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Smart clothing for falls protection and detection: User-centred co-design and feasibility study

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Abstract. The prevalence and impact of hip fractures on the health and wealth of nations is a global problem and source of health inequalities. This paper reports on the co-design and feasibility testing of a new range of protective, smart clothing. The feasibility of research in a population of older adults in supported living is explored, as are the conceptualisation and measurement of adherence.

Keywords. Hip protection, falls detection, fall protection, co-design, feasibility study

1. Introduction

Globally, hip fractures are common, particularly in female adults aged over 80 years (1) and create a significant impact on individuals and the economy (2). It is estimated that In the 75,000 in the United Kingdom and 250,000 people in the United States of America suffer a hip fracture each year. On any one day over 15% of orthopaedic hospital beds in Northern Europe are occupied by people who have a hip fracture and 20% of these injuries are followed by death within 12 months and fewer than half of those experiencing fracture fully recover (3). There are a number of risk factors for a hip fracture including low bone density (osteoporosis), low body mass index, reduction in capacity to protect from the fall (putting arms out to break the fall), impaired balance and environmental hazards which contribute to fracture in the event of a sideways fall with impact on the greater trochanter (outer facing part) of the proximal femur (upper part of the thigh bone) (1, 2, 4).

Although these factors may be present in any group, it is the elderly population which has the greatest risk. The rates of hip fractures are set to increase yet further with an increasingly aging population. A global figure of 6.26 million hip fractures per year by 2050 has been estimated (5). The annual cost of hip fracture treatment in the UK alone is £1.9bn and estimates from insurance data in the United States put the annual cost at $5 billion (2).

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1.1 Interventions to prevent fracture and fall

A number of interventions have been developed to reduce hip fractures including increasing bone density and improving gait and balance (6). The idea of reducing impact from a fall as a means to reducing hip fractures was introduced in the late 1980's (7) and both hard-shelled and soft protectors have been developed since in various forms. The soft pads of a hip protector are designed to compress and absorb the energy from the force of a fall. The typical force from a fall likely to cause a fracture has been established in biomechanical studies, and protectors can be tested in a standard way to confirm that they can reduce the forces transmitted to a hip to a level below the typical fracture threshold (1). The evidence for the medical efficacy of existing products is mixed. Systematic reviews of randomised and non-randomised clinical trials suggest that the provision of hip protectors for residents of nursing care facilities slightly reduces the number of hip fractures; however this finding has not been replicated in community-dwelling samples (Santesso et al, 2014; Parker, et al 2006; Kannus et al, 2000).

1.2 Adherence/compliance to using hip protectors

Evidence on the efficacy of hip protectors is difficult to evaluate, however, as compliance and adherence rates to the intervention are usually low (and comparisons are complicated by different definitions of compliance and adherence). As reported in a recent Cochrane review Santesso et al (2014), adherence has been defined in a variety of ways, including "all the time" at 6 months (Cameron 2011), 2 years (Cameron 2001) and 28 months (Birks 2003); "hours worn" (Harada 2001, Kannus 2000, Koike 2009); wearing "when visited" (Lauritzen 1993, van Schoor 2003, O'Halloran 2004, Kiel 2007) and "regular wearers" (Hubacher 2001). Other studies were not clear when reporting adherence. In light of the inconsistency among definitions, the review did not attempt to formally synthesise adherence across the studies and instead reported adherence narratively: adherence varied between 20% and 80%. Kurrle (2004) conceptualised acceptance as the 'percentage of people initially agreeing to wear the hip protectors' and adherence as the 'wearing of the hip protectors in accordance with the recommendations of the study protocol', definitions which have been adopted by the international Hip Protector Research Group (Cameron 2010). A recurrent theme, however, is of partial usage, with participants wearing hip protectors for some but not all of the day; moreover, it is unclear whether night-time use of hip protectors is important to the definition of adherence. It could be claimed that transitioning in and out of bed and moving around at night are activities that create additional risk. Therefore, night time use could be a critical factor for effectiveness of the intervention.

A systematic review of acceptance and adherence of using hip protectors in 2002 (Van Schoor et al) reported acceptance ranging between 37% to 72% with a median of 68% and adherence ranging between 20% and 92% (median 56%). Reasons for not wearing protectors included comfort, extra effort in dressing, urinary incontinence and physical difficulties/illness. There appears to be an unmet need for a flexible, comfortable and unobtrusive hip protector. New alternatives to traditional hip protectors are required (Santesso et al, 2014). In addition to this, the concept of adherence and the manner in which it is recorded requires attention.

