Using a Wearable Activity Monitor to Accurately Measure Mobility After Surgery for Hip Fractures (MASH)—A Feasibility Study Protocol

James T. Berwin¹, Hamish Macdonald¹, Tom Fleming¹, Peter Kempshall¹, and Daniel Engelke¹

Abstract

Introduction: Hip fractures are the most common reason for acute orthopaedic admission in the United Kingdom (UK) and pose a substantial cost to the National Health Service (NHS). A significant proportion of this expenditure is accounted for by hospital bed days, with additional contributions from health and social aftercare. Early ambulation following hip fracture surgery improves outcomes by accelerating functional recovery and reducing the need for ongoing care. The ability to track a patient’s rehabilitation is important in assessing their care needs. While this is challenging to assess accurately, doing so may help to further improve outcomes. The aim of this feasibility study is to determine whether it is possible to accurately measure Mobility After Surgery for Hip fractures (MASH) in the immediate post-operative period by tracking the frequency of mobilization, distance walked and overall activity in the first week following surgery using a wearable activity monitor, the activPAL device.

Methods and Materials: A total of 50 patients will be recruited to participate in the study. Ethical approval was given to recruit patients with and without capacity to consent. Immediately after undergoing hip fracture surgery, a activPAL monitor weighing 9 grams and measuring 23.5 mm x 43 x 5 mm in size will be applied to the anterior aspect of the participants thigh with a standard adhesive dressing. We will be assessing the feasibility of using the activPALto measure mobility in this patient group.

Discussion: The MASH study will contribute to the design and execution of the MASH trial, which will seek to assess the accuracy by which mobility can be measured following hip fracture surgery and how this information can best be used to improve rehabilitation and care.

Keywords

hip, fracture, rehabilitation, outcomes

Submitted January 27, 2020. Revised August 12, 2020. Accepted September 16, 2020.

Introduction

Approximately 70–75 000 hip fractures occur annually at a medical and social care cost of £2 billion.¹ Outcomes after hip fracture surgery are related, in part, to the amount of activity patients are able to undertake during recovery, with early ambulation leading to accelerated functional recovery and decreased need for care.² “Starting rehabilitation at least once a day, no later than the day after surgery,” constitutes one of 6 key quality indicators set by the National Institute for Health and Care Excellence (NICE) for the management of adult hip fractures in the UK.³ Failure to provide postoperative physiotherapy has financial implications to trusts in England, losing £1,335 of best practice tariff (BPT) per patient.³

Building a picture of the trajectory of a patient’s rehabilitation is important in assessing their care needs. Objectively tracking post-operative mobility, while challenging, may help to improve outcomes. The National Hip Fracture Database (NHFD) defines post-operative mobility as a patient being “able to get out of bed by being helped to stand or being hoisted

¹ Gloucestershire Royal Hospital, Gloucester, United Kingdom

Corresponding Author:
James T. Berwin, Gloucestershire Royal Hospital, Great Western Road, Gloucester GL1 3NN, United Kingdom.
Email: jtberwin@hotmail.com

Creative Commons Non Commercial CC BY-NC: This article is distributed under the terms of the Creative Commons Attribution-NonCommercial 4.0 License (https://creativecommons.org/licenses/by-nc/4.0/) which permits non-commercial use, reproduction and distribution of the work without further permission provided the original work is attributed as specified on the SAGE and Open Access pages (https://us.sagepub.com/en-us/nam/open-access-at-sage).
out of bed by the day following their operation,” a definition unhelpfully summed up as “bum-off-bed.”

The NHFD subsequently attempted to define rehabilitation using the 2017 Hip sprint audit. The Hip Sprint audit found significant variation in performance against this indicator. The number of patients mobilizing the day after surgery was 68%, almost 10% less than the NHFD had published the same year. This discrepancy suggests a degree of accuracy of measurement or perhaps the introduction of subjectivity when determining whether a patient has mobilized and how they have mobilized.

Clarifying the definition of mobilization after hip fracture surgery as well as a need for a more objective method of assessing mobility, are key issues if the NHFD is to continue to support and monitor local performance and help drive quality improvement through investment in perioperative care and rehabilitation.

ActivPAL is a non-invasive wireless wearable device validated to quantify sedentary, upright and ambulatory activities. It is worn discretely on the participant’s thigh for a week at a time using an adhesive dressing. Physical activity is measured through dynamic acceleration and inclination logging technology. The pattern (sedentary, standing, stepping) and intensity of a participant’s activities can be captured and analyzed using custom software. Results are downloaded for analysis. While similar studies using accelerometers to measure activity following hip fracture surgery have been performed, none have yet been published in the context of UK hip fracture care.

