The Step Home Trial: Utilising Physical Activity data in the Acute Post-operative setting

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Aims

1. To assess how post-operative inpatient physical activity levels correlate with patient recovery and duration of stay following elective surgical operations.
2. To investigate the utility of physical activity data to the post-operative surgical team as part of standard patient observations

Background

The importance of patients ambulating following their surgery has long been recognised as an important factor for post-operative recovery. From the reduction of chest infection and venous thromboembolism, to promoting the maintenance of muscle mass, activity following surgery is an essential component of the enhanced recovery after surgery (ERAS) paradigm.(1) In our pre-trial questionnaire from a multidisciplinary cohort of clinicians at an enhanced recovery workshop 85% of respondents thought that physical activity post operatively was highly important (LCA ERAS event – unpublished data).

Furthermore, physical activity is also used as a marker for assessing recovery after an operation. When a surgical team reviews patients on the post-operative ward round they frequently seek the patient's physical activity status, which is then used in conjunction with

other observations (e.g. heart rate, blood pressure, temperature) and patient examination to assess a patient's progress and plan for their discharge home.
Hospitals use technology in a variety of ways to monitor patients, these include more invasive methods (e.g. oesophageal Doppler monitoring for cardiac output) as well as less invasive methods of observations (e.g. pulse oximeter for heart rate and oxygen saturation measurements, electronic blood pressure monitors). Currently, however, there is no valid objective measure for physical activity, and responses with regard to how a patient's activity is progressing is subjective and can be variable.

Recent advances in technology have led to the emergence of wearable devices that are small and minimally invasive with the ability to monitor not only the basic baseline observations (heart rate, temperature etc.) but also to monitor physical activity levels.(2) The integration of Bluetooth and other wireless technologies have improved communication and interfacing with smart devices such as mobile phones and tablet computers. Such technologies provide a very realistic platform to facilitate the collection and collation of large amounts of data which can be processed and presented to the surgical team to allow objective analysis of patients post-operatively and aid decision-making.

Some groups have begun to investigate activity levels using wearable sensors, for example monitoring of physical activity in patients undergoing ambulatory pH monitoring, (3) and the development of an objective mobility assessment tool using a wearable motion sensor after lower limb reconstruction.(4) However, there has been minimal objective information gained with regard to inpatient activity and how this correlates both with the duration of hospital stay and longer term outcomes.

One study, (5) looking at day case laparoscopic cholecystectomy patients used accelerometery data to monitor physical activity levels one week before and one week following surgery. They found that the majority of patients did not return to their baseline activity level until at least one week following surgery. A further study, (6) looking at cardiac surgery in-patients showed a correlation between the number of steps a patient took each day following surgery and their length of hospital stay.

This study will provide further evidence for the usability and utility of wearable sensors in the inpatient surgical setting. It will provide supporting evidence for surgeons to confidently

analyse and assess patients in hospital, allowing for safe and expedient discharge home as well as identify high-risk patients who are likely to require extra support and surveillance in the community setting.

Hypotheses

1. Inpatient physical activity is a predictor of length of stay
2. Physical activity data has important utility as an objective measurement for surgical teams

Methods

Trial Design

A single-centre observational study will be conducted at Imperial College NHS healthcare Trust (UK). The work will be split into two phases.

Phase One

50 patients due for elective surgical procedures will be recruited from St Mary's Hospital outpatient general surgical clinics. Potential participants will be given a participant information sheet and then time to consider whether they wish to participate. If patients wish to participate they will have the opportunity to ask questions before signing a consent form.

At the pre-operative assessment (1-2 weeks prior to operation) participants will be given a wrist-worn motion sensor (AX3 accelerometer, Axivity, Newcastle upon Tyne, UK) together with an information sheet to explain how and when they must wear it. The participants will also be given a generic self-reported Health Related Quality of Life questionnaire (SF-36) to complete.

