

Christine McMonagle
NCPO, Department of Biomedical Engineering
131 St. James Road
University of Strathclyde
Glasgow G4 0LS

Tel: 0141 5483525 e-mail: christine.mcmonagle@strath.ac.uk

Other Investigator Details:

Susan Rasmussen

Senior Lecturer

School of Psychological Sciences and Health

University of Strathclyde

40 George Street

Glasgow G1 1QE

Tel: 0141 548 2575   e-mail: s.a.rasmussen@strath.ac.uk

*If you are **unhappy** and have any **concerns**,* during or after the investigation, or **wish** to **contact** an **independent person** to **discuss** your **concerns**, you can contact the **Patient Advice** and **Support Service.** You can **contact** the **Patient Advice** and **Support Service** through your **citizens advice** bureaux.

Phone numbers for local **citizens advice** bureaux (CAB) are:

Airdrie CAB: 01236 754 109
Bellshill CAB: 01698 748 615
Clydesdale CAB: 01555 664 301
Coatbridge CAB: 01236 421 447
Cumbernauld and **Kilsyth** CAB: 01236 723 201
East Kilbride CAB: 01355 263 698
Hamilton CAB: 01698 283 477
Motherwell and **Wishaw** CAB: 01698 251 981

Appendix 5.3: Consent Form for Beliefs Elicitation Study (Chapter 5)

Patient Identification Number for this study:

CONSENT FORM: Beliefs Elicitation Study

Title of Project: **An investigation into the use of ankle-foot Orthoses (splints) in people with stroke**

Name of Researcher: **Christine McMonagle**

Please **initial all boxes**

1. I **confirm** that I have **read** and **understood** the **information** sheet (28/05/14 -version 3) for the above study. The **researcher** has **answered** any **queries** to my satisfaction. ☐
2. I **understand** that my participation is **voluntary.** I am **free** to **withdraw** from the study at **any time without giving reasons** and this **will not affect** my **future clinical care** in any way. ☐
3. I **understand** that I can **withdraw** my **data** from the study at **any time**. ☐
4. I **understand** that any **information** recorded in the study will **remain confidential**. **No information** that **identifies** me will be made **publicly available**. ☐
5. I **understand** that **data collected** during the **study** may be **looked at** by **individuals**. These **individuals** may be from **regulatory authorities** or from **NHS Lanarkshire**. This **data** may be looked at where it is **relevant** to my **taking part** in this **research**. I **give permission** for these **individuals** to **access** this **information.** ☐
6. I **agree** to **take part** in the above **study**. ☐

Please **turn over** the **page**

Name of Participant	Date	Signature
Name of Person taking consent	Date	Signature

Appendix 5.4: Interview Schedule for Beliefs Elicitation Study (Chapter 5)

Interview Form –Elicitation of Beliefs about using AFOs

Read out to Participant: We are conducting a study of people with stroke who have been prescribed AFOs.

We are interested in your thoughts about using an AFO. We will use this information in a questionnaire to ask questions to other people with stroke who use AFOs. This will give us an understanding of beliefs about using an AFO from the patients' perspective.

There are no right or wrong answers- please answer the questions as honestly as possible. Your answers will be treated confidentially and used for research purposes only.

Do you have any questions about the information in the Patient Information Sheet?

Collect Consent form

Part 1- Clinical and Demographic details

Q1.1 Are you:

Male ☐

Female ☐

Q1.2 How old are you?

……………… Years old

Q1.3 Are you:

Married ☐

Divorced ☐

Widowed ☐

Living with a partner ☐

Single ☐

Q1.4 Do you have an AFO:

Yes ☐

No ☐

Q 1.5 Do you use your AFO?

Yes ☐

No ☐

Q1.6 Do you use your AFO(s): ***Please tick one option***

More often than recommended ☐

About as often as recommended ☐

Less often than recommended ☐

Don't know – I was not told how often to use the AFO ☐

Don't know – I can't remember ☐

Q1.7 When did you get your most recent AFO?

