

BMJ Open Peri-Operative Wearables in Elder Recover after Surgery (POWERS) study: a protocol for a multicentre, prospective cohort study to evaluate perioperative activity with postoperative disability in older adults after non-cardiac surgery

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ABSTRACT

Introduction The ageing population has led to an increasing proportion of surgical patients with greater frailty and comorbidity. Complications and mortality within 30 days of a surgical procedure are often used to evaluate success in the perioperative period however these measures can potentially underestimate a substantial level of morbidity associated with surgery. Personal wearable technologies are now readily available and can offer detailed information on activity intensity, sedentary behaviour and sleeping patterns. These devices may provide important information perioperatively by acting as a non-invasive, and cost-efficient means to risk stratify patients.

Methods and analysis The Peri-Operative Wearables in Elder Recover After Surgery (POWERS) study is a multicentre observational study of 200 older adults (≥65 years) having major elective non-cardiac surgery. The objectives are to characterise the association between preoperative and postoperative activity monitor measurements with postoperative disability and recovery, as well as characterise trajectories of activity and sleep in the perioperative period. Activity will be monitored with the ActiGraph GT3X device and measured for 7-day increments, preoperatively, and at 1 week, 1 month and 3 months postoperatively. Disability will be assessed using the WHO Disability Assessment Schedule 2.0 assessed at 1 week, 1 month and 3 months postoperatively.

Ethics and dissemination The POWERS study received research ethics board approval at all participating sites on 1 August 2019 (REB # 19-121 (CTO 1849)). Renewal was granted on 19 May 2022.

INTRODUCTION AND BACKGROUND

As the population ages, healthcare systems must confront the challenge of treating elderly patients with complex medical needs in an era of diminishing and strained

STRENGTHS AND LIMITATIONS OF THIS STUDY

- ⇒ A large generalisable sample of 200 older adults across multiple centres undergoing surgeries where information on the risk of new disability might inform preoperative decision-making, have a relatively high risk of major complications, and with outcomes where patients expect to return to equivalent or improved function.
- ⇒ Baseline evaluation using patient reported questionnaires and wearable technologies to describe the association more accurately between preoperative and postoperative activity levels with postoperative disability and recovery.
- ⇒ Several measures of physical activity will be collected including step count, time spent in moderate-vigorous physical activity, sedentary behaviour, total sleep time and sleep efficiency.
- ⇒ Participants will undergo close prospective follow-up after surgery to ascertain disability, postoperative complications, functional capacity, health-related quality of life, pain severity and cognitive impairment.
- ⇒ Possible limitations include compliance; scalability; and heterogeneity of the study sample. Additionally, the study uses a relatively expensive device that may prohibit its routine use in other settings. However, the measurements and associations derived in our study may be applied to other commercially available monitors after appropriate validation studies.

resources. Surgical patients are older and live with greater comorbidity, posing significant implications for morbidity, mortality and healthcare usage.^{1–3} In the context of rapid population ageing, there is an urgent need to re-evaluate how patients, clinicians,

researchers and administrators estimate preoperative risk and assess optimal recovery after surgery.

The current approach often involves predicting and determining whether an individual dies or develops a major complication in the 30 days after surgery. This approach has fundamental limitations. First, even in high-risk patients, the risk of 30-day mortality is low. For example, in a population-based study, the risk of 30-day death after major elective non-cardiac surgery was <3%, even among *frail* individuals.⁴ This low death rate underestimates the substantial level of potential morbidity among patients who survive. Second, postoperative complications have important non-cardiac beyond 30 days, including worsened disability and quality of life which are currently rarely considered.^{5 6} Third, even seemingly uncomplicated recovery after major surgery may result in worsened function among older patients.⁷ Thus, there is a significant demand within perioperative medicine for new, feasible approaches to provide accurate, individualised and timely risk prediction of outcomes that are patient centric.

Personal wearable activity monitors are now readily available and have evolved beyond the initial iterations of simple step counting (ie, pedometers). Newer monitors can collect data on several parameters including activity intensity, sedentary behaviour and sleeping patterns. These new capabilities present an important opportunity to improve perioperative care by providing a cost-effective, non-invasive means to risk stratify patients preoperatively and develop new measures of recovery/disability after surgery.

We therefore propose to conduct the Peri-Operative Wearables in Elder Recover After Surgery (POWERS) study which will be a prospective multicentre cohort study to evaluate the performance of activity monitors as measures of preoperative risk and postoperative recovery of function. Specifically, our primary aim will be to evaluate the association between time spent in moderate-vigorous activity and disability at 3 months after surgery. We will also explore the associations between other measurements including step count and sedentary behaviour with secondary outcomes such as health-related quality of life and cognition.

METHODS AND ANALYSIS

Patient and public involvement

Patient representatives will provide ongoing input into study conduct and will be involved in determining methods for the dissemination of study results.

