A clinical trial evaluating the feasibility and acceptability of orthotic shorts for walking function in people with multiple sclerosis.

Background

Multiple sclerosis (MS) is a chronic neurological disease characterised by plaques of demyelination and transection of axons in the central nervous system. In the UK, 76% of people with MS (PwMS) have mobility problems (Jones et al, 2013) and 70% say that difficulty walking is the most challenging aspect that they face (LaRocca, 2011).

PwMS walk more slowly, take fewer steps, have a shorter step length, a more prolonged double support phase and a wider base of support than non-neurologically impaired people (Givon et al, 2009). Walking pattern is variable from one step to the next, even in PwMS who are not aware of any impairment (Flegel et al, 2012; Spain et al 2012). In addition to walking problems, PwMS have balance difficulties, fear of falling, low levels of physical activity and fatigue (Garg et al, 2016). Recent studies have demonstrated that slowed somato-sensory conduction, particularly in the spinal cord, is a common problem leading to poor balance and slowed postural responses (Cameron et al, 2008a; Huisinga et al, 2014).

Fabric orthoses have been suggested to be helpful for PwMS (Hassan and Snowdon, 2015; Miller et al, 2015). These are garments, made from elasticated fabrics, that are suggested to dampen down error in uncoordinated movement, provide external support for unstable joints and enhance sensory feedback (Watson et al, 2007). Orthotic shorts are a type of fabric orthosis designed to support the hips and pelvis. These may be particularly important for PwMS because pelvic movement in walking has been shown to be particularly variable, especially in the medio-lateral plane (Huisanga et al, 2013), and this lack of stability around the hips and pelvis may negatively impact balance and walking.

Research on other types of elasticated supports indicates that orthotic shorts might improve sensory feedback and movement control. For example, studies have shown an improvement in proprioception with Neoprene joint supports (e.g. Collins et al, 2011; van Tiggelen et al, 2008; Newcomer et al, 2001). Cameron et al (2008b) demonstrated that compression shorts could significantly improve proprioception at the hip in an active lower limb task in standing in healthy participants. In addition to demonstrating an immediate improvement in hip proprioception, Kraemer et al (1998) demonstrated an improvement in power output during a vertical jump in healthy participants wearing compression shorts.

Previous research suggests that orthotic shorts might provide crucial stabilisation around the hip. Maguire et al (2010) investigated Theratogs shorts in stroke survivors and showed that they improved gait speed, whilst increasing hip abductor activity at the affected hip. However, there is very limited research investigating fabric orthoses in MS, with only one previous trial looking at sleeves for ataxia in the upper limb (Miller et al, 2015) and one study investigating sleeves and socks as an adjunct to Botulinum toxin (Stone, 2014).

A key controversy around the use of any fabric orthoses lies with their acceptability, which was found to be poor in children with cerebral palsy in some of the early research (Knox et al, 2003; Blair et al, 1995). However, a more recent survey found that 94% of families surveyed found the orthoses helpful for their children (Raper et al, 2011) and orthoses were found to be acceptable in recent MS trials (Miller et al, 2015; Stone, 2014). Some specific guidelines have been developed for assessment of individual's motivations prior to prescription of fabric orthoses (Wakefield Clinical Commissioning Group, 2014). Improved understanding of who might benefit and who is likely to persist with using an orthosis is an important area for further investigation.

The authors have recently conducted a small, unpublished qualitative study with PwMS who regularly use fabric orthoses. The data suggested a number of key factors determining whether an orthosis would be used in the longer term. These factors were the importance to the individual of the problem that the orthosis was designed to address, the immediate impact of the orthosis when it was first worn and the support provided by healthcare professionals in the initial period of wear. Non-use of prescribed orthoses is also an issue for ankle-foot orthoses (McMonagle et al, 2016) and maybe other orthoses and so further investigation as to the factors impacting upon acceptability may be important for wider practice.

In conclusion, it is suggested that orthotic shorts might improve walking in PwMS, however, with little previous research informing their use, it is crucial to determine acceptability and feasibility of the shorts prior to investing in a larger effectiveness study.

Aims and objectives

The proposed study aims to determine the acceptability and feasibility of orthotic shorts for improving walking in PwMS. Feasibility of the intervention includes assessment of the immediate, short-term effect of orthotic shorts on walking ability and whether the acceptability of the shorts can be predicted from the initial consultation or the initial experience of use. In addition, the study will pilot methods for a potential future trial by testing procedures for prescription of the shorts and determining the most appropriate outcome measures.

The study objectives are:

1. To investigate the acceptability of orthotic shorts.
    a. Determine how often the shorts are used and whether recommendations for wear are adhered to
    b. Determine perceptions of the advantages and disadvantages of wear, including perception of initial effect.
    c. Determine views of participants on whether they would continue to wear shorts and, if so, how and why
    d. Determine participants' views on the prescription protocol, such as the information given about the shorts, the wearing routines, expectations and adapting the shorts.

2. To explore the short-term effect of wearing orthotic shorts on walking and to determine the most relevant outcome measures for a future study
    a. Determine whether there is any change in response to wearing orthotic shorts in spatio-temporal gait parameters, trunk stability in walking, walking speed and dual task cost.
    b. Determine whether there is any change in response to wearing orthotic shorts in self-reported walking ability, balance confidence and incidence of falls
    c. Investigate participant perception of outcome measures used, such as whether they capture elements of walking ability that are considered important.

3. To explore whether there are any potential determinants of longer term orthotic use by investigating if there are emerging relationships between participants' decisions about longer term use and:
    a. the motivations and expectations expressed at the initial consultation
    b. participant perceived effect of the shorts on walking ability on first usage

c. the effect of the shorts on measures of spatio-temporal gait parameters, trunk stability in walking, walking speed and dual task cost
d. the effect of the shorts on self-reported walking ability, balance confidence and incidence of falls
e. the perceived advantages and disadvantages of wearing shorts.

Methods

Study design

This is a mixed methods, randomised cross-over study investigating orthotic shorts versus a placebo pair of shorts. The shorts will be tested in two main ways, firstly, the impact of the shorts on objectively assessed walking ability when first worn and, secondly, acceptability and impact of the shorts on self-perceived ability over a two-week period when the shorts are worn in the community.

Participants

Participants will be PwMS who identify themselves as having some difficulty walking, with a lack of stability around the hips and/or lower trunk. The study aims to recruit 16 PwMS over a 12-14 month period between January 2018 and February 2019. It is felt that a sample size of 16 will enable the shorts to be trialled with participants with a range of different movement problems as well as different ages, genders and activity levels. These are characteristics that we suspect may impact upon the impact and acceptability of the shorts. Table 1 summarises the eligibility criteria.

Table 1: Eligibility criteria

Inclusion criteria	Exclusion criteria
Diagnosed as having multiple sclerosis of any type (relapsing-remitting, primary progressive or secondary progressive). Clinically stable – have not experienced relapse in the last 4 weeks; have not commenced a novel therapy in the last 3 months. Able to travel to Sheffield Hallam University for assessments. Have difficulty walking with a subjective feeling of instability around the hips or lower trunk. Able to walk for at least 2 minutes at a time. Able to provide a written record of informed consent.	People who do not meet inclusion criteria. Skin conditions that may be exacerbated by tight clothing. Circulatory problems that may be exacerbated by tight clothing, such as varicose veins, previous thrombosis, venous or arterial insufficiency. Cognitive problems including memory disturbance that may impact on recall of experience and adherence to guidance. Pregnancy – because of related circulatory problems. Living further than 10 miles from Sheffield if they are unable to provide own transport and the home visits would be too far for the researcher to travel. Have previously used orthotic shorts.

Recruitment

Recruitment will utilise a number of strategies in order to obtain the required number of participants in the proposed time period (Carter et al, 2015). Participants will be recruited from both Sheffield Teaching Hospitals NHS Foundation Trust and via community groups for people with multiple sclerosis (PwMS).

Participants will be made aware of the study in a number of ways:

- Flyers (see Appendix 1) will be left at MS clinics and in therapy departments at both the Royal Hallamshire Hospital and Northern General sites.
- About 5-10 potential participants already known to the therapy team at Sheffield Teaching Hospitals will be contacted by telephone by the Principal Investigator (a clinical physiotherapist at Sheffield Teaching Hospitals). He will ask if they would like to receive information about the study. If they do, then the Participant Information Sheet will be posted or e-mailed to them, according to their preference. This will be recorded on a recruitment log to ensure that people are not approached more than once and to record recruitment rates.
- The Chief Investigator will raise awareness of the study via presentations to healthcare staff working with PwMS at Sheffield Teaching Hospitals and these physiotherapists, occupational therapists and MS Specialist nurses will raise awareness of the study when they meet potential participants in the course of their duties. They will provide flyers to potential participants containing contact details for both the Chief Investigator and Principal Investigator. If these people contact either investigator, a record will be made in the recruitment log.
- During periods of low recruitment, the Chief Investigator will attend MS clinics so that any potential participants can talk directly with the Chief Investigator.
- We will seek to advertise the study on the webpage for the national MS Society UK and promote the study at local MS Society events and at the MS Therapy Centre in Sheffield.

Interested participants will contact the Chief Investigator or the Principal Investigator by telephone, e-mail or face to face. The researchers will explain the study and provide them with the Participant Information Sheet (see Appendix 2) directly or by post or e-mail. Researchers will arrange time for a follow-up contact with the Chief Investigator when the potential participant has had chance to consider their involvement. At the follow-up contact, the Chief Investigator will phone the potential participants, answer any questions, confirm eligibility, check their extent of involvement in any other research studies and either record in the recruitment log any reasons offered for non-engagement or arrange a time for the potential participant to attend Sheffield Hallam University for the first appointment. At the first appointment, potential participants will have a further opportunity to ask questions and, if they are happy to be involved in the study, they will sign an informed consent form (Appendix 3).