Month ……………….. Year ……………….

Part 2 –Beliefs

What do you believe are the **advantages** of using an AFO (splint)?

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(Prompt: anything else, that beneficial or good/ positive about using an AFO?)

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What do you believe are the **disadvantages** of using an AFO?

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(Prompt: anything else that's negative/ bad/ causes you problems when using an AFO?)

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Is there any other thoughts you have about using the AFO?

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Can you think of any individuals who **would approve of you** using an AFO?

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(Prompt: anyone else/ any other group?)

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Are there any individuals or groups who would disapprove of you using an AFO?

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(Prompt anyone else/ any other group?)

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Are there any other groups or individuals who come to mind when you think about using an AFO?

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What factors/ circumstances would make it hard for you to use an AFO?

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(Prompt: anything else that makes it hard / more difficult/ more of a challenge for you/ that stops you from using an AFO?)

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What factors/ circumstances make it easy to use an AFO?

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(Prompt: anything else that makes it easy/ straightforward/ reduces effort to use an AFO?)

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Is there anything else which comes to mind when you think about the challenges of using an AFO?

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Thank you for your answers.

Appendix 5.5: Behavioural, Normative and Control Beliefs Elicited and Resultant Themes

Beliefs	**Theme**
Advantages	
Easier to walk	Increased Mobility
Easier to move around environment i.e. visit other places (toilet, shops)	Increased Mobility
It lets me get around better	Increased Mobility
Keeps foot flat on floor	Supports position of leg or foot
Builds up confidence	Gives Confidence
Can see yourself getting better …walking is improving	Improves quality of walking
Helps with dropped foot	Supports position of leg or foot
Stops me from falling over/ less likely to fall	Improves balance/ prevents falls
For better balance	Improves balance/ prevents falls
I am more likely to walk outside (in better weather)	Increased Mobility
I can walk with it (I can't walk without it)	Increased Mobility
It supports your ankle / foot	Supports position of leg or foot
I would be too worried to walk without it	Gives Confidence
I can do standing activities (e.g. cooking)	Increased Mobility
It helps me get mobile (rehab)	Provides improvement in rehabilitation
Not dragging my leg as much	Supports position of leg or foot
I feel safer	Gives Confidence
Helps me to be straighter	Improves quality of walking
Going about in the garden	Increased Mobility
It gives strength and support to my leg	Supports position of leg or foot
I was struggling, then when I got the splint I could walk around my bed	Increased Mobility
It keeps my foot straight / stops it from turning in	Supports position of leg or foot
I could use less walking aids	Improves quality of walking
I started going to clubs outside	Increased Mobility
I felt I was achieving something with it	Provides improvement in rehabilitation
It helped me get back on my feet at the time Walking is more natural	Provides improvement in rehabilitation Improves quality of walking

Beliefs	**Theme**
Disadvantages	
Weight / heaviness	Heavy
Can't bend knee	Limits motion
Have to buy bigger footwear	Footwear size/ fit
Have to buy / wear different shoes (trainers/ orthopaedic footwear)	Footwear style
Can't wear with dressy shoes	Footwear style
Have to buy 2 pairs of shoes (different size)	Footwear size/ fit
(worried about) sweating in hot weather	Discomfort
Caused a rash	Discomfort
Trying to find shoes to fit	Footwear size/ fit
Limitations in clothing / (going to a wedding)	Clothing problems
I feel my leg is very stiff	Limits motion
Can't wear (orthopaedic shoes) in summer	Footwear style
Velcro sticks to trousers	Clothing problems
Discomfort	Discomfort
Want to wear a comfy pair of shoes	Discomfort
I can't be bothered to put it on	Effort required
It blocks movement (at ankle)	Limits motion
My leg is swelling	Sweating
Weight of the shoes	Heavy
Clumsy (shoes)	Footwear style
I have to wear a long sock	Clothing problems
People who would approve	
Friends	Friends
Nurses	Health Professionals
Spouse	Family
Children	Family
Physiotherapist	Health Professionals
OT	Health Professionals
Orthotist	Health Professionals
Sister	Family
Fellow users	Other users
Neighbours	Friends
People who would disapprove	
Spouse (the family)	Family
Children (the family)	Family
Neighbours (made a negative comment)	Acquaintances
Grandchildren	Family
Strength and movement teachers	Exercise Professionals