The aim of this feasibility study is to determine whether it is possible to measure Mobility After Surgery for Hip fractures (MASH) more accurately in the immediate post-operative period compared to the current NHFD standard, by tracking patient activity in the first post-operative week using a wearable activPAL device. If feasible, this study will help to inform a larger trial designed to define a set of objective rehabilitation goals set by parameters that can be accurately measured by the activPAL device.

The primary objectives of this feasibility study are to identify challenges in recruitment, assess the feasibility of measuring post-operative mobility using the activPAL device, assess the compliance of wearing the activPAL device for the first post-operative week and to assess whether data captured by activPAL exceeds current NHFD standards.

The Primary feasibility outcomes are as follows:

1. Number of potentially eligible patients identified
2. Number of patients approached to take part in the study
3. Proportion of patients who consented to take part in the study (out of those approached)
4. Proportion of patients who for whom 7 days of data was captured and reasons for any non-compliance
5. Logged physiotherapy assessments of mobility during the same study period defined by the parameters set by the NHFD.

The secondary feasibility outcome measures are as follows:

1. Demographic data: Age, sex, American Society of Anesthetists (ASA) grade, fracture type (AO classification), laterality of fracture, Acute Mental Test (AMT) score, Consent form 1 or 4
2. Anesthetic received intra-operatively
3. Record device used to treat the hip fracture
4. Time to mobilization (defined by point at which steps were measured from the time the patient is back on the ward from recovery)
5. Total activity in the first week post-operatively (defined by activity score, total number of sitting bouts, upright events, sit-to-stands, steps and acceleration)
6. Blood pressure post-operatively
7. Analgesic requirements post-operatively

Methods and Materials

Recruitment

We plan to prospectively recruit 50 patients who have sustained an acute hip fracture and are assessed and treated at Gloucestershire Royal Hospital. Only patients who meet the below inclusion criteria will be eligible for recruitment.

Inclusion Criteria

- Patients aged 60 or more with an isolated acute hip fracture
- Were able to mobilize independently at worst with the aid of a Zimmer frame or walker prior to sustaining their hip fracture
- Any patient with the capacity to consent for their operation (Consent form 1) or any patient who lacks the capacity to consent for their operation (Consent form 4)
- Any patient with an isolated intra- or extra-capsular hip fracture (AO 31. A, B and C type fractures, up to 5 cm below the lesser trochanter) requiring operative fixation or replacement using any device or implant deemed appropriate by the operating surgeon can be included, provided the above conditions are met.

Exclusion Criteria

- Patients less than 60 years of age
- Patients with a diaphyseal femoral fracture, distal femoral fracture, pathologic fracture, bilateral hip fractures, previous surgery on the currently fractured hip
- Patients who have sustained multiple injuries, either to major organs or other limbs such that their rehabilitation may be hindered
- Patients who have sustained their hip fracture while an inpatient
- Patients who were unable to mobilize independently pre-operatively, or who were wheel chair bound, bed bound, or required a hoist transfer
Sample Size

As this is a feasibility study, it is not powered for pre-defined statistical tests. Instead, 50 participants have been recommended to be sufficient to enable an accurate estimation of the standard deviation used for sample size calculation for the definitive trial. With a sample size of 50, we will be able to estimate a drop-out rate of 80% to within a 95% confidence interval of +/- 11%.

Eligibility and Recruitment

Provided the inclusion criteria and not the exclusion criteria are met, patients with or without capacity to consent to their participation in this study are both eligible for recruitment.

Consent

This is a vulnerable group of patients. Extra care when consenting potential participants into this study is to be taken to ensure that consent is voluntary and fully informed.

Should the patient have the capacity to consent, they will first be asked by one of the clinicians, who is a member of the research team, if they would like to read a written information sheet detailing the study. This can be read to the patient if they have problems with sight or would prefer not to read it. The patient will be given as much time as they need to consider whether they would like to participate, but they will need to have made their decision either way prior to their operation.

The participant will then be given the opportunity to ask questions and discuss the study with their family and carers for as long as they require. They will then be asked to provide written consent to participate in the study.

If an eligible patient does not wish to participate, they will be asked if they would be willing to provide a reason for this. Patients are under no obligation to do so, but this information will be used to inform the main trial. General Practitioner’s (GPs) will not be routinely notified of their participation in this feasibility study.