1.3 Innovative co-design of smart clothing for fall protection and detection

A new, flexible, breathable hip protector that is half the thickness of existing available products and biocompatible has been created. The protector pads contain sensors which can monitor fall falls, track temperature and allow for live stereoscopic gait data to be collected from either hip via an integral 3-axis accelerometer. The system is designed to work with a smartphone to send a distress call if a fall is detected and to support independent living. It allows users to maintain an active lifestyle in the knowledge that if they fall the pads will help to reduce the risk of suffering a hip fracture and the sensors will send a signal for help if needed. The live gait monitoring will allow for the analysis of gait patterns with the aim of providing an early warning system if a person becomes less active or their walking starts to change. This could be sent to a career or medical professional to allow for early interventions to be put in place.

Using cooperative evaluation methods, a Beta (24-hour wear) and Gamma (48-hour wear) trial was conducted to support the development of the Hip Protector design. Field visits to deliver the Hip Protectors and one-to-one discussions were conducted in testers' homes to explore the contextual use of the product from January 2016 until the end of July 2016. In total 18 older adults helped to co-create solutions to identified problems. Activities of daily living and fall history were recorded. Tester's views on the size, comfort, style, washing of the hip protectors were explored. This paper reports the phase 2 of this work to establish the feasibility of the hip protector intervention.

2. Methods

A single-arm feasibility study with nested qualitative investigation, quantitative self-report measures of adherence, and automated, passive electronic recording of adherence using temperature and motion as a proxy.

2.1 Aims and Objectives

To determine whether it is feasible and acceptable to conduct a controlled trial into the efficacy of the Hip Protectors on a sample of older adults (>=65 years) who are residents of assisted living schemes and residential care homes.

The objectives were to:
1. Determine issues affecting staffing capacity and willingness to support the use of hip protectors in such settings;
2. Determine the likely recruitment, retention and adherence rates for a future definitive study;
3. Observe reactions to the hip protectors from older adults including ability to don the garments, extent of adherence and any barriers to use;
4. Assess the likely outcome measures and data collection methods for a definitive trial;
5. Identify how the hip protectors will most appropriately be deployed in a definitive trial;
6. Evaluate the reliability and validity of the data-recording and collecting mechanisms and procedures, and of the data itself, as collected via these mechanisms.

2.2 Settings and participants

The study sites were housing schemes, including supported-living and care homes where appropriate, selected from regions represent a spread of rural/urban and socially deprived/affluent areas. Based on recruitment from Beta and Gamma the aim was to recruit approximately 50 participants. The number of sites required to achieve this would depend on uptake and therefore was not pre-specified. Participants were to be older adult (>=65 yrs.) residents of supported housing schemes/care homes who spoke and understand English, had the cognitive ability to provide informed consent and were medically stable enough to test the hip protectors, as confirmed by housing scheme managers.

All older adults who met these criteria were assessed at baseline for medical conditions and previous falls/fractures in the past 12 months. Participants were characterized as at risk' (fall/s in the previous 2 years and/or previous broken hip) or 'healthy' volunteers. Participants with cognitive impairments (including Dementia and Mild Cognitive Impairment) were excluded from the study as detailed feedback of the intervention was required from users. Participants were not allocated to separate intervention control groups as the primarily concern was with ascertaining the feasibility of the recruitment strategy, delivery of the intervention, and data collection procedures, as well as estimating likely adherence and dropout rates. Sequence generation, allocation concealment mechanisms or blinding was not assessed at this stage.

2.3 Intervention

The intervention was the supply of a garments containing integrated, reduced-thickness, hip protectors with embedded sensors for fall detection (Figure 1). The pre-production prototype can be CE marked class I and passes the draft BSI test standard prEN8575 for clinically effective medical hip protectors. It has reduced thickness compared to traditional protectors, a key factor to drive adherence. A 3D knitting technique has been used to produce a seamless garment to hold the protector, a feature paramount in improving wearability and reducing potential skin irritation or complications. The protective element is manufactured using Armourgel, a strain-rate sensitive material which is soft and flexible, and hardens upon impact before returning to its soft state (Figure 2). In addition to this, the protector houses a sensor suite which would collect data on gait, movement and activity levels. The data from the sensors will be used to refine initial algorithms that will, in the event of a fall and without any action from the wearer, automatically raise a fall alert in or out of the home and provide detailed fall information such as the type of fall, its direction and impact. This feature would negate the need for the wearer to raise an alarm or press an alarm pendant, which may not be possible due to their condition, how they have fallen or their frailty, and enables help to be summoned quickly. The sensor suite will also collect data on body temperature and activity levels which will permit some measure of adherence monitoring.

Figure 1. Hip protector garment.

Figure 2. Protective Armourgel pad

The garments were to be worn 24 hours a day, morning and night and removed only for cleaning purposes. All participants would be issued with 3 pairs of the garments for a 28-day test of feasibility. The garments would be issued in the size closest matching the participant's clothing size. The garments come in sizes Small (8-10), Medium (12-14), and Large (16-18). The garments became available on 9th November for roll out of the intervention in the study.