Beliefs	**Theme**
Factors that make it difficult to use	
Obstacles in street (e.g. paving stones)	Obstacles in the environment
Ill health	Being unwell
Going up and down stairs	Obstacles in the environment
I need a hand to get it off	Needing help to get AFO on and off
It's not made for someone with one hand	Limited/ poor hand function
If family/ help is not available to put on and off	Needing help to get AFO on and off
Ramps/ inclines/ gradients	Obstacles in the environment
Camber on pavements	Obstacles in the environment
Having a bad day	Feeling low or tired
AFO doesn't fit into boots	Poor fit of AFO with shoe
I don’t have the money to buy to different shoes (sizes)	Poor fit of AFO with shoe
Weather- affects the footwear I can use	Obstacles in the environment
If my leg got sorer	Muscle weakness or tightness
If the AFO causes pressure	AFO causing pain or discomfort
Low mood / can't be bothered	Feeling low or tired
People would be looking at me	Feeling self-conscious
Uncomfortable (digs in when I'm sitting down	AFO causing pain or discomfort
Self-conscious when wearing it	Feeling self-conscious
People with strokes have lost a lot of power anyway	Muscle weakness or tightness
Stairs	Obstacles in the environment
I get tired / feeling tired	Feeling low or tired
Can't feel where my foot is	Lack of/ poor sensation
If my leg swells up	Swelling of leg
A numb feeling/ pain up the legs	Lack of / poor sensation
If the shoes don't fit	Poor fit of AFO with shoe
Heavy footwear	Weight
Sometimes my heel wouldn't go right in (to the splint)	Muscle weakness or tightness
The home helps put it on too tight	AFO causing pain or discomfort
My hand doesn't work	Limited or poor hand function
If the AFO was thinner it could fit in different footwear	Poor fit of AFO with shoe
If they could make it less bulky	Bulky
If the AFO was lighter	Weight
If the AFO fitted better	Poor fit of AFO on leg
Factors that make it easy	
Getting used to putting it on	Having had experience in putting AFO on
The wedges for using in different shoes	Use of wedges for tuning
A bit of practice	Practice in using the AFO

Appendix 5.6: Behavioural Beliefs of Participants Grouped into Themes

Themes	Total number of participants expressing belief	Participant Number												
		1	2	3	4	5	6	7	8	9	10	11	12	13
Advantages														
Increased mobility	9	✓	✓		✓	✓	✓	✓		✓			✓	✓
Balance/ Falls	5			✓	✓		✓		✓					✓
Supporting the leg / position of foot	9		✓	✓		✓	✓	✓	✓		✓	✓		✓
Improved quality of walking	5		✓			✓	✓					✓		✓
Confidence	7		✓	✓		✓	✓	✓	✓		✓			
Provides improvement in rehabilitation	2					✓							✓	
Disadvantages														
Heavy	4		✓				✓			✓			✓	
Footwear size & fit	5			✓	✓	✓							✓	✓
Footwear style	5				✓	✓	✓		✓				✓	
Clothing problems	4					✓	✓	✓						✓
Discomfort	8				✓		✓		✓	✓	✓	✓	✓	✓
Limits motion	3		✓			✓				✓				
Swollen Leg	1										✓			
Effort required	1							✓						

Appendix 5.7: Normative Beliefs of Participants Grouped into Themes

Themes	Total number of participants expressing belief	Participant Number												
		1	2	3	4	5	6	7	8	9	10	11	12	13
People who approve														
Family	10		✓	✓	✓	✓	✓	✓	✓		✓	✓		✓
Friends	7	✓			✓	✓		✓			✓	✓		✓
Health professionals	9	✓	✓	✓			✓	✓	✓	✓	✓		✓	
Other users	1							✓						
People who disapprove														
Family	2			✓			✓							
Acquaintances	1						✓							
Exercise Professionals	1									✓				