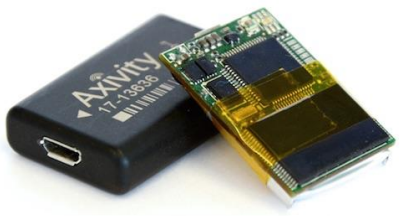


Figure 1. Axivity AX3 logging accelerometer

The AX3 is an ADXL345 tri-axial accelerometer manufactured by Analog Devices, weighing 11g and contains a non-volatile flash memory chip linked by a USB enabled microcontroller. A temperature sensor, ambient light sensor, real time clock (RTC) and lithium polymer battery are also integrated into the sealed polycarbonate puck. The product is compliant with the Directive 2004/108/ EC; (CE marked). The product has been tested to BS EN 61000-6-1:2007 and BS EN 61000-6-3:2007.

Figure 2. Axivity AX3 accelerometer worn on the wrist.

Participants will be asked to wear the wrist-worn sensor at all times (it is showerproof) except if they are swimming or taking a bath, and will be advised to go about their normal daily activity. The patient will continue to wear the sensor on admission and throughout their hospital stay, it will be collected back just prior to discharge.

At follow-up clinic, 2-3 weeks post-operatively, patients will be asked to complete a further generic self-reported Health Related Quality of Life questionnaire (SF-36). A further Health related Quality of Life questionnaire will be completed at 3-6 months at the next follow-up outpatient clinic.

Staff (theatre, recovery and ward) will be briefed before patient recruitment is started and there will be a feedback period for both staff and patients early in the data collection period to ensure that there are no issues with patient safety or any other concerns that need to be addressed. The first 5 patients will be asked to complete a feedback form at their follow-up patient clinic in order to identify any issues or concerns early on in the data collection period.

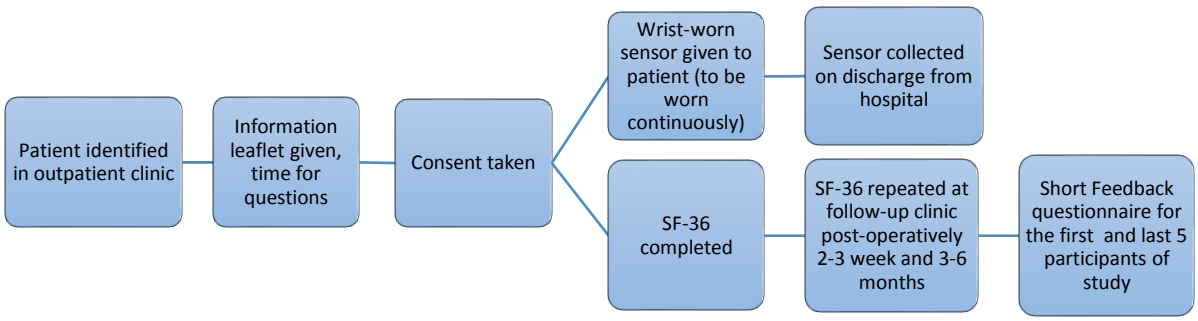
The SF-36(7), which has been validated as a measure of post-operative recovery, (8) assesses eight health concepts including physical activity, mental health and general health perceptions. The questionnaire yields scores (0-100) for each concept which are then combined to produce a physical component score and a mental component score.

Inclusion	Exclusion
Undergoing elective surgical operative procedure	Unable to mobilise independently
	Have medical condition characterized by movement disorder e.g. Parkinson's Disease
	Unable to understand and complete the SF-36 (unless interpreter present) or lack capacity to consent
	Psychological Disorder
	Aged less than 18

Consenting

The principal researcher will take consent (following an initial verbal consent by the surgeon indicating the patient's agreement to be contacted by the researcher as well as for their records to be viewed by the researcher). The patient will have time in the clinic to read the information sheet, ask any questions and decide if they wish to participate. If the patient is happy then written consent will be taken (including consenting to fully understanding the participant information sheet).

Participant schedule



Outcome measures

Primary outcomes

- Pre and post-operative (inpatient) physical activity levels
- Length of stay

Secondary:

- Self-reported quality of life: SF-36 score, broken down into physical and mental component scores
- 30 day readmission
- Complications: Wound infection, chest infection, abdominal/pelvic collection, deep vein thrombosis/pulmonary embolism, myocardial infarction, need for reoperation/further procedure

Patient demographics will be collected via medical records. This includes medical history (including surgical history, comorbidities) and biometrics such as age, gender, weight, height.