Procedure

The proposal will be submitted to the Sheffield Teaching Hospitals NHS Trust Research and Development department and the National Research Ethics Service. The study will commence once all relevant Ethics permissions have been confirmed.

An overview of the study process for each individual participant is provided in Figure 1. In brief, each participant will visit Sheffield Hallam University on four occasions and be seen at home on three occasions.

The first Sheffield Hallam visit (Appointment 1) will include informed consent, collection of basic participant details, an initial interview around expectations and motivations, completion of self-report measures, assessment and measurement for shorts with a representative from DM Orthotics and provision of a falls diary for completion over the following two weeks. Participants will be randomly assigned to the order in which the different shorts will be tested.

The second and third Sheffield Hallam visits (Appointments 3 and 5) follow the same structure with one visit testing one pair of shorts and the other visit the other pair of shorts. Firstly, walking ability without the shorts will be measured. They will put the shorts on and spend about 30 minutes becoming familiar with wearing the shorts before the objective measures are repeated. After the objective assessments,

participants will be provided with further information on wearing and caring for the shorts and a wear diary and falls diary to be completed whilst the shorts are trialled at home.

The final Sheffield Hallam visit (Appointment 7) will include a final measure of walking ability without shorts plus a semi-structured interview around the participants' experiences of the shorts and the trial.

In between the above visits to Sheffield Hallam, there will be three shorter visits. These are termed "home visits" in Figure 1 but each participant can choose to attend university or meet in an agreed location if preferred. The first home visit (Appointment 2) will be with the representative from DM Orthotics to check the fit of the shorts and measure the pressure exerted by the shorts. If adjustments are required at this point, this will be done within 3 days and the shorts will then be delivered to the chief investigator. The second and third home visits (Appointments 4 and 6) are to collect the shorts, the diaries and the self-report measures reporting the perceived impact of the shorts after the period of home wear.

Intervention

The orthotic shorts (see Appendix 4) will be custom-made by DM Orthotics, a UK based company that specialises in dynamic, elastomeric orthoses for healthcare and sport. They will provide both the orthotic shorts and a pair of placebo shorts for each participant, both constructed from a 275 g/m2 fabric, which is 51% Polyamide, 32% Dorlastan and 17% cotton. The placebo shorts will fit snugly enough to stay in place but provide minimal compression or support. The company representative who will assess each participant will decide the compression and fit of the shorts, such as whether support for the lower trunk is required. The shorts can be manufactured with a toileting hole, if preferred, allowing participants to toilet without removing the shorts. Shorts with a toileting hole are worn beneath usual underwear.

The company's identity will not be revealed to participants to prevent participants finding information about the shorts from online resources. Neither shorts will have a logo or label identifying the manufacturer.

Randomisation and allocation

Counter-balancing will ensure that half the group use the orthotic shorts first and half the placebo shorts first. A randomisation schedule will be created by a using the Sealed Envelope online system at https://www.sealedenvelope.com/simple-randomiser/v1/lists for blocked randomisation. Shorts will be placed into sealed envelopes labelled "Shorts 1" and "Shorts 2" by a third party using the randomisation schedule.

Data collection

Qualitative semi-structured interviews

Semi-structured interviews will be conducted on two occasions for each participant. Topic Guides are provided in Appendix 5.

At Appointment 1 at Sheffield Hallam, participants will be interviewed to explore their motivations for joining the study, their expectations of the shorts, their current daily activities and their readiness for change. The data from this interview will enable investigation of whether certain aims, motivations or perceptions impact upon the eventual acceptability of the shorts. This may enable us to develop advice for potential future users and funders of orthotics regarding factors that predict continued use. This initial interview is likely to last 20 - 40 minutes.

At Appointment 7 at Sheffield Hallam, participants will be interviewed about their experiences during the study. This interview aims to determine the acceptability of the shorts and participants' views on the study processes such as the information and support they received, and the outcome measures used. Prior to the interview, the interviewer will review the data and reflective notes from the initial interview; the wear diaries and the Participant Global Rating of Change scores at the initial assessment and will use

this information to inform the questions that are asked. This will ensure the interviews are focussed on aspects that are important to each participant. This final interview is likely to last 40 - 60 minutes.

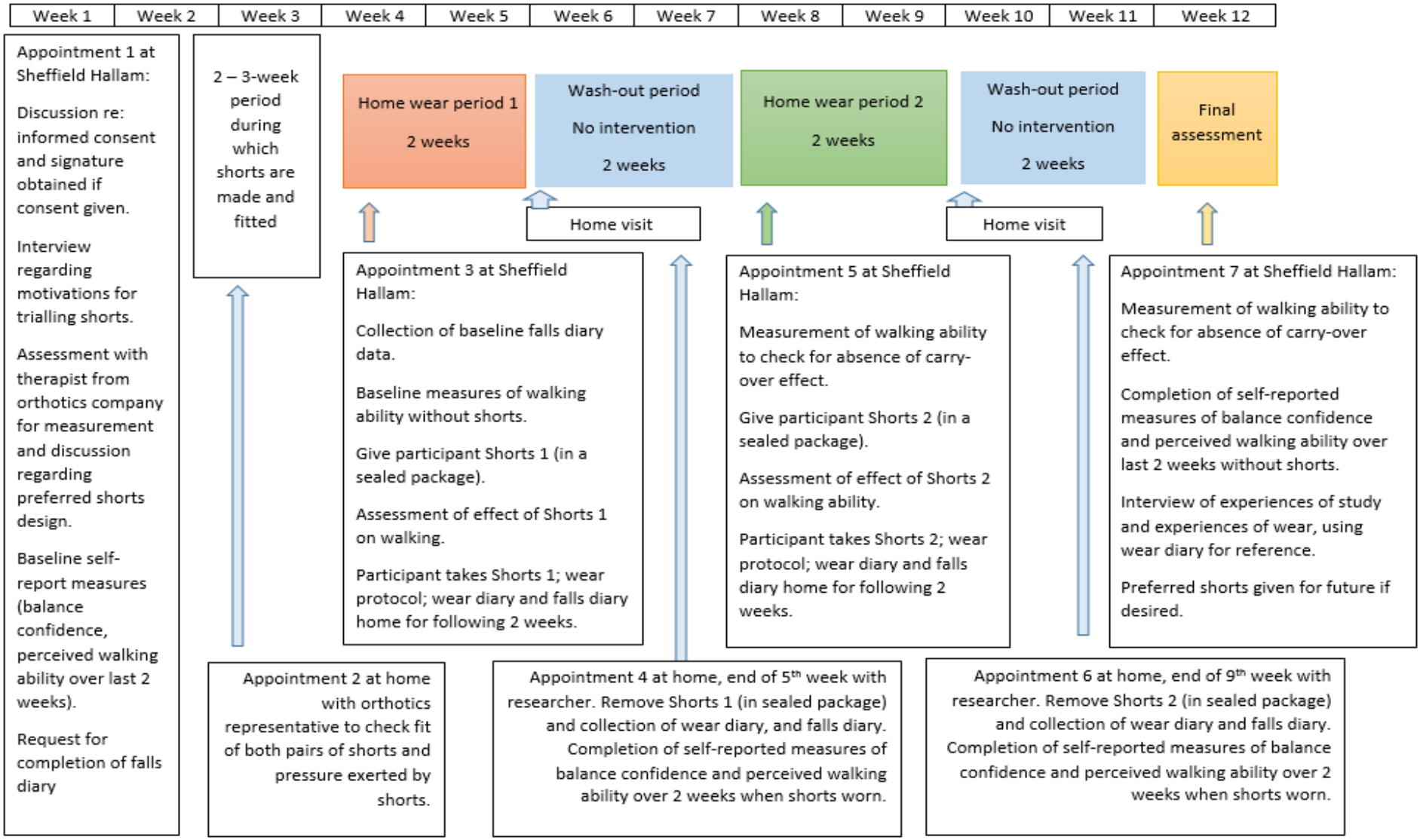

Figure 1: An overview of study design

Each interview will be transcribed verbatim and transcripts utilised for the data analysis. In addition, a reflective diary will be kept by the interviewer for noting initial reflections and experiences on the participants' non-verbal communication and on the interview process itself.

Objective measures of walking ability

Measures of walking have been chosen according to current guidelines on the most relevant assessment battery for PwMS (Bethoux and Bennett, 2011; Capra et al, 2014; Gijbels et al, 2012) and from recommendations on outcome measures for investigating lower limb orthotics (Brehm et al, 2011). All assessments will be performed by giving clear instructions at the start of the test and no verbal encouragement during the test. Walking aids may be used during each assessment and, wherever possible, testing conditions will be kept the same across the different assessment points.

The research team have piloted the proposed measures with one individual with multiple sclerosis who currently uses cycling shorts to stabilise his hips. The proposed measures were completed in an acceptable time frame. He felt that all measures captured important elements of his walking difficulties and important ways in which he felt the shorts helped his movement. Some fatigue was noted towards the end of testing, therefore, we plan to randomise the order in which the measures are taken for the different participants, to limit the impact of an order-effect on our appraisal of the measures.

Spatio-temporal parameters of gait

Spatio-temporal parameters will be assessed using the GAITRite 3.8, which is a 5.18m walkway containing sensor pads that detect footfall. The GAITRite system is a commonly used research tool for multiple sclerosis research. It has been shown to have excellent agreement with the Vicon motion analysis system (Webster et al, 2004) and to be a reliable and valid method of recording spatio-temporal gait parameters in multiple sclerosis (Sosnoff et al, 2015).