Appendix 5.8: Control Beliefs of Participants Grouped into Themes

Themes	Total number of participants expressing belief	Participant Number												
		1	2	3	4	5	6	7	8	9	10	11	12	13
Factors that make it difficult to use an AFO														
Need help to get AFO on and off	4		✓	✓									✓	
Environmental obstacles	5	✓		✓	✓					✓		✓		
Being unwell	3	✓							✓		✓			
Pain or discomfort	4				✓		✓		✓				✓	
Poor fit of AFO with footwear	3				✓	✓						✓		
If I am feeling low/ tired	4			✓	✓					✓		✓		
Feeling self-conscious	2				✓		✓							
Weight	2									✓			✓	
Muscle weakness or tightness	3				✓		✓						✓	
Poor sensation	2									✓	✓			
Poor hand function	2						✓							✓
Bulk/ size	1						✓							
Fit of AFO	1								✓					
Factors that make it easy														
Practice/ training	2							✓				✓		
Experience	1							✓						
If the alignment is right	1							✓						

Appendix 6.1 TPB Questionnaire

This questionnaire asks about **your beliefs** about using an **ankle-foot orthosis** (AFO/splint). Please fill in all sections. Even if you **do not use** your AFO, **you can complete** the questionnaire. There are **no right** or **wrong answers** - please answer the questions **honestly**. Your answers will be treated **confidentially**. Your **answers** will be **used** for **research purposes** only.

Some of the **answers ask you** to **tick** a **box, circle** an **answer** or **tick** on a **scale**. **Some** answers ask you to **write** a **short answer**.

Section 1: Background Information Code:

Q1.1 Are you:

Male ☐

Female ☐

Q1.2 How **old** are you?

………….. Years old

Q1.3 Are you:

Married ☐

Divorced ☐

Widowed ☐

Living with a partner ☐

Single ☐

Q1.4 When did you have a **stroke?** *If you are not sure, give your best guess*

Month …………………… Year …………………

Q1.5 In general would you say your health is: *Please tick one option*

Excellent ☐

Very Good ☐

Good ☐

Fair ☐

Poor ☐

Q1.6 How serious was your **stroke?** *Please circle the answer closest to how you feel*

Very Serious	**1**	**2**	**3**	**4**	**5**	**6**	**7**	Not Serious at all

Section 2: About your AFO:

If you **have an AFO**, please **answer** the questions **below**
If you are **still waiting** for an **AFO,** go to **Section 3.**

Q2.1 Which leg is your **AFO** made for**?**
(If you use an AFO on both sides, indicate your most affected side)

Right Leg ☐
Left Leg ☐

Q2.2 When did you get your **current AFO?** *If you are not sure, give your best guess (e.g. Year: 2010, Month: March)*

Year …………. Month ………………………..

Q2.3 Do you **use** your **AFO?**

Yes ☐ **If yes,** please **go to Q2.5**
No ☐ **If no,** please **go to Q2.4**

Q2.4 a Do you **still have** the **AFO**?

Yes ☐ ***(If yes, please go to Q 2.4b)***

No ☐ **(If no, go to Q 3.1)**

Q2.4 b **Why** do you **not use** the **AFO**? ....
....
....
....

(Now go to Q 3.1)

Q2.5 Approximately, how many hours a day did you use the AFO in the last month?

................hours per day

Q2.6 Approximately, how many days a week did you use the AFO in the last month?

...............days per week

Q2.7 Do you use your AFO(s): *Please tick **one** option*

More often than recommended ☐

About as often as recommended ☐

Less often than recommended ☐

Don't know – **I was not told how often to use** the AFO ☐

Don't know – **I can't remember** ☐

Q2.8 How satisfied are you with the current AFO?