Study design and location

The POWERS study is a prospective, observational cohort study that will take place across six academic hospitals in Canada located in Toronto, Ottawa and Kingston. It is nested within the Functional Improvement Trajectories After Surgery (FIT After Surgery) study.⁸ The study design is outlined in figure 1. All participants will receive

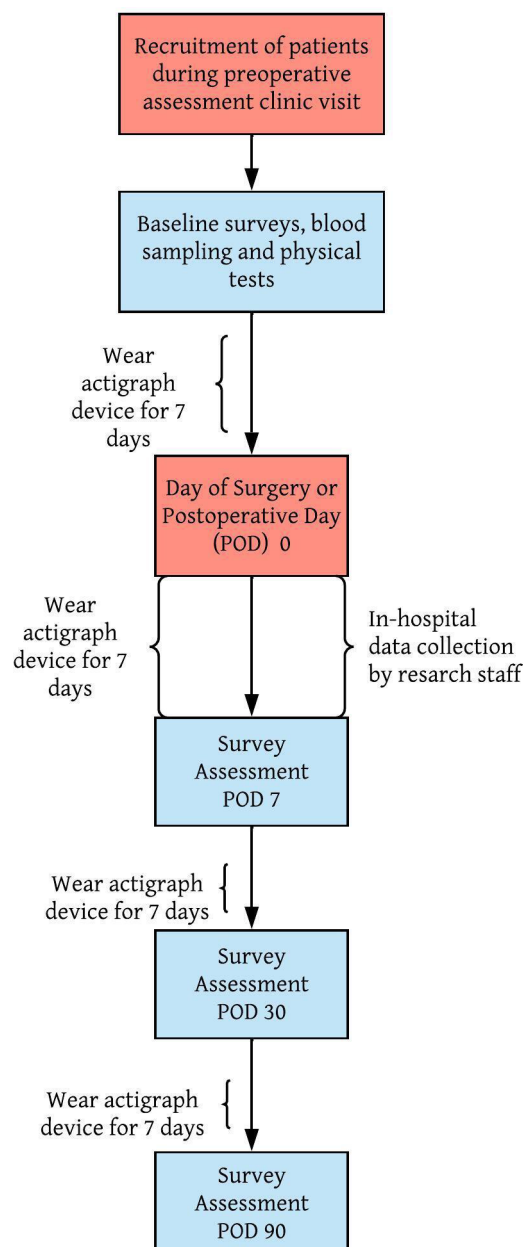


Figure 1 Overall design of the Functional Improvement Trajectories After Surgery cohort study.

an ActiGraph device and have regular assessments using standardised survey instruments throughout the perioperative period.⁹ No intervention will occur based on the information obtained from the device.

Eligibility criteria

Participants will be recruited from preoperative assessment clinics at participating sites. Eligible patients are aged 65 years or older, are scheduled to have elective surgery with a minimum expected postoperative hospital length-of-stay of 2 or more days, and at least 3 days between enrolment and the scheduled procedure to allow for an adequate baseline assessment period. Elective surgery includes time-sensitive scheduled procedures where delays exceeding 1–6 weeks could negatively

Inclusion Criteria:

- Age >65
- Expected Length of Stay >2 days
- Elective surgery with at least 3 days from recruitment till day of surgery

Exclusion Criteria:

- Cardiac, joint replacement, palliative or intra-cranial procedures
- Need for walker or wheelchair
- Severe dementia
- Movement disorder
- Working knowledge of English

Figure 2 Definition of inclusion and exclusion criteria.

affect outcome. A full description of eligibility criteria is provided in figure 2. Procedures without planned curative intent (ie, palliative procedures) are excluded since no long-term return to equivalent or better function is expected. Intra-cranial neurosurgery, cardiac surgery and joint replacement surgery will also be excluded since these surgeries have distinct mechanisms of disability or trajectories of recovery. This study will therefore include abdominal, thoracic, pelvic, head-and-neck or open vascular procedures—which represent >60% of older patients (≥65 years) having elective inpatient surgery.¹⁰ Patients who require a walker or wheelchair or have a movement disorder are excluded given the inability to accurately record activity data. Patients with known severe dementia (based on the judgement of the most responsible physician or site principal investigator) will not be considered if they are unable to answer the study surveys. All participants will provide written, informed consent at time of recruitment to the study.