The GAITRite system will be used to provide data on the following parameters, which are known to be altered in PwMS (Givon et al, 2009): cadence, step length, proportion of gait cycle in double support and width of base of support. A mean value for each parameter will be calculated for each assessment, for both legs together and each leg in turn, enabling assessment of symmetry of gait. In addition, the variability of step length, stride time and step width will be calculated using both the standard deviation and coefficient of variation. Variability of walking has been shown to be a key feature that distinguishes people with MS from non-neurologically impaired people (Flegel et al, 2012) and is closely related to falls risk (Allali et al, 2016; Socie et al 2013). Measures of variability of gait may be more sensitive to change than other gait parameters (Hausdorff, 2005).

Participants will perform four consecutive walks over the GAITRite walkway. Each walk will commence 2m before the walkway and finish 2m after the walkway so that a steady state of gait is assessed. Konig et al (2014) reported that more than 10 gait cycles need to be assessed in order for the measures of variability to be reliable in healthy people. Previous research on gait variability in MS has utilised at least two trials over the walkway on either a 7.9m or 10m walkway (Socie et al, 2013; Flegel et al, 2012) so we estimate that four trials over the 5.18m walkway will enable reliable measures of variability.

Trunk stability during walking

An alternative method for assessing gait variability is to assess movement of the trunk and pelvis whilst walking. It has been shown that PwMS sway more in standing and walking than do non-neurologically impaired people and that more trunk sway is associated with higher levels of disability (Corporaal et al, 2013). The orthotic shorts are hypothesized to have their main effect via stabilising the hips and pelvis.

Trunk sway will be measured using Inertial Measurement Units as described by Huisanga et al (2013). Sensors are mounted on belts that enable firm positioning over the sternum, 2cm below the sternal notch and over the sacrum. These are attached over clothing so assessor blinding to the intervention can be maintained.

Participants will walk along a corridor of approximately 100 feet and sensors will record trunk and pelvic movement for 30s of steady-state walking. The following variables will be extracted for movement in the medio-lateral direction: peak-to-peak amplitude of the acceleration traces, mean and standard deviation of acceleration and mean velocity of movement.

Walking speed

Walking speed is an indicator of walking function. For example, there is a moderate correlation between walking speed and step count measured over a week (Motl et al, 2013) and walking speed may predict employment status (Capra et al (2014). Walking speed will be assessed using the Timed 25-foot Walk (T25FW). This is a commonly used clinical and research assessment of walking ability shown to be reliable in PwMS (Cohen et al 2014; Coleman et al. 2012; Hobart et al, 2013). A change of 20% is considered clinically meaningful (Hobart et al, 2013; Kaufman et al, 2000).

Participants will perform the test twice, with a short rest of less than 5 minutes, between each trial and the mean speed for both trials will be calculated (Hobart et al, 2013). They will start from standing and be asked to walk as quickly as they can.

Cognitive demand of walking

PwMS appear to compensate for difficulty walking by increasing cognitive control (Etemadi et al 2016; Wajda et al, 2013; Nilsagaard et al, 2009). Our qualitative findings suggest that cognitive demand of walking might be decreased when wearing orthotic shorts and this is important because cognitive demand of walking may increase fatigue in MS (Hamilton et al 2009). The cognitive demand of walking is assessed using a Dual Task Cost paradigm.

Dual task cost will be calculated using measurement of the T25FW as described by Sandroff et al (2015). Having first recorded the mean time taken for two trials as described above, participants will be asked to walk as fast as possible a third and fourth time, whilst naming alternate letters of the alphabet. The Dual Task Cost is the percentage change in T25FW (walking speed as a single task minus walking speed as dual task divided by walking speed for single task multiplied by 100). To discourage participants from prioritising walking over the cognitive task (Wajda et al, 2016), participants will be asked to divide their attention equally between the cognitive and walking task and the number of letters correctly given will be recorded.

Participant rated perception of effect

Participant perception of whether the shorts improve walking may be a factor that determines ongoing wear and if this is the case then this could be a routine part of assessment. This will be assessed at appointments 3 and 5 at Sheffield Hallam, whilst the participant still wears the shorts and following the objective measurements described above.

The scale used to assess this shown in Figure 2 is a Global Rating of Change scale designed according to the guidelines suggested by Kamper et al (2009).

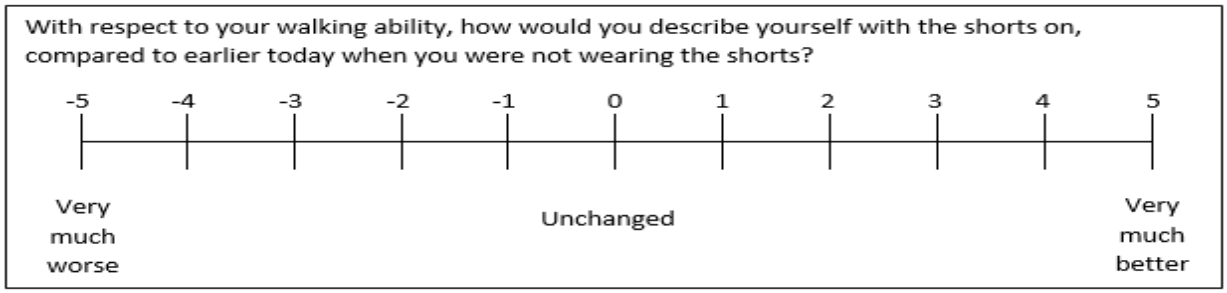

Figure 2: Global Rating of Change Scale

Self-report measures of walking and balance

Participants will complete the self-report measures at the beginning and the end of the study and following the home wear period for each pair of shorts. Each measure takes 5-10 minutes to complete.

Self-perceived walking ability

Assessment of self-perceived walking ability will complement the laboratory measures used and enable a rating of the impact of shorts in daily life. The 12-item Multiple Sclerosis Walking Scale (MSWS-12) will assess self-perceived walking ability. This is the only measure designed specifically for this purpose in MS (Kieseier and Pozzilli, 2012). It asks how much MS has impacted upon various aspects of mobility over the previous two weeks, such as running, stairs, effort, distance, speed, smoothness of walking and need for support. It is believed to capture quality of movement, not just speed and endurance (Pilutti et al, 2013), correlates well with overall walking function (Kieseier and Pozzilli, 2012; Motl et al, 2013) and there is evidence of strong psychometric properties, including internal consistency and responsiveness (Hobart et al, 2013; Motl and Snook, 2008).

Balance confidence

Balance confidence is closely related to walking ability (Nilsagard et al 2012) and could be impacted upon by improvement in stability around the hips and pelvis. Balance confidence will be measured using the Activities Specific Balance Confidence scale (ABC), which asks questions about confidence performing a range of tasks. It has been shown to be a reliable and valid measure of balance confidence having good internal consistency (Nilsagard et al 2012) and test-retest (Cattaneo et al, 2007) reliability and relating closely to measures of balance function, including frequency of falls (Cattaneo et al, 2007).

Frequency of falls

Whilst prevention of falls is not a primary focus of the study, if improving stability around the hips and trunk can limit the number of falls, this would be extremely important. Falls are hard to predict using only measures of walking ability and balance confidence (Coote et al, 2014) and, therefore, participants will complete a falls diary for multiple two week periods – at baseline, in the final two weeks of the study (without shorts) and during the two home wear trial periods. The definition of a fall used is “an unexpected event in which you come to rest on ground, floor or a lower level”.

It is likely that recording falls over only a 2-week period will not fully capture any impact of the shorts on falling. Coote et al (2014) recommend a 3-month recording period with bi-weekly reminders by phone and monthly returns for falls intervention studies. However, including this measure within the feasibility study will enable feedback on participant burden and perceived relevance to the intervention and so, inform future studies.

Pressure exerted by the shorts

Because it is possible that the shorts may have some of their effect by compression of the tissues and measurement of pressure is strongly recommended for research into compression garments (MacRae et al, 2011), the pressure beneath the shorts will be measured at the initial fitting. A Kikuhime pressure monitor will measure pressure over the gluteus medius muscle. This device is commonly used in compression garment studies and is reliable and valid for this purpose (Brophy-Williams et al, 2014).

Data analysis

Mixed methods studies are characterised by integration of qualitative and quantitative data (Cresswell and Plano Clark, 2011). The proposed project will be a convergent parallel design in which qualitative and quantitative data are first analysed separately (as detailed in Appendix 6). After this, data will be merged, partly by transforming qualitative into categorical data where this provides a valid representation of the data and partly by comparing, contrasting and relating the findings of the different data types for each objective.

Qualitative data analysis will use the Framework Approach to thematic analysis, first described by Ritchie and Spencer (Ritchie et al, 2013; Gale et al, 2013). Transcripts will be coded according to themes decided a priori and data relating to each theme will be placed into a matrix. This allows the data for each participant and for each theme to be carefully compared. The analysis will be largely deductive, however, each transcript will be checked after coding to avoid missing any points that do not fit the predetermined themes. The coding, charting of the data into the matrix and the interpretation of findings from that matrix will be reviewed by a supervisor experienced in qualitative data analysis.

Descriptive quantitative data analysis will determine individual and average changes on each measure and effect sizes for the impact of the shorts. For interval level data, each dataset will be tested for normal distribution; normally distributed data will be analysed with means, standard deviation, coefficient of variation and a standard effect size. Non-normally distributed interval data, ordinal and categorical data will be analysed using non-parametric tests. For example, data will be described with median and range and effect size will be calculated using the formula devised by Pallant (2007) and the Fischer's Exact Test will indicate if they might be any relationships between different categorical variables, such as expectations and whether the shorts are worn in the longer term. This test is considered a good choice for investigating relationships between categorical variables for a small sample.