Very satisfied ☐

Satisfied ☐

Dissatisfied ☐ ***Please state why***

....

Very dissatisfied ☐ ***Please state why***

....

Section 3: Your beliefs about using an AFO as recommended

To answer most of the questions, you need to place a tick somewhere on a scale.

Here is an example:

I like to **use** my **AFO** to **walk inside** the house

Strongly agree ____ : ____ : ____ : ____ : ____ : ____ : ____ **Strongly disagree**

If you **place** your **tick closer** to **"strongly agree"**, you are the **sort of person** who **likes to use** their **AFO** to walk inside the house. **If** you **place** your **tick closer** to **"strongly disagree"** you are the **sort of person** who **does not like** to **use** their **AFO** to walk inside the house. **If** you **tick** the **middle** of the scale this means you **neither agree** nor **disagree** with the statement.

The following questions relate to using your AFO as recommended:

Q3.1 **I intend** to **use** my **AFO** in the next month

True ____: ____: ____: ____: ____: ____: ____ **False**

Q3.2 It is **up to me if I use** my **AFO** in the next month

Strongly Agree ____: ____: ____: ____: ____: ____: ____ **Strongly Disagree**

Q3.3 **Using** my **AFO** in the next month would be

Pleasant ____: ____: ____: ____: ____: ____: ____ **Unpleasant**

Q3.4 Most **people** who have an **AFO** after **stroke** will **use** their **AFO** in the next month

Very Likely ____: ____: ____: ____: ____: ____: ____ **Very Unlikely**

Q3.5 **For me, using** my **AFO** in the next month would be

Safe ____: ____: ____: ____: ____: ____: ____ **Unsafe**

Q3.6 I am **confident** that I can **use** my **AFO** in the next month

True ____: ____: ____: ____: ____: ____: ____ **False**

Q3.7 How many **people after stroke** do you **think** will **use** their **AFO** in the next month?

None of them ____: ____: ____: ____: ____: ____: ____ **All of them**

Q3.8 **For me, using** my **AFO** in the next month would be

Easy ____: ____: ____: ____: ____: ____: ____ **Difficult**

Q3.9 **I want** to **use** my **AFO** in the next month

Strongly Agree ____: ____: ____: ____: ____: ____: ____ **Strongly Disagree**

Q3.10 Most **people important** to **me** would **want** me to **use** my **AFO** in the next month

Strongly Agree ____: ____: ____: ____: ____: ____: ____ **Strongly Disagree**

Q3.11 **Using** my **AFO** in the next month will be under **my control**

Strongly Agree ____: ____: ____: ____: ____: ____: ____ **Strongly Disagree**

Q3.12 **I** am **planning** to **use** my **AFO** in the next month

False ____: ____: ____: ____: ____: ____: ____ **True**

Q3.13 **For me, using** my **AFO** in the next month would be

Harmful ____: ____: ____: ____: ____: ____: ____ **Beneficial**

Q3.14 Most **people important** to **me** would **approve** of me **using** my **AFO** in the next month

Strongly Agree ____: ____: ____: ____: ____: ____: ____ **Strongly Disagree**

Q3.15 **How likely** is it that **you will use** your **AFO** in the next month?

Very Unlikely ____: ____: ____: ____: ____: ____: ____ **Very Likely**

Q3.16 **For me, using** my **AFO** in the next month would be

Uncomfortab le	____: ____: ____: ____: ____: ____:____	**Comfortable**

Q3.17 **I** will **try** to **use** my **AFO**

Strongly Agree	____: ____: ____: ____: ____: ____: ____	**Strongly Disagree**

Q3.18 **I** am **confident** in **my ability** to **use** my **AFO** in the next month

True	____: ____: ____: ____: ____: ____: ____	**False**

Q3.19 **For me, using** my **AFO** in the next month would be

Good	____: ____: ____: ____: ____: ____: ____	**Bad**

Q3.20 If I **wanted** to, I could **easily use** my **AFO** in the next month

Strongly Agree	____: ____: ____: ____: ____: ____: ____	**Strongly Disagree**

Q4. Listed below are possible outcomes of using an AFO

How likely or **unlikely do you think it** is that each of the following outcomes will result from **using** your **AFO as recommended** over the **next** month