Data Analysis

The sensor data will be analysed using software compatible with the specific accelerometer sensor. The processing that is carried out provides more easily understandable and manageable values for both statistical analysis and graphical representation of results.

SPSS (IBM Corp. Released 2013. IBM SPSS Statistics for Windows, Version 22.0. Armonk, NY) will be used to analyse the data.

Data we will collect includes

- Overall physical activity level
- Frequency and duration of bursts of physical activity
- Intensity levels of activity each hour and day
- Patient activity behaviour – times of day activity occurs

Data we will analyse

- Correlation between pre-operative +/- post-operative activity levels and length of stay – Spearman Rank Correlation
- Correlation between the difference between pre-op and post-op activity levels and length of stay - Spearman Rank Correlation
- Correlation between physical activity levels and the SF-36 score, 30 day readmission rates and complications - Spearman Rank Correlation

Phase Two

An extra 5-10 patients will be recruited and the exact same participant schedule will be followed. However, once the patient has been discharged from hospital the activity level data of these patients will be presented to the clinical team. We will then ask the members of the team to fill in a questionnaire/feedback survey with regard to the results presented in order to find out the utility of the data and what clinical teams think about the usability of the data.
The patients themselves will also be told their activity level data in the follow-up clinic and will also asked to fill in a questionnaire/feedback survey to help us understand how patients view this data and its uses.

Ethical Approval

The Chief Investigator has obtained approval from the NRES Committee London – City Road & Hampstead Research Ethics Committee. The study has also been submitted for Site Specific Assessment (SSA) at Imperial College NHS Healthcare Trust. The study will be conducted in accordance with the recommendations for physicians involved in research on human subjects adopted by the 18th World Medical Assembly, Helsinki 1964 and later revisions.

Confidentiality

The Chief Investigator will preserve the confidentiality of participants taking part in the study and is registered under the Data Protection Act.

Indemnity

Imperial College London holds negligent harm and non-negligent harm insurance policies which apply to this study.

Sponsor

Imperial College London will act as the main Sponsor for this study. Delegated responsibilities will be assigned to the NHS trusts taking part in this study.

Funding

Imperial College London are funding this study.

Audits

The study may be subject to inspection and audit by Imperial College London under their remit as sponsor and other regulatory bodies to ensure adherence to GCP and the NHS Research Governance Framework for Health and Social Care (2nd edition).

Publication Policy

We intend to publish the results of this study in high quality peer-reviewed international journals and at a similar standard conferences. In addition if the results could lead to improvement in clinical practice we would look to cite the publication or provide a separate summary for relevant clinical bodies, including advisers of local protocol.

Organisation

We will be recruiting only cases from one specific consultant to remove any bias, we should therefore be able to recruit 2-3 patients per week and would conduct the study over 5-6 months in order to recruit 55-60 patients.

Clinical Impact of Research

This study will provide objective evidence of a link between physical activity and length of hospital stay. This will act as a clear rationale for developing a system to provide activity observations for doctors. Giving hospital staff access to patient activity data has potential utility for surgeons, physicians and other allied healthcare professionals. As technology progresses further, collection of all patient 'observations' is likely to become possible using wearable devices.

Summary

This project will provide supporting evidence for surgeons to confidently, and safely, expedite patient discharge from hospital. This boasts advantages financially, freeing up bed space, and also to the patients themselves, both physically and psychologically. Furthermore, it may help to identify those at high-risk who require extra support in the community setting.

Appendices

A. Phase One

a. Participant Information sheet V2.2
b. Patient Consent form V1.2
c. Patient Feedback form V1.1
d. Clinician Information sheet V1.2
e. Clinician Consent form V1.2
f. Clinician Feedback form V 1.1

B. Phase Two
a. Participant Information sheet V1.2
b. Patient Consent form V1.2
c. Patient Feedback form V1.1
d. Clinician Information sheet V1.2
e. Clinician Consent form V1.2
f. Clinician Feedback form V1.1

C. SF-36 Questionnaire

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