Patients without the capacity to consent are to be included in this feasibility study. Hip fracture patients are frequently cognitively impaired or become cognitively impaired during treatment. We must therefore determine whether it is also feasible to measure mobility in this patient group using activPAL. Under sections 30 to 34 of the Mental Capacity Act 2005 (UK law), the necessary documentation for recruiting patients who lack capacity to consent will be given to relatives or friends of patients.

Ethical Approval

This study was given a favorable outcome by the HRA and Health Care Research Wales (HCRW) research ethics committee on the 19th January 2019 (REC reference: 19/WA/0016).

Entry to the MASH Study

Following consent, patients will be registered into the study using an anonymized trial ID.

Activity Monitor and Intervention

The activPAL activity monitor is a CE-marked device that has been validated for research use as a monitor of movement. Each monitor weighs 9 grams and measures 23.5 mm x 43 x 5 mm in size. The activPAL activity monitor will be applied to the patient’s thigh using a standard adhesive dressing. The application of the monitor is non-invasive. The battery life of the monitor is 7 days, with the aim of collecting data to monitor activity levels during the key days of recovery. The monitor will then be removed, cleaned and the data downloaded on to software for analysis. The device will then be re-charged and re-calibrated before applying it to the next eligible participant. The initial pilot work will establish the feasibility and acceptability to patients of using the monitor during their recovery and the feasibility of using this data to supplement core outcome measures.

Blinding

This study is not designed to compare the mobility of patients with and without the activPAL device applied, therefore MASH will be an open study where those delivering care will not be blinded to the activPAL monitoring device, nor will the patient who is receiving it, or the outcome assessors.

Participant Withdrawal

Participants are free to withdraw at any time. If participants choose not to continue to use the monitor this will not lead to a change in the care the patient receives.

If participants choose not to continue to use the activPAL device this will not lead to withdrawal from the study unless they also request no further data collection or follow-up. A participant withdrawal form will be completed for each participant who wishes to withdraw.

Qualitative Data & Outcome Assessment

Qualitative data and patient reported outcome measures: A short daily qualitative questionnaire as to how the device is being tolerated will be documented to find reasons for non-compliance. Patients will also be given a number of questionnaires to enable correlation between the quantitative data measured by activPAL and qualitative data that is validated for use in a cohort of hip fracture patients. These include Hip Pain rating scale, Falls efficacy scale, Hospital Anxiety and depression score, and the Nottingham Extended ADL score.

While self-report is vulnerable to bias, an observational study of over 88,000 non-institutionalized older adults observed a concordance rate of 80% between self-report and
professional assessment of mobility.\textsuperscript{12} It is therefore important to determine the feasibility of collecting qualitative data and whether it should be included in the design of a larger trial.

**Secondary Outcomes**

Data on secondary outcomes will be taken from operative notes, anesthetic charts and patient observation charts with written consent.

**Data Analysis**

Data analysis will take place once the last patient to be recruited has reached their final assessment at the end of the first post-operative week. The analysis will extract data about the average level of activity during a given time of the day and will provide a breakdown of how long the patient is sitting, standing and walking. As this is a feasibility study, we will not perform any statistical analysis of differences in clinical outcomes between groups. Descriptive analysis of outcome data will be carried out using appropriate summary measures.

**Data Protection**

Participant confidentiality will be maintained at all times, following NHS policies, UK research policies and the Data Protection Act. No member of the research team has a conflict of interest. Tissue samples will not be collected. To achieve data recording consistency across the study we will train all members of the research team individually.

The main ethical and legal concerns are surrounding the secure collection and storage of data. We have addressed these by ensuring the Chief Investigator at Gloucestershire Royal Hospital registers the project with the local Research and Audit department and identifies members of the direct clinical care team to collect data.

All research teams will store data locally on secure NHS Trust computers in a password-protected document. All activity on these computers is logged. All data will be anonymized once it is complete, identifiable data will be destroyed immediately, and data will then be sent to the Chief Investigator in fully anonymized form only for collation. Anonymized data will be kept in password-protected documents on secure NHS Trust computer, and will be destroyed at a set time point (20 years after study completion).

**Feedback of Results**

No feedback of data will be provided to patients. Feedback of overall study results (including publications) will be provided upon request. Should results of the depression scale cross a threshold triggering an alert, the clinical team will be advised so that they can take further action.

**Study Funding**

The unit cost of an activPAL3 is £180. The charging docking station costs £125. Smith & Nephew purchased 10 activity monitors and 2 docking stations and loaned them for use in this feasibility study.