Effect sizes will indicate which measures are most responsive to this intervention and this information may be used to inform a sample size calculation for future studies.

Appendix 6 shows the relationship between the study objectives, data collection methods and data analysis.

Dissemination strategy

Once approved, the study protocol will be submitted for publication in a suitable journal such as Trials or Contemporary Clinical Trials. Findings from the study will be disseminated via professional conferences and to user groups via the MS Society UK. It is anticipated that at least two research papers will arise from this project and we will submit for publication in relevant professional journals such as those specialising in orthotics, multiple sclerosis and rehabilitation.

Timeline

Data collection will commence in January 2018 and continue until February 2019. Figure 3 shows a Gantt chart for the study.

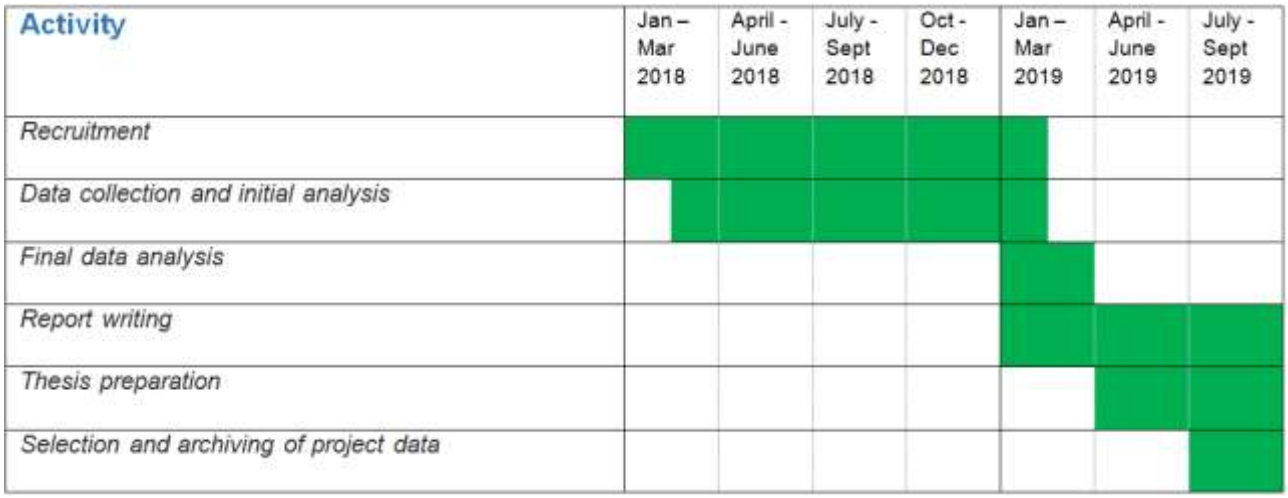

Figure 3: Gantt chart showing study timeline

Ethical considerations

All study procedures will protect the dignities, rights, safety and wellbeing of participants and potential participants.

The recruitment strategy, information sheet and consent form have been designed according to the guidelines published by the Health Research Authority (2014). Participants are able to withdraw from the study at any time without giving a reason.

A risk assessment has been carried out to minimise risks to the participants and research staff (Appendix 7).

A Site File will be kept and stored securely at Sheffield Hallam University with hard copies of the participant list and consent forms kept in a locked cupboard. Participants will not be identifiable in any electronic data. Electronic data will be kept in the secure university Q-drive during the project. A full Data Management Plan is provided in Appendix 8.

In the Information Sheet, we describe that we are comparing two types of shorts, when in fact we consider one of the pairs of shorts to be a placebo. Describing the study as a comparison between two pairs of shorts is an accurate statement and we will warn the participants that one pair of shorts is more supportive than the other. The placebo shorts will look similar but not provide any compression and very little support. We will explain to participants at the end of the final interview that the looser pair of shorts was not expected to have any effect and we will offer an opportunity for them to express their feelings about this (Topic Guide for final interview, Appendix 5). We feel it is unlikely that participants will object to this. If participants do feel that they have been deceived and express concerns about this, we will ask if they wish to withdraw their data from the project and will abide by their wishes.

Benefits of the study

There is a scientific justification for this study in that it fills a gap in the research and systematically investigates a potentially effective intervention. We believe this topic is of importance to service users because both Hassan and Snowdon (2015) and our unpublished qualitative study with service users found

high levels of frustration with both the lack of health service support for provision of these orthoses and the paucity of research.

Earlier in this doctoral programme, the chief investigator presented her early ideas to service users from the Sheffield Ataxia UK organisation. They could see the potential for a positive effect but none had heard of this concept previously, indicating that therapists rarely suggest fabric orthoses. They expressed concerns around just how acceptable such orthoses might be, for example, might they restrict movement too much or cause skin soreness. They also suggested that whether there really is any impact on movement control should be relatively easy to determine. These two key arms of investigation are developed in this study – acceptability of the orthoses and whether any measures detect a change in movement.

This study is a preliminary investigation. If the shorts are acceptable, then a fully powered study will be designed into the effectiveness of these shorts and that future study would be built upon the knowledge gained here. The information about measurement would inform the choice of primary outcome measure and the sample size required to test effectiveness. In addition, we will gain crucial information about recruitment rates and acceptability of the study processes. It may be that the shorts are acceptable to only certain people, in which case a future study could be targeted at such individuals.

Beyond the focus on fabric orthoses, we aim to learn more about the wider process of providing orthotics to people with impairments. By investigating whether there are any possible determinants of future use, we could better inform the provision of many other sorts of orthotics. Orthoses such as ankle-foot-orthoses for ankle instability are effective in improving walking in many neurological problems (Prenton et al, 2016) but still users choose not to wear them (e.g. Vinci et al , 2008). If we better understood the determinants of long-term use of orthoses we could inform people better and target such interventions on those who are likely to benefit. This study hopes to inform this under-researched but important issue.

Resources and costs

This study is supported by Sheffield Hallam University in the form of venue, technical support and equipment. The Department of Allied Health Professions is supporting the doctoral studies of the Chief Investigator and this includes research time for recruitment, data collection and analysis. Sheffield Teaching Hospitals NHS Trust will assist with recruiting participants and fund the principal investigator. Other than this no additional funding is available for this study.

Additional funding is sought to cover travel expenses. If this is not successful then the researcher's personal funds will cover these expenses.

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Appendix 1 – Poster advertising study

Sheffield Hallam University

Participants required for research

Can orthotic shorts help people with multiple sclerosis (MS) to walk?

We are looking for people with MS:

- who have some difficulty walking,
- who feel "unstable" and "wobbly" around their hips or trunk and
- who can trial some shorts and give us feedback.

The study involves having two pairs of shorts made to measure, having your walking tested in a number of ways, wearing the shorts at home for 2 weeks each and being interviewed about your experiences. If the shorts are helpful, you can keep them after the study.

Testing takes place at Sheffield Hallam University at Collegiate Crescent. We can help with transport costs, if you live within 10 miles.

For further information please contact either:

Nicky Snowdon, Lecturer in Physiotherapy, Sheffield Hallam University.
0114 225 5751
n.snowdon@shu.ac.uk

Lee Drake, Clinical Specialist Physiotherapist in Multiple Sclerosis, Sheffield Teaching Hospitals.
0114 271 3090

Sheffield Hallam University

Participant Information Sheet

A clinical trial evaluating the feasibility and acceptability of orthotic shorts for walking function in people with multiple sclerosis.

1. Introduction and purpose of the study

We would like to invite you to take part in our research study. Before you decide, we would like you to understand why the research is being done and what it would involve for you. Talk to others about the study if you wish. Ask us if there is anything that is not clear.

The first part of this information sheet will tell you why we are doing this study. We will then explain what will happen to you if you take part. Then we will give you some supporting information about the study.

This research study will investigate the impact of two types of shorts. These close-fitting, elasticated shorts are designed to provide stability around the hips and trunk. They are usually worn beneath normal clothing.

What is the purpose of the study?

We want to find out whether orthotic shorts improve walking ability in people with multiple sclerosis (MS). Walking can be slow and unsteady in people with MS. Support around the hips might make walking smoother and steadier.

Orthotic shorts are similar to the tight clothing worn to improve performance in athletes. Research suggests that such shorts help people who have had a stroke to walk faster. Some people with MS find that similar garments improve coordination and stability. Currently, some people with MS get funding for garments such as these to be provided on the NHS. However, there is no research investigating whether they work in people with MS.

This research study has two aims. Firstly, we want to know whether the shorts might improve walking. If they do, we want to know how best to measure this. Secondly, we want to know whether the shorts are

acceptable to people with MS. In other words, will people choose to wear them or are tight shorts impractical in daily life?

Why have I been invited?

We are looking for people with MS who have difficulty walking and feel unsteady around their hips or lower trunk. You need to be able to walk for at least two minutes in order to do the walking tests. You need to be able to travel to Sheffield Hallam University, where the testing will take place. Your MS needs to be stable. If you are not stable at the moment, you could join the study at a later time.

Do I have to take part?

Your decision to take part in this study is entirely voluntary. You may refuse to participate or you can withdraw from the study at any time. Your refusal to participate or wish to withdraw would not influence any future services you might receive.

2. What the study involves

What will happen to me if I take part?

If you take part, you will try out two different pairs of orthotic shorts that will be made-to-measure for you. The two pairs of shorts differ in the degree of support that they provide. One pair is tighter than the other.