Using my AFO over the next month will…~~:~~	**Very likely** / **Very unlikely**
(i) … increase my mobility	____ : ____ : ____ : ____ : ____ : ____ : ____
(ii) … make my walking look more natural	____ : ____ : ____ : ____ : ____ : ____ : ____
(iii) … help with balance/ prevents falls	____ : ____ : ____ : ____ : ____ : ____ : ____
(iv) … increase my confidence	____ : ____ : ____ : ____ : ____ : ____ : ____
(v) … support my foot/ leg	____ : ____ : ____ : ____ : ____ : ____ : ____
(vi) … help me to improve during rehab	____ : ____ : ____ : ____ : ____ : ____ : ____
(vii) … make my leg feel heavy	____ : ____ : ____ : ____ : ____ : ____ : ____
(viii) …make my leg swell	____ : ____ : ____ : ____ : ____ : ____ : ____
(ix) … cause me discomfort /pain	____ : ____ : ____ : ____ : ____ : ____ : ____
(ix) … make it difficult to find footwear that fits	____ : ____ : ____ : ____ : ____ : ____ : ____
(x) … make it difficult to use footwear that looks good or matches my clothing	____ : ____ : ____ : ____ : ____ : ____ : ____
(xi) … limit my choice of clothing	____ : ____ : ____ : ____ : ____ : ____ : ____
(xii) … limit the motion at my joint(s)	____ : ____ : ____ : ____ : ____ : ____ : ____
(xiii) … require a lot of effort	____ : ____ : ____ : ____ : ____ : ____ : ____

Q5. Listed below are various groups of people

How much do you **think** each of **these groups** will **approve** or **disapprove** of you **using** your **AFO as recommended** over the **next month**

	Strongly Approve						Strongly Disapprove
(i) … Family	___	___	___	___	___	___	___
(ii) … Friends	___	___	___	___	___	___	___
(iii) … Health Professionals	___	___	___	___	___	___	___
(iv) … Other AFO users	___	___	___	___	___	___	___
(v) … Exercise professionals	___	___	___	___	___	___	___
(vi) … Other, please specify _______________-_______________	___	___	___	___	___	___	___

Q6. Listed below are **things** that **might make using** the **AFO as recommended easier** or more **difficult**

To **what extent** do you think each of **these** factors **will** make **using** your **AFO easier** or more **difficult over the next month**	**Makes** it **easier** to **use** my **AFO**						**Makes** it more **difficult** to **use** my **AFO**
(i) … Needing help to put on and take off the AFO	___ :	___ :	___ :	___ :	___ :	___ :	___
(ii) … Obstacles in the environment (e.g. kerbs, slopes, weather)	___ :	___ :	___ :	___ :	___ :	___ :	___
(iii) … Muscle weakness or tightness	___ :	___ :	___ :	___ :	___ :	___ :	___
(iv) … Lack of/ poor sensation in my leg	___ :	___ :	___ :	___ :	___ :	___ :	___
(v) … limited/ poor hand function	___ :	___ :	___ :	___ :	___ :	___ :	___
(vi) … Being Unwell (e.g. sickness)	___ :	___ :	___ :	___ :	___ :	___ :	___
(vii) … Poor fit of AFO on my leg or foot	___ :	___ :	___ :	___ :	___ :	___ :	___
(viii) … Poor fit of AFO with my shoes	___ :	___ :	___ :	___ :	___ :	___ :	___
(ix) … The AFO causing pain or discomfort	___ :	___ :	___ :	___ :	___ :	___ :	___
(ix) … Feeling self-conscious	___ :	___ :	___ :	___ :	___ :	___ :	___
(x) … Feeling low or tired	___ :	___ :	___ :	___ :	___ :	___ :	___
(xi) … The weight of my AFO or footwear I have been advised to use with it	___ :	___ :	___ :	___ :	___ :	___ :	___
(xii) … The bulk or size of my AFO	___ :	___ :	___ :	___ :	___ :	___ :	___
(xiii) … Practice using my AFO	___ :	___ :	___ :	___ :	___ :	___ :	___
(xiv) … Training using my AFO	___ :	___ :	___ :	___ :	___ :	___ :	___
(xv) … The right angle/ tilt of my AFO	___ :	___ :	___ :	___ :	___ :	___ :	___