This study was accepted onto the National Institute for Health Research (NIHR) portfolio (CPMS ID: 41009). This will enable clinical research nurses at Gloucestershire Hospital to be involved with enrolling patients into the study and data collection.

**End of Sub-Study**

The formal end of the study is the date of the last data capture following the last visit or contact with the last participant, or after the return of the last monitor, whichever is latest.

**Discussion**

Early ambulation following hip fracture surgery improves outcomes by accelerating functional recovery and reducing the need for ongoing care. Building a picture of the trajectory of a patient’s rehabilitation is important in assessing their care needs. Objectively tracking post-operative mobility, while challenging, may help to improve outcomes.\textsuperscript{1,2,4,13}

The MASH study aims to inform the design of the main MASH trial. This includes an assessment of the activPAL device to accurately capture the pattern and intensity of a subject’s activity in the first 7 days after hip fracture surgery. The feasibility of recruitment, quantitative and qualitative data collection will also be determined.

**Declaration of Conflicting Interests**

The author(s) declared the following potential conflicts of interest with respect to the research, authorship, and/or publication of this article: Smith & Nephew loaned the use of the activPAL devices, but have not influenced study design, data collection, analysis and interpretation of data in the writing of this report.

**Funding**

The author(s) disclosed receipt of the following financial support for the research, authorship, and/or publication of this article: This study is supported by the National Institute of Health Research (NIHR) [CPMS ID: 41009, 2019].

**ORCID iD**

James T. Berwin https://orcid.org/0000-0001-9893-5434

**References**

1. National Institute for Health and Clinical Excellence Scope 1 Guideline Title Hip Fracture: The Management of Hip Fracture in Adults. Published 2009. Accessed June 8, 2020. www.sign.ac.uk/guidelines/fulltext/56/index.html
2. Oldmeadow LB, Edwards ER, Kimmel LA, Kipen E, Robertson VJ, Bailey MJ. No rest for the wounded: early ambulation after

---

**Geriatric Orthopaedic Surgery & Rehabilitation**

---

---
hip surgery accelerates recovery. ANZ J Surg. 2006;76(7):607-611. doi:10.1111/j.1445-2197.2006.03786.x

3. College of Physicians R. Falls and Fragility Fracture Audit Programme National Hip Fracture Database (NHFD) Annual Report 2017. Published 2017. Accessed June 8, 2020. www.rcplondon.ac.uk

4. FFFAP/Physiotherapy Hip Fracture Sprint Audit Map. Accessed June 8, 2020. https://www.ffhap.org.uk/FFFAP/landing.nsf/phfsa.html

5. Edwardson CL, Winkler EAH, Bodicoat DH, et al. Considerations when using the activPAL monitor in field-based research with adult populations. J Sport Heal Sci. 2017;6(2):162-178. doi: 10.1016/j.jsbs.2016.02.002

6. PAL Technologies Ltd. Providing the Evidence. Accessed June 8, 2020. http://www.palt.com/

7. Zusman EZ, Dawes MG, Edwards N, Ashe MC. A systematic review of evidence for older adults’ sedentary behavior and physical activity after hip fracture. Clin Rehabil. 2018;32(5):679-691. doi:10.1177/0269215517741665

8. Leino KA, Kuusniemi KS, Lertola KK, Olkkola KT. Comparison of four pain scales in patients with hip fracture or other lower limb trauma. Acta Anaesthesiol Scand. 2011;55(4):495-502. doi:10.1111/j.1399-6576.2010.02373.x

9. Yardley L, Beyer N, Hauer K, Kempen G, Piot-Ziegler C, Todd C. Development and initial validation of the Falls Efficacy Scale-International (FES-I). Age Ageing. 2005;34(6):614-619. doi:10.1093/ageing/afi196

10. Snaith RP. The Hospital Anxiety and Depression Scale. Health Qual Life Out. 2003;1:29. doi:10.1186/1477-7525-1-29

11. Harwood RH, Ebrahim S. The validity, reliability and responsiveness of the Nottingham Extended Activities of Daily Living scale in patients undergoing total hip replacement. Disabil Rehabil. 2002;24(7):371-377. doi:10.1080/10.1080/09638280110101541

12. Spitzer S, Weber D. Reporting biases in self-assessed physical and cognitive health status of older Europeans. In: Origo FM, ed. PLoS One. 2019;14(10):e0223526. doi:10.1371/journal.pone.0223526

13. Boulton C. In Association with Commissioned by Recovering after a Hip Fracture: Helping People Understand Physiotherapy in the NHS. Published 2018. Accessed June 8, 2020. www.rcplondon.ac.uk