You will test the shorts by wearing them during formal assessments of your walking ability and by wearing them at home. This will involve you visiting Sheffield Hallam University on four occasions and us visiting you three times. When we visit you, this can be at your home or, if you prefer, we can meet in another quiet and private location. Overall, your involvement in the study would last approximately 12 weeks.

The formal assessments of your walking ability capture common difficulties that people experience with MS. They are:

- How fast you can walk over a short distance
- How hard you have to concentrate when you walk (how much you slow down when you have to speak at the same time)
- Exactly how you take steps (for example, step length and how far apart your feet are when you walk)
- How variable your walking is from one step to the next and
- How steady your hips and trunk are when you walk.

At university, one measure will involve attaching two small movement sensors to your body.

We will interview you twice about your experiences. There will be a 20-30 minute interview at the first appointment to explore your current challenges and your expectations of the shorts. After you have tested both pairs of shorts at home, a longer interview will discuss your experiences. We also ask you to complete questionnaires a number of times: one about your walking and one about your balance.

We ask that you trial each pair of shorts at home for two weeks. After each home trial, there will be two weeks where you do not wear the shorts and do not attend any appointments.

As mentioned above, the study will require seven appointments:

- Appointment 1 will be at Sheffield Hallam University. We will discuss the study and you would sign a consent form to confirm your involvement. We will interview you about your current challenges and your expectations. We will ask you to complete questionnaires about your walking and your balance. You will be measured for your shorts, by an employee from the company who makes the shorts. This will be a healthcare professional, either a physiotherapist or occupational therapist.

- Appointment 2: the person who measured you for the shorts will visit you at home to check that both pairs of shorts fit you. We will measure how tight the shorts are and then take them away for any adjustments.

- Appointment 3: you will come to Sheffield Hallam University. We will assess your walking with and without one of the pairs of shorts using the measures described earlier. We will decide which shorts you will test first and which you will test at Appointment 5. After this appointment, you will take the shorts home and wear them at home.

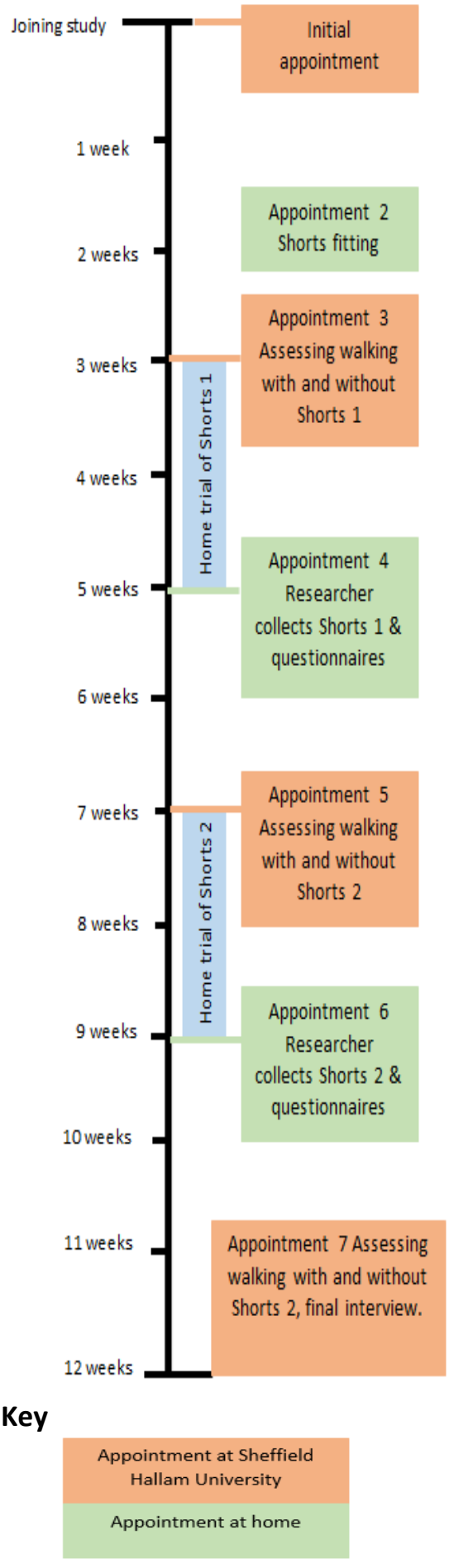
- Appointment 4: about 2 weeks later, a researcher will visit you at home. We will collect the shorts. You will complete questionnaires about your walking and your balance whilst you were wearing the shorts.

- Appointment 5: you will come to Sheffield Hallam University and we will assess your walking in the same way as at Appointment 3. This time you will try out the second pair of shorts. Once again, you will take the shorts away and try them out at home.

- Appointment 6: about 2 weeks later, a researcher will visit you at home. We will collect the shorts and the questionnaires about your walking and balance whilst wearing the shorts.

- Appointment 7: For this last appointment, you will come to Sheffield Hallam University. We will assess your walking one last time, without any shorts. This is to check whether your walking has changed during the study. We will then interview you about your experiences with the shorts and with the study as a whole.

Timeline



Key

How would I wear the shorts at home?

You should wear the shorts for only one hour on your first day with them at home. You should double how long you wear them each day as follows:

- First day – 1 hour of wear
- 2nd day – 2 hours
- 3rd day – 4 hours
- 4th day – 8 hours
- 5th day and thereafter – all day.

If the shorts become uncomfortable, you must contact the research team for advice. They should not be worn in bed.

We would like you to wear the shorts for a range of activities, particularly when you are walking and standing. The shorts may be more useful in some activities than others. If you find it impractical to wear the shorts all day or every day, you are not obliged to wear them.

We will ask you to keep a diary of when you wear the shorts at home. You can use the diary to record what you did whilst wearing the shorts and how they felt. We would like to know any feedback on your experiences, whether these are positive or negative.

Most people like to wear these shorts next to the skin but over normal underwear. If you sometimes need to use the toilet urgently, we can adapt the shorts to include a "toileting hole". You would wear these adapted shorts underneath your underwear and would not need to remove the shorts to use the toilet.

What are the possible risks and disadvantages of taking part?

The main disadvantage is the time that the study will take up. Each visit to Sheffield Hallam University will last 1 ½ to 2 hours, plus your travel time. You may find the visits tiring. Each batch of walking tests will take about 30 minutes, including a chance to rest every 2-5 minutes. If you are not used to a lot of walking, you may find that you are tired or sore the next day. If you do not want to complete all the walking tests, then you do not have to.

Our visits to your home will last about 30 minutes each.

During the walking tests, there is a small risk of falling. However, you will be supervised by an experienced neurological physiotherapist who will be on hand to steady you if required.

There may be some disadvantages in trialling the shorts at home. You might need to change your usual routines, for example to wash the shorts. There is a risk you will find the shorts uncomfortable or difficult to get on and off. You may find you need help from someone else to get dressed and undressed, even if usually you do not need help. We will ask for feedback on these types of issues as part of the interviews.

Are there any benefits to taking part?

The shorts might help your walking and your balance. If they are helpful, then you may keep them as long as you wish after the study. We would not be able to fund additional pairs of shorts in the future but we can provide you with information about how to purchase them.

By participating in this study, you will be helping us to contribute towards our understanding of walking in MS. If we demonstrate that the shorts are effective, they may become more readily available for others.

3. Supporting information about the study

Can I bring someone with me when I visit the university?

You can bring a friend or family member with you when you come to the university. You may need some help to change into your shorts on Appointments 3 and 5. The research team will be happy to help but you may prefer to have someone you know instead.

How will I get to the university?

We are happy to pay for a return taxi fare for you, if you live within 10 miles. Alternatively, if you are able to drive or be brought in, we have disabled parking immediately outside the building. The testing will take place at the Robert Winston Building at 11-15 Broomhall Road in Sheffield, S10 2BP, which is at the Collegiate Crescent Campus.

How will you ensure that my taking part in the study will be kept confidential?

The testing and the interview will take place in a quiet area in the university. Sometimes there may be other participants present in the testing area at the same time as yourself. There will be screens or toilet facilities where you may change.

All data collected will not have your name attached but just a code identifying you. You will not be identifiable in any reports. The recordings of your interviews will be kept securely, typed out by the Chief Investigator and deleted following the study.

Documents relating to the administration of this research, such as the consent form you sign, will be kept in a folder called a Site File. This is locked away securely. The folder might be checked by people in authority who want to make sure that researchers are following the correct procedures. These people will not pass on your details to anyone else.

How long will this study last?

Your individual involvement in the study will last approximately 12 weeks. We intend to recruit 16 people to the study. The study commenced in January 2018 and we estimate that it will finish in February 2019.

If you join this study, we will keep your contact details for 12 months and may use these to invite you to a follow-up study if you continue to use the shorts. Your contact details will be destroyed 12 months after study completion.

What will happen to the results of this study?

We will prepare a report for publication in a research journal so that people can benefit from what we learn. We will share the findings at professional conferences and at events for people with MS, such as those organised by the MS Society UK. If you would like to be sent a report, please let us know.

The data that we collect will be stored safely and anonymously. At the end of the study, we plan to make some data openly available. It may be used by other researchers and by the company who manufacture these shorts. The interview recordings and transcripts will not be shared, to ensure that you are not identifiable. You will be asked to consent specifically to your data being shared with others; you do not have to consent to this.

Who is organising and funding this study?

The study is organised by the Department of Allied Health Professions at Sheffield Hallam University in conjunction with the Therapy Services Team at Sheffield Teaching Hospitals. The project is part of a programme of doctoral research for the Chief Investigator.

The sponsor of the study has the duty to ensure that it runs properly and that it is insured. In this study, the sponsor is Sheffield Hallam University.

Who has approved this study?