Thank you for **completing** the **questionnaire.** Please **return** the **questionnaire** in the **stamped addressed envelope**.

Appendix 6.2 Participant Information Sheet for TPB Study (Chapter 6)

Title of the study: An investigation into the use of ankle-foot Orthoses (splints) in people with stroke

Invitation

A **research team** is **inviting** you to **take part** in a **research** study. **Before** you **decide** to take part, you **need** to **understand why** the research is being done. You also **need** to **know what** the researchers are **asking** you to do.

This **information** sheet **tells you** about the study. Take **time** to **read** the information sheet carefully. You can **talk to others** about the study. You can **ask** the **researcher** if there is anything you do **not understand**. You can also **ask** for more information.

Purpose of the Study

The **research team** wishes to **investigate** use of **ankle-foot orthoses (AFOs or leg splints)**. The **research team** wants to **know** about people with **stroke**. The researchers **want** to find out about the **factors affecting use** of **AFOs** (splints). This **information** will **help** researchers **design interventions**. The interventions **may help** people with **stroke** make **better use** of **AFOs** (splints).

The researchers will ask **you** to **fill** in a **questionnaire**. **After 1 month**, the researchers will **send** you a **2nd questionnaire**. We will ask you to **fill in both** questionnaires.

Christine McMonagle is the **main researcher**. Christine is an **orthotist** who works at the University of Strathclyde. This **research** is part of a **PhD**. Christine studies her PhD in the **School of Psychological Sciences and Health**.

Christine can be **contacted** at the following **address**:

Christine McMonagle
NCPO, Department of Biomedical Engineering
University of Strathclyde
131 St. James Road
Glasgow G4 0LS
Tel: 0141 5483525
e-mail: christine.mcmonagle@strath.ac.uk

Other investigators are **Dr Susan Rasmussen** and **Dr Mark Elliott.** They work at the School of Psychological Sciences and Health at the University of Strathclyde.

Do I have to take part?

It is **your decision** to take part. The information sheet **describes** the study. We will **give** this **sheet** to **you**. You will **have time** to **think** about **taking part**. You will be able to **ask questions** about the study.

You need to **sign** a **consent form** to take part. This shows you have **agreed** to **take part.** You **can withdraw** at any time. You do **not need** to give a **reason**. You can ask to **withdraw** your **information**. Withdrawal **does not affect** your **care** or your future treatment.

Why have I been invited to take part?

You have been invited to take part because:

- You have had a **stroke**
- You have been **prescribed an AFO** (splint) to help your standing or walking
- You are **over 18 years old**
- You are **able** to **share** your **beliefs** about using the AFO (splint).

Even if you **do not use** your **AFO** you can still **take part.**

What will I do in the study?

You will **fill in** a **questionnaire**. After **1 month**, the researchers will **send** you a **2nd questionnaire**. You should **fill out both** questionnaires.

The questionnaire should take **20 minutes** to **complete**. The questionnaire has some **statements** about **use** of **AFOs** (splints). The questionnaire asks you to **rate** the **statements.** You should **return** the **questionnaire** in the **pre-paid envelope** supplied.

In the **2nd questionnaire most** of the **questions** are the **same**. The researcher can **see** if your beliefs have **changed** over time.

You should be **able** to **consent** to take part. This means you should **understand** the **information** given to you. You should **understand what** the **researchers** are **asking** you to do. You should **freely volunteer** to take part.