Smartphones were placed in participants' rooms and/or in a communal area in order to collect and transmit data from the sensors embedded in the hip protectors on a daily basis. Data collected was anonymous and transmitted over Wi-Fi or GSM to secure servers, where it was encrypted and stored

2.4 Data collection

- From discussions with scheme managers' notes would be taken to determine whether there is capacity and willingness to support the use of hip protectors in a supported-living setting. This would be further supported by assessing recruitment rates throughout the study.
- Self-reported current activities of daily living (Barthel Index of Activities of Daily Living).
- Self-reported history of falls and physical health Participant's reactions to donning the garments were documented at the start of the 28-days' wear and at the end of the 28 days. At the end of the 28 days we will discuss the wear of the garments with participants and record self-reported adherence and barriers to wear. Issues such as comfort, style, confidence, perceived self-image and practicalities of wearing the garment were discussed.
- Recruitment: number of people consenting versus number approached. Reasons and recurrent themes for non-interest were noted.
- Retention: the number and percentage of participants who complete the study period.
- Adherence: reported % of day and night time adherence at weeks 1, 2, 3, 4 as reported by participants and/or by the scheme manager.

- Additionally, data from sensors embedded in the protectors provided adherence data (from activity recordings) which can be used to judge the accuracy of self-reported adherence.
- Number of participants who experience fall(s) (with or without a resultant fracture) was recorded by self-report in data sheets given to participants, by housing scheme records and by electronic data from the sensors.

2.5 Ethics

A favourable ethical opinion for the study was obtained from the University of Sheffield Ethics committee REF 009034 on the 13/09/2016. Participants were to be informed that they were free to leave the study at any point during the trial if they were uncomfortable.

2.6 Data Analysis

Audio data was transcribed and analysed using content analysis to identify issues relating to adherence and acceptability of the intervention. Notes from diaries were typed up and any fall incidents were recorded and followed up with the participant. Descriptive analysis of data collected relating to recruitment, retention, adherence, falls and injuries were conducted.

3. Summary of the results

In total 12 sites and 31 participants took part in the final trial. Attrition was high and the result of multiple factors including the need for a larger-sized garment, the desire for slimmer protective pads for aesthetic reasons, and forgetfulness. Increased frailty in the winter months due to worsening arthritis may have made donning and doffing of garments difficult for some participants. Adherence across participants varied greatly. Only two participants wore the protectors as directed, day and night.

Qualitative data collection revealed that site managers felt that this intervention would be beneficial and there would be a large amount of support for monitoring the use of the product. Residents of supported housing schemes found the intervention exciting and promising, particularly the monitoring functions of the intervention. All participants who felt the sizing of the garment was accurate for them found the garment to be comfortable and the material of good quality. They reported that the garment washed well but often took a long time to dry due to the protective material.

Data collection during the study was problematic and the quality of returned data is poor, due predominantly to the demographics of the sample. Requested self-reported adherence logging and retrospective recall was poor due to problems associated with memory. Only four completed adherence data log sheets were collected at the end of the trial.

Large amounts of high quality data were recorded through the sensors. Over 1.5 Billion data points including 2000 hours of motion data and over 2500 fall

analogous events. The electronic sensor data on motion and adherence is still being processed. Results will be presented in full at the conference. The fall analogous events consisted of all near zero-g, or freefall, events and have been used to develop an algorithm to remove false positives from the system. More details of this process will be discussed at the conference. The use of sensor data offers a possible solution to the problem of poor quality data collection from residents.

During the study 3 falls occurred. Two of the participants were wearing their protectors at the time of the fall. One of these falls led to an impact on the femur. No hip fractures occurred. No records of the falls were found at the supported living.

4. Conclusions

In summary, this study, while not achieving the projected compliance rates, has provided a rich seam of information and knowledge. Qualitative feedback from participants drawn from the population of potential end-users of the garment provides invaluable insights into their everyday needs and concerns. The experiences of researchers in the course of the study reveal much about the residential and care home environment and the particular difficulties of conducting formal studies with members of this sector of the community. And experienced housing site managers were able to add their own opinions of (and support for) the product and the role it could play in a care home setting.

As a whole, this experience confirms that a demonstration of its effectiveness as a hip injury prevention/alleviation intervention via a gold-standard controlled randomised trial would be lengthy, difficult and costly process, and, moreover, one that might not necessarily be a requisite for a successful product. As such, given the aim of the study was to investigate the feasibility of conducting such a trial, it was concluded that such a trial is impractical and is not to be recommended. The outcomes of the study remind us that – as might be expected for any product – the garment is not for everyone, that each individual has his or her own needs and wants. As such, this will not be a product for everyone, and nor is it one that is necessarily for continuous, everyday use. However, there were enough participants who did like the product, who wore it for an extended period, and found it comfortable and a reassurance, to lend encouragement to the idea that the hip protector garment does indeed have the potential to be a success. The garment is now in production and available on the market.

Full results from the feasibility study will be presented at the conference.

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