All research in the NHS is reviewed by an independent group of people, called a Research Ethics Committee, which is there to protect your safety, rights, dignity and wellbeing. This project has been reviewed and was given a favourable option by the Leeds East Research Ethics Committee.

Who do I contact if I have any concerns?

If you have any concerns or complaints about anything to do with this study then you can contact the Chief Investigator, Nicky Snowdon:
E-mail n.snowdon@shu.ac.uk and phone 0114 225 5751.

Alternatively, you can contact the main project supervisor: Dr Sionnadh McLean
E-mail s.mclean@shu.ac.uk and phone 0114 225 2271.

If you would rather contact someone independent of the study, you can contact Dr. Nikki Jordan-Mahy, Chair of the Faculty Research Ethics Committee.
E-mail: n.jordan-mahy@shu.ac.uk and phone 0114 225 3120.

I would like to participate in this study, what do I do next?

Please contact the researcher directly to arrange to start the study, either by e-mail or telephone.
Chief investigator: Nicky Snowdon,
E-mail n.snowdon@shu.ac.uk and phone 0114 225 5751

We will have a telephone conversation to answer your queries. We will check that you meet the study criteria, described above under “Why have I been invited?” We will then arrange provisional dates for the visits. The researcher will contact you in writing by post or e-mail, to confirm the times and travel arrangements.

Sheffield Hallam University

Participant Consent Form

Title of Project: A clinical trial evaluating the feasibility and acceptability of orthotic shorts for walking function in people with multiple sclerosis.

Researcher: Nicky Snowdon

Participant Identification Number for this trial:

Please initial box

1. I confirm that I have read the information sheet dated..... for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily. ☐
2. I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason, without my care or legal rights being affected. ☐
3. I agree that the data collected may be used to support other research in the future. This data will not include my personal details. *(Optional)* ☐
4. I agree that data collected may be made openly available, shared with other researchers and with the company who have manufactured the orthotic shorts. This data will not include my personal details or the interview records. *(Optional)* ☐
5. I understand that information about me collected during the study may be looked at by responsible individuals from Sheffield Hallam University, 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 my personal details. ☐
6. I consent to be contacted again about follow-up projects/I do not consent to be contacted again about follow-up projects. *(Please delete one option)* ☐
7. I agree to take part in the above study. ☐

Name of Participant	Date	Signature
Name of Person taking consent	Date	Signature

Appendix 4 – information about orthotic shorts

How the shorts should look when worn

Wearing

The shorts should be worn next to the skin, under your clothes. Shorts without a toileting hole should be worn over your underwear. If your shorts are made with a toileting hole, put your underwear over the shorts.

You should build up how much you wear the shorts slowly over the first week, doubling the amount of wear time daily until the shorts are worn throughout the day. If they become uncomfortable, you should stop wearing them and contact the research staff for advice.

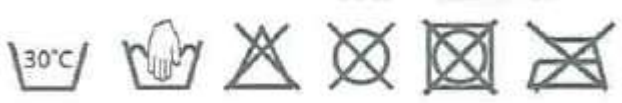
For example,

- First day – 1 hour of wear
- 2nd day – 2 hours
- 3rd day – 4 hours
- 4th day – 8 hours
- 5th day and thereafter – all day.

You should wear the orthotic shorts when you are most active. They should NOT be worn in bed.

Washing instructions

The shorts can either be hand-washed or machine washed at 30 degrees and then spun.



If hand washed, the shorts should be wrapped up briefly in a dry towel to remove excess moisture before hanging to dry on a clothes airer. (Do not place the shorts directly on a radiator but you can use a radiator drier). Machine washing is less likely to damage the fabric. Do not wear the shorts if they are damp as this may cause skin soreness.

DO NOT TUMBLE DRY – This will cause the shorts to shrink.

Appendix 5 – topic guides for interviews

Initial interview regarding motivations for trialling shorts

Aim and context of interview

This interview will take place immediately following the informed consent process. The aim of this interview is to explore participants' initial views so that these can be compared to their experiences at the end of the trial, their wear routines and their choice of whether to continue use following the initial 12-week study period. Some of the questions are designed to ascertain the participants' "readiness for change" by asking whether they have already contemplated adaptations to their activities and lifestyles. The data from this interview will enable investigation of whether certain aims, motivations or perceptions impact upon the eventual acceptability of the shorts. In turn, this may enable us to develop advice for potential future users and funders of orthotics regarding factors that predict continued use. This initial interview is likely to last 20 - 40 minutes.

Topic guide

Many thanks for being interviewed. As I have said, we will be talking about your expectations of these shorts and of the wider study. Can I just double check that you are OK that I am recording the interview?

1. So firstly, could you tell me why you are interested in participating in this study?
    - Is there anything about trialling the shorts themselves that appeals to you?
    - Do you think the shorts might help with anything in particular?

2. Have you tried any other possible solutions for managing that problem/those problems prior to joining this study?
    - For example, physiotherapy?
    - Any other aids?
    - Any adaptations to your activities?
    - How did you get on with those other things that you have tried?
    - Are there any other ways of overcoming those problems that you have been considering?

3. Do you have previous experience of using a splint or a support of any kind?
    - For example, an ankle-foot orthosis or "Foot-Up" device? If so, how did you get on with those orthoses?
    - Have those experiences impacted upon your expectations of these shorts?

4. Can you tell me a little about your current day-to-day routines?
    - For example, what is a typical day like for you?
    - What activities might you do in your spare time and at work?
    - Are there any activities that you find particularly difficult at the moment?

5. What are you expecting the shorts might be like?
    - Do you think they might make a difference to what you are able to do?
    - Walking or balance?
    - Independence?
    - Specific participation goals?

Final interview of experiences of study and experiences of wear

Aim and context of interview

This interview aims to determine the acceptability of the shorts and participants' views on the study processes such as the information and support they received, and the outcome measures used.

The interview will take place at the final visit to Sheffield Hallam (Visit number 4). At this point they will have experienced three assessments of their walking ability; the home trials of using the shorts and the final wash-out period. At this interview, the interviewer will be "unblinded" to when the different shorts were worn. The interviewer will review the data from the initial interview, the wear diaries and the Participant Global Rating of Change scores prior to this interview and will use this to inform the questions that are asked. This will ensure the interviews are focussed on aspects that are important to each participant. This final interview is likely to last 40 - 60 minutes.

Topic Guide

Many thanks for being interviewed. As I have said, we will be talking about your experiences of wearing the shorts, your feelings about whether to wear them in the future and your feedback on being in the study. Can I just double check that you are OK that I am recording the interview?

1. Please tell us a little about the differences between the two pairs of shorts that you have used.
    - How different did they feel?
    - In what way did they differ?
    - Immediate effect and day-to-day effect?

2. When we first talked at the start of this study, you explained that one of the main things that you have difficulty with were …
    - Can you tell me whether either of the shorts had any impact on this?
    - How did the shorts compare to ... (the other things that had been tried previously)?

3. Also, when we first talked, you were thinking that the shorts might help you to achieve…
    - Can you tell me whether either of the shorts had any impact on this?

4. Was there anything that the shorts helped with that you weren't expecting?
    - Movement control?
    - Fatigability?
    - Stability?
    - Any specific functions or activities that you found easier with the shorts?
    - Was there anything you could do with the shorts that you would struggle to do without the shorts?

5. Did the impact of the shorts change over time?
    - For example, as you got used to the shorts did you find it any easier to move in them?
    - Was there any particular point at which you felt the shorts made (the most /a) difference?

6. Overall, did the shorts meet your expectations or were you at all disappointed with their effect?
    - Do you wish we had discussed your expectations more at the start of the study?

7. What were the disadvantages of using the shorts?
    - Getting them on and off?
    - Getting to the toilet?

- Washing and drying?
- Restriction of movement?
- Discomfort?
- Appearance?
- Was there anything that you were unable to do with the shorts on that you can usually do without the shorts?

8. Can you tell us more about your experiences of wearing the shorts?
   - When you wore the shorts at home, how did you get on with wearing them for the time periods that we recommended?
   - What do you think about the recommendations we gave you for wearing the shorts?
     - Were they helpful?
     - Were they achievable in your lifestyle?
     - Did you think the gradual increase in wear over the first few days was important?
   - Are there ways in which you have adapted your routines in order to wear the shorts?
     - Getting up earlier?
     - Changing your daily activities?
     - Getting help with dressing or undressing?

9. If someone with MS asked for your opinion on whether orthotic shorts might help them, what would you say?

10. Now that this part of the study is complete, do you want to keep either of the pairs of shorts to wear again in the future?
    - Which pair – or both pairs?

a. If participants want to continue using shorts:

- How do you think you will use the shorts in the future?
  - How often might you wear them?
  - Any specific activities – or times of day?
  - Are there particular situations when you think you will wear them – or when you probably wouldn't wear them?
- Can you explain what the shorts do for you that make you want to continue to use them for these activities?
- Do you think that when you wear the shorts for longer periods of time, that this might have any impact on your underlying strength and ability?
- If we were able to adapt these shorts for you, is there anything that you would change?

b. If participants do not want to continue wearing shorts:

- What are the most important factors that have made you choose not to wear the shorts? (use previous comments from earlier in the interview as prompts).
- If we were able to adapt the shorts in any way, would that make you any more likely to want to continue to wear them?

Thank you for explaining your experiences with the shorts. It would be really helpful for us to understand your experiences with the wider research project as well. This will help us to design future studies as well as to help us understand what advice to give people who want to try these shorts in the future.

First, I have some questions about the information we gave you at the start of the study.