If you are **not able** to **fill in** the questionnaire **yourself**, a **carer, family member** or **guardian** can **fill** it **in for you**, but you **still** must **give** your **own consent.**

Are there any risks in taking part?

You will **fill in** a **questionnaire twice**. The **questions** will **ask you** to **think** about using an AFO (splint). Thinking may make you **feel** more **tired**. The questionnaire can be **filled in** over a **few days**. The researchers do **not think** that **tiredness** will be a major **problem**.

There are **no other risks** involved in this study.

Are there any benefits?

The researchers **cannot promise** any **direct benefits** to you. However, the researchers **hope** the **information** you give can be **used in future**. The **information** you **give** may **help others**. The researchers want to **help others** make **best use** of **AFOs** (splints).

What happens to the information in the study?

The researchers will **separate** the **consent form** and **questionnaire**. They will **give** a **code** to your questionnaire. **Only** the **researchers** will have **access** to the **coded list**, with your contact details.

Your information will be kept **confidential**.
The **researcher** will store the data in a **secure** locked **filing cabinet**. The cabinet is in the researcher's **office.** The office is **locked** when empty.

The researcher will also **store** the information **electronically**. This will be stored on a University **server**. Access to the server is **password protected**.

The **researchers** will **send** a **summary** document to you with **findings** of this **study**. The researchers can make a more **detailed report** of the final results available to you **on request**. We also **intend** to **publish** our **results** in a peer reviewed academic **journal**.

Four years after the study is **completed**, **all confidential information** will be safely **destroyed**.

The **University of Strathclyde** is **registered** with the **Information Commissioner's Office**. The Commissioners office implements the **Data Protection Act 1998.** All **personal data** on participants will be processed in **accordance** with the Data Protection Act 1998.

Please **ask** if you have any **questions** about how the **data** is **handled**.

Who has reviewed this study?

An **independent group** of people **look** at all **research** in the **NHS**. The group is called a **Research Ethics Committee**. The Ethics Committee **protect your interests**. **Newcastle** and **North Tyneside** 1 **Proportionate Review Sub Committee** has **reviewed** and **approved** this study.

What happens next?

If you are **happy** to **take part**, **sign** the **consent form**. **Fill in** the **questionnaire**. **Return** the **consent form** and the **completed questionnaire** to the **researchers**, using the **stamped addressed envelope.**

The **researchers** will **send** you a **2nd questionnaire**, after **1 month**. You should **fill** it **in also**. **Return** the **questionnaire** to the researcher using the **stamped addressed envelope.**

If you **do not** want to be **involved**, we **thank you** for **reading** this information sheet.

Questions?

*If you have **any questions** you should **ask** to **speak** to the **researchers**. The researchers will try to **answer** your questions. Their **contact details** are below.*

Chief Investigator Contact Details:

Christine McMonagle

NCPO, Department of Biomedical Engineering

131 St. James Road

University of Strathclyde

Glasgow G4 0LS

Tel: 0141 5483525 e-mail: christine.mcmonagle@strath.ac.uk

Other Investigator Details:

Susan Rasmussen

Senior Lecturer

School of Psychological Sciences and Health

University of Strathclyde

40 George Street

Glasgow G1 1QE

Tel: 0141 548 2575 e-mail: s.a.rasmussen@strath.ac.uk

*If you are **unhappy** and have any **concerns**,* during or after the investigation, or **wish** to **contact** an **independent person** to **discuss** your **concerns**, you can contact the **Patient Advice** and **Support Service.** You can **contact** the **Patient Advice** and **Support Service** through your **citizens advice** bureaux.

Phone numbers for local **citizens advice** bureaux (CAB) are:

Airdrie CAB: 01236 754 109
Bellshill CAB: 01698 748 615
Clydesdale CAB: 01555 664 301
Coatbridge CAB: 01236 421 447
Cumbernauld and **Kilsyth** CAB: 01236 723 201
East Kilbride CAB: 01355 263 698
Hamilton CAB: 01698 283 477
Motherwell and **Wishaw** CAB: 01698 251 981