11. Is there anything that you think you could have been told at the start of the study that would have helped you better understand what the shorts might be like – or what we were asking you to do?
    - Can you think of anything that you wish you had known at the beginning of the study?
    - Would further information about the shorts themselves have been helpful? If so, what.

Secondly, it is really important for us to understand how you felt about all the measures that we took during the study.

12. Did you feel over-burdened by the number of measures that we used?
    - In the movement laboratory, we measured how fast you could walk, whether your walking was slowed by talking and thinking as you walked and exactly how you were walking.
    - Whilst you trialled the shorts at home, we asked you about the impact of MS on your walking ability, your confidence with your balance and whether you were having any falls.

13. Did any of the measures feel particularly relevant to you?
    - For example, did any of the measures capture the most important ways in which MS changes your ability?
    - Did any of the measures capture the effect of the shorts particularly well?
    - Which, if any of the measures seemed the most important to you?
    - If we were to remove any of these measures in future studies, which would you suggest is least useful?
    - Is there anything you think we should have measured but didn't?

14. That is all extremely helpful. Is there anything else that you would like to tell me that I have not asked you about?

15. If the nature of the placebo shorts has not already come up in the interview, this will be explained at the end. For example:
    - We were not really expecting the looser shorts to make any difference to your walking. They had been designed as a sham or placebo intervention to help us test the effect of the close-fitting shorts. We did this because there was a risk that comparing the shorts to no intervention at all might exaggerate how useful the shorts were. Do you have any thoughts on the use of the loose shorts?

Thank you for your time.

Appendix 6 – objectives, data collection and data analysis

Table 1: Relationship between study objectives, data collection and data analysis for Objective 1 - acceptability

Study objective	Approach	Data collection method(s)	Data analysis
1a. Determine how often the shorts are used and whether recommendations for wear are adhered to	Quantitative	Wear diaries – frequency and total time worn for each individual.	Description of median and range of wear frequency and total time worn for each individual. Description of wear as a proportion of recommended wear. Compare frequency and total time worn between the two types of shorts (descriptive data).
1b. Determine perceptions of the advantages and disadvantages of wear, include perception of initial effect.	Qualitative	Second qualitative interview following experience with both pairs of shorts. Interview will refer to data in wear diaries and patient perceived rating of initial effect.	Qualitative Framework analysis to determine advantages and disadvantages, including perception of initial effect.
1c. Determine views of participants on whether they would continue to wear shorts and, if so, how and why	Qualitative	Second qualitative interview following experience with both pairs of shorts, including participant decision about whether to keep shorts for further wear.	Qualitative Framework analysis to determine themes around future use.
1d. Determine participants' views on the prescription protocol, (e.g. information, wearing routines, managing expectations and adapting the shorts).	Qualitative	Second qualitative interview following experience with both pairs of shorts.	Qualitative Framework analysis to determine views on prescription process

Table 2: Relationship between study objectives, data collection and data analysis for Objective 2 – short-term effect and piloting outcome measures

Study objective	Approach	Data collection method(s)	Data analysis
2a Determine whether there is any change in response to wearing orthotic shorts in spatiotemporal gait parameters, trunk stability in walking, walking speed and dual task cost.	Quantitative	Baseline measures of: Spatiotemporal gait parameters, trunk stability in walking, Timed 25-foot Walk and dual task cost. Measures as above with both orthotic and placebo shorts.	For each outcome measure, determine whether baseline values appear to have changed over time for individuals and for the group as a whole (graphical representation, averages and variability measures). For each outcome measure, calculate the difference between walking ability in the placebo compared to the orthotic shorts for the group as a whole (graphical representation, effect size and average effect). The non-parametric effect size is calculated by dividing the Z statistic from the Wilcoxon test with the square root of the number of observations (Pallant, 2007). For each measure, where a known Minimum Clinically Important Difference exists, determine whether individuals deteriorate, remain similar or improve by a clinically significant amount compared to their average baseline measure. Cross-tabulate to compare effect of placebo versus orthotic shorts on the different measures.
2b. Determine whether there is any change in response to wearing orthotic shorts in self-reported walking ability, balance confidence and incidence of falls	Quantitative	Baseline measures of self-reported walking ability, balance confidence and falls incidence. Measures as above for the two weeks over which shorts are trialled at home.	Analysis is as Objective 2a (above).
2c. Investigate participant perception of outcome measures used	Qualitative	Second qualitative interview following experience with both pairs of shorts.	Qualitative Framework analysis of participant perceptions of outcome measures.

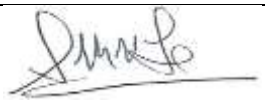
Table 3: Relationship between study objectives, data collection and data analysis for Objective 3 – potential determinants of longer-term orthotic use

Study objective	Approach	Data collection method(s)	Data analysis
3a Explore relationship between participants' decisions on longer term use and the motivations and expectations expressed at the initial consultation	Qualitative/mixed methods	Decision regarding whether to continue wearing shorts after the feasibility study. First qualitative interview (participants' motivations and expectations prior to being given shorts).	Qualitative Framework analysis comparing data in first interview between participants who choose longer term wear of the shorts compared to those who do not. If data on motivations and expectations of the shorts allows participants to be categorised according to their views, then cross-tabulation (Fischer's Exact Test) will compare initial expectations and motivations to the decision regarding whether to continue wearing shorts after the feasibility study.
3b Explore relationship between participants' decisions on longer term use and the participant perceived effect of the shorts on walking ability on first usage	Quantitative	Decision regarding whether to continue wearing shorts after the feasibility study. Participant perceived Global Rating of Change for initial effect.	Cross-tabulation (Fischer's Exact Test) comparing patient perceived global rating of change for initial effect with the decision regarding whether to continue wearing shorts after the feasibility study.
3c Explore relationship between participants' decisions on longer term use and the effect of the shorts on measures of spatio-temporal gait parameters, trunk stability in walking, walking speed and dual task cost.	Quantitative	Decision regarding whether to continue wearing shorts after the feasibility study. Spatiotemporal gait parameters, trunk stability in walking, walking speed and dual task cost at baseline and with both types of shorts.	Calculate change in spatiotemporal gait parameters, trunk stability in walking, walking speed and dual task cost with orthotic and placebo shorts compared to average baseline for each individual. Calculate effect sizes for each outcome measure separately for the two groups, where one group is the people who choose to continue to wear and the other is the group who choose not to. Determine whether any measures seem more relevant to this decision than others.

3d Explore relationship between participants' decisions on longer term use and the effect of the shorts on self-reported walking ability, balance confidence and incidence of falls	Quantitative	Decision regarding whether to continue wearing shorts after the feasibility study. Self-reported walking ability, balance confidence and incidence of falls at baseline and with wearing both types of shorts at home for two weeks.	Calculate change in self-reported walking ability, balance confidence and incidence of falls with orthotic and placebo shorts compared to average baseline for each individual. Calculate effect sizes for each outcome measure separately for the two groups, where one group is the people who choose to continue to wear and the other is the group who choose not to. Determine whether any measures seem more relevant to this decision than others.
3e Explore relationship between participants' decisions on longer-term use and the perceived advantages and disadvantages of wearing shorts.	Qualitative/mixed methods	Decision regarding whether to continue wearing shorts after the feasibility study. Second qualitative interview following experience with both pairs of shorts.	Qualitative Framework analysis comparing data in second interview between participants who choose longer term wear of the shorts compared to those who do not. If data on perceived advantages and disadvantages of the shorts allows participants to be categorised according to their views, then cross-tabulation (Fischer's Exact Test) will compare perceived advantages and disadvantages to the decision regarding whether to continue wearing shorts after the feasibility study.

Appendix 7 – risk assessment

PROJECT SAFETY PLAN: Risk Assessment Form

TITLE:	A clinical trial evaluating the feasibility and acceptability of orthotic shorts for walking function in people with multiple sclerosis.	**LOCATION:**	A level 2 practical room in the Robert Winston Building at Sheffield Hallam and either the participant's home or other private place that is mutually agreed
PROJECT SAFETY OFFICER:	Nicky Snowdon	**ASSESSMENT CARRIED OUT BY:**	Nicky Snowdon
SUPERVISOR:	Sionnadh McLean		
SIGNATURE OF SUPERVISOR		**DATE:**	10th January 2017

ACTIVITY	HAZARD ASSOCIATED WITH THE ACTIVITY	HAZARD RATING (High, Medium or Low)	**CONTROL MEASURES TO BE TAKEN**
Assessment of walking ability	Participants might fall during testing. Participant might feel overly burdened by the number of measures and may fatigue to an unacceptable level during testing. Risk of soreness or tiredness following testing.	Medium Medium Medium	The researcher will stand and walk close to participants during testing. Chairs will be available within the testing spaces enabling the participant to sit if tired. Either a second assistant will be present during testing or the researcher will have a mobile phone on their person throughout, containing numbers for first aid staff in the building. Testing will only take place when there are first aid qualified staff in the building. The voluntary nature of the testing procedures will be stressed to the participant. If participant complains of fatigue or appears to be fatiguing, then testing will be halted or there will be a break in testing to see if fatigue lessens. Participants will be warned both verbally and in the Information Sheet of the risk of some post-exercise muscle soreness. They will be reassured that this is unlikely to last beyond 48 hours and given some simple advice regarding rest and warmth to manage any soreness. They will be advised to contact the researcher for advice if the soreness does not resolve.

Trial of shorts in the home environment	The shorts could cause problems with circulation or skin soreness. The tight shorts may cause problems dressing and undressing, which may lead to problems with continence.	Low	In checking eligibility, researchers will discuss circulatory problems and skin conditions and people who may be predisposed to such issues will not be recruited to the study. The fit of the shorts will be checked and adjusted by the experienced DM Orthotics staff prior to testing. With appropriate fitting, problems are extremely rare. An information sheet about the shorts will be given to each participant and its contents will be discussed with each participant when they are given their shorts for the home trial. They will be asked to: cease wearing the shorts if they become uncomfortable or are difficult to manage; contact the research team if there is a problem; gradually increase wear time over 5 days and not wear shorts in bed. Any adverse events and adverse reactions will be discussed with the participants at each appointment.
Home visits for appointments 2, 4 and 6	Personal safety of researcher, going into an unfamiliar setting	Low	The researcher will write down the details of where they are going and who they are going to see and give this to a colleague in a sealed envelope. They will inform that colleague by mobile phone when they are going into the property and when they are leaving. If the researcher does not call in to confirm their wellbeing, the colleague will open the envelope and alert authorities local to the interview about the researcher's lack of response.
Interviews and self-report measures	Participant distress caused by discussing impairments.	Low	The researcher is an experienced physiotherapist in the field of neurological rehabilitation so has skills in reassuring people in this situation. In advance of each interview, she will look up the details of local support resources for people with MS on the MS Society webpage and take these details with her.

Appendix 8 – data management plan

Project details

Project Name: A clinical trial evaluating the feasibility and acceptability of orthotic shorts for walking function in people with multiple sclerosis.

Project Identifiers: IRAS ref no. 222166, STH project number STH19679

Principal Investigator / Researcher: Nicola Snowdon

Project Data Contact: n.snowdon@shu.ac.uk

Description: This is a feasibility and acceptability study investigating orthotic shorts for people with multiple sclerosis (MS). The purpose of the project is to determine whether the shorts are acceptable to people with MS; to determine which, if any, measures respond to the impact of the shorts and whether there are any emerging relationships between participants' decisions regarding longer-term use and their motivations, experiences of the shorts or the measurable impact of the shorts. This preliminary study should inform future larger scale investigations into effectiveness.

Institution: Sheffield Hallam University

This data management plan was produced with DMPOnline using the Sheffield Hallam University guidance.

Data collection

What data will you collect or create?

For a planned sample size of 16 participants, the following data will be collected:

Numerical data

- downloaded data from the GAITRite 3.8 system on individual steps (step length, stride time, stride width) and average data from each walk across the walkway on cadence, velocity, percentage of time spent in double support for each leg in turn.
- calculations made from the GAITRite data means of the above variables across 4 walks over the walkway for each leg in turn and both legs, standard deviations and coefficient of variation of the step length, stride time, stride width
- downloaded raw data from the Inertial Measurement Units and processed data from same
- scans of data collection record sheets for each visit for each participant that will include data on walking speed and dual task cost as well as observations.

For numerical data, all data will be downloaded into Excel for storage and analysis. Approximately 830MB of data, much of which will be from the Inertial Measurement Units.

Self-report measures and diaries

Raw data from self-report measures, wear diaries and falls diaries will be collected initially in a paper format. Paper copies will be digitised for safe storage; producing approximately 34MB scanned questionnaires and 180MB of scanned diaries.

Interview recordings and transcripts

Interview digital recordings will be saved as mp3 files, encrypted using 7zip (approximately 80MB per participant so 1280MB for whole study). Transcripts in Microsoft Word (1500KB).

Total storage for this project will be approximately 2400MB.

How will the data be collected or created?

Data collection will be spread over a 16-month period. Data for each individual participant will be recorded both in hardcopy and as downloaded electronic data. Each visit will be guided by a paper checklist (data collection record sheet), which will also form part of the data set because simple data such as time taken and distance walked will be collected on the record sheet. The paper checklists will be scanned and stored electronically as well as within the Site File.

Electronically, a folder will be created for the raw data for each individual participant and within that folder will be sub-folders containing the data collected at each visit.

Each raw data file will be named with the following convention: participant code number/visit number/data source/with or without shorts (if data for different conditions downloaded to different files)/date as DDMMYY. For example "FSP1 V1 GAITRite 160417" or "FSP1 V1 initial interview 160417". When initial analysis of numerical data is conducted, this will be done on a new version of each spreadsheet so that the raw data is unaltered. New versions will be labelled as such in the file name with (1) after the original file name.

Once all data has been collected for a participant, the chief investigator will be unblinded and data inputted into spreadsheets collating data across the different participants. These files will be named according to the data collection method e.g. "GAITRite data"; "sensor data". Versioning is unnecessary for these files as data is saved elsewhere.

Documentation

What documentation and metadata will accompany the data?

A description of folder format and file names will be recorded in a Word document with the data and in the Site File.

Ethics and legal compliance

How will you manage any ethical issues?

The Participant Information Sheet informs the participant that data may be shared with other researchers in the future and consent for this will be specifically recorded on the consent form. All data will be anonymised and labelled by code number only. As described below, all data will be stored and transported securely.

How will you manage copyright and Intellectual Property Rights (IPR) issues?

Ownership of the data lies with Sheffield Hallam University.

Research findings may be shared with the company DM Orthotics, who will part fund the project by providing the orthotic shorts being tested. However, raw data will not be shared until it is made openly available after the project.

Storage and backup

How will the data be stored and backed up during the research?

Data will be downloaded and stored on a folder on the university's Q-drive, which is specifically designed for research data for live projects and is networked allowing access both on and off campus. The drive is backed up automatically on a daily basis. The data is stored in more than one data centre ensuring excellent recovery as detailed at http://research.shu.ac.uk/library/rdm/research-store.html

At project close down relevant data relating to this project will be securely archived in the Sheffield Hallam Research Data Archive (SHURDA) and all data will be deleted from the Q-drive.

How will you manage access and security?

Only the chief investigator, supervisors and Faculty Health-data stewards (Professor Shona Kelly and Rachel Ibbotson) will have access to the Q-drive folder via their Sheffield Hallam University log-in. Collaborators at Sheffield Teaching Hospitals and DM Orthotics will not have direct access to raw data during the study.

Security of the Q-drive is ensured as detailed at the link given above.

Data collected outside the university setting will be: a data collection record sheet, paper self-report questionnaires and diaries. Paper records will be transported immediately back to the university site with the chief investigator. They will be scanned and stored on the Q-drive within 2 days and paper copies will be stored in the Site File in a locked cupboard on secure university property.

The interview recording will be made on a digital recorder that is not password protected. This will be downloaded immediately following the interview to a password protected laptop computer and deleted from the recording device. The interview recording will be uploaded to a secure drive as soon as internet access is available. Following the study, the interview recordings will be deleted and only the transcripts will be stored in the longer term. The digital recorder will be kept secure at all times during the study, either with the researcher or locked away. When the study is completed, the recorder will be completely cleared by recording background noise until the memory is full, ensuring that deleted files are over-written.

Selection and preservation

What data are of long-term value and should be retained, shared, and / or preserved?

All data (raw and analyzed) will be deposited in the University's Research Data (SHURDA) at the end of the research project. The data will be retained in the archive for a period of 10 years since the last time any third party has requested access to the data. When depositing the data, no further changes to data formatting will

be required as all necessary actions will have been conducted as the research progresses. All data will be shared as Open Access, with the exception of the interview transcripts, because participants are potentially identifiable from what they say.

What is the long-term preservation plan for the dataset?

All 'raw' data (other than interview transcripts) and the analyzed data will be made available after any embargo period has expired. This approach to open access will ensure the legacy of the project by enabling follow-up and/or longitudinal studies to be compared with these raw data sets.

Data sharing

How will you share the data?

A data sharing agreement with re-users of the data will not be required, as the raw anonymized data and the data collection methodologies will be made available on a Creative Commons with Attribution (CC-BY) or equivalent license.

While a robust approach to ensuring consent is received from all respondents in the study to allow raw data to be shared, should some respondents refuse permission, these data will be removed before depositing the data in the SHU Research Data Archive (SHURDA). Nicky Snowdon, the Chief Investigator, will ensure that any data collected from participants who refuse data sharing is clearly labelled as such and the absence of such data from the archived dataset is explained. The responsibility for ensuring extraction of data from those declining will be with the Chief Investigator.

Are any restrictions on data sharing required?

We will deposit and share our data at the end of the project within two months of project completion. Any research outputs that are published will contain a statement that refers to the underlying datasets and how these datasets can be accessed; any restrictions to access will be outlined and justified in this statement. The raw anonymized data and the data collection methodologies will be made available on a Creative Commons with Attribution (CC-BY) or equivalent license.

While a robust approach to ensuring consent is received from all respondents in the study to allow raw data to be shared, should some respondents refuse permission, these data will be removed before depositing the data in the SHU Research Data Archive (SHURDA). Nicky Snowdon, the Chief Investigator, will ensure that any data collected from participants who refuse data sharing is clearly labelled as such and the absence of such data from the archived dataset is explained. The responsibility for ensuring extraction of data from those declining will be with the Chief Investigator.

Responsibility and resources

Who will be responsible for data management?

The Chief Investigator, Nicky Snowdon, will implement this Data Management Plan, under the supervision of the Chief Investigator's director of studies Dr Sionnadh McLean. The Director of Studies has responsibility for

the research data management and will review the data management plan during and at the close of the project.

The safe storage and archiving of data will be resourced by Sheffield Hallam University.

What resources will you require to deliver your plan?

To deliver this plan, we will require a folder on the University Q-drive for during the project and space in the SHURDA repository at the end of the project.

To ensure safe and secure management of the data, a Sheffield Hallam password protected laptop has been obtained specifically for data collection and storage. The laptop will be loaded with software to operate the Inertial Measurement Units, as well as data analysis software (SPSS) to facilitate the organisation and storage of data. This will enable data to be recorded and then uploaded to Q-drive in a secure and timely way.