Outcome measures

Primary outcome

The primary outcome will be the difference in preoperative and postoperative level of disability at 3 months following index surgery. The extent of disability in participants is measured through the 12-item WHO Disability Assessment Schedule 2.0 (WHODAS 2.0) questionnaire. Each questionnaire item is scored on a Likert scale ranging from 0 to 4. The sum of the responses can be expressed as a percentage of a maximum possible score and used to grade disability as none (0%–4% impairment), mild (5%–24% impairment), moderate (25%–49% impairment), severe (50%–95% impairment) or complete (96%–100% impairment).¹¹ Based on normative data,

an 8% absolute difference in mean WHODAS disability scores is relevant in individuals with versus without physical or mental disorders.¹²

Secondary outcomes

Secondary outcomes include (a) functional capacity, (b) health-related quality of life, (c) pain and (d) cognitive impairment. These will be measured through a series of survey instruments including the Duke Activity Status Index (DASI), Short Form 12 (SF-12), Pain Intensity Form 1a and Pain Interference Short Form 6a (PROMIS) and Telephone Interview for Cognitive Status (TICS-m), respectively. The DASI is a self-reported 12-item questionnaire with face, content, construct and criterion validity for measuring functional capacity in surgical patients.^{13–15} The SF-12 is a 12-item self-reported generic Health-Related Quality of Life questionnaire that measures perceived physical and mental health.¹⁶ Thus, it measures a different, although related, construct from WHODAS, which captures restrictions on daily living activities and social engagement. The PROMIS Pain Interference and Intensity scales are reliable and validated self-reported questionnaire that characterise pain severity and its interference with life functions.¹⁷ The TICS-m is an instrument that can assess cognitive impairment both as a screening tool as well as in longitudinal studies.^{18 19} Unlike many other tools to assess cognitive impairment, the TICS-m can be administered over the phone as well as in person.

Exposure measures

All study participants will receive the ActiGraph GT3X (ActiGraph, Pensacola, FL, USA), which contains a triaxial accelerometer, for the duration of the study. The GT3X is a medical-grade device that has been used extensively in clinical trials including several large cohort studies such as the most recent round of the National Health and Nutrition Examination Survey, the Women's Health Study and the Age, Gene/Environment Susceptibility-Reykjavik Study (AGES-Reykjavik).^{20–22} The device has also undergone extensive use and validation in elderly populations. A review performed in 2014 included 59 studies that examined its use in trials focused on elderly adults.²³

The device is water resistant (immersion in 1 m of water for up to 30 min), has a battery life of 25 days and a data storage capacity of 180 days.⁹ Thus, there will be no reliance on cloud storage for data or requirements of synchronisation to a cell phone. While this is beneficial for ensuring patient privacy, it also allows for the inclusion of patients who do not own a smart phone, which is a realistic issue for some older surgical patients as frequent internet use is lower in those aged over 65.²⁴ The long battery life and water resistance also helps to increase compliance rates as patients do not have to remove the device as frequently for recharging. The device stores raw accelerometer data that can be analysed using publicly available and validated algorithms. This contrasts with commercially available devices that only output measurements derived from proprietary transformations, making



it difficult to determine whether they are suitable for research specific to older populations who tend to be more sedentary.²⁵

This study will derive several measures of physical activity based on measurements obtained from the wearable device to determine their predictive value and association with postoperative recovery. These include time spent in moderate-vigorous physical activity (primary exposure), step count, sedentary behaviour, total sleep time and sleep efficiency.²⁶ Measurements will be adjusted for patient compliance with the monitor using validated wear-time algorithms.^{27 28}

Patient demographic, comorbidities and survey data

At the time of recruitment, information on demographics, and comorbidities will be documented in addition to the five survey instruments being administered. Frailty will be measured and assessed by the Clinical Frailty Scale.²⁹ Participants will also undergo baseline blood sampling and perform two brief performance-based physical tests. The blood tests will establish risk for complications and include haemoglobin, creatinine and brain natriuretic peptide.^{30–32} The physical tests are the Timed Up and Go test, and grip strength measurement by the Jamar hand dynamometer which are validated and easy to perform test of mobility and strength.^{33 34}

Data collection

Research personnel will screen for participants in the preoperative assessment clinics of study sites. Consecutive eligible patients will be approached for informed consent and their decisions (including reasons for declining participation) will be recorded. We will also obtain permission from participants to seek help, if needed, from their family members or caregivers to complete the study surveys. After written, informed consent is obtained, baseline covariates, as defined above, will be collected through a combination of interview and information available in the medical record. Patient contact information will also be collected for follow-up purposes and will be encrypted and stored in a separate database from the research database.

At the time of consent, the patient will receive an Acti-Graph device. Device serial numbers will be logged in a database and linked to unique a patient identifier. The devices will not contain any identifiable information and thus if lost will not threaten patient privacy. Study patients will be requested to wear the activity monitor for minimum of three and maximum of seven continuous days prior to their intended operation. Patients will then remove the monitor during the operation and have it replaced immediately in the postoperative care unit or intensive care unit depending on disposition. Patients will then be asked to wear the monitor for seven consecutive days after surgery. This will be followed by two more 7-day time periods which will occur in the week before the 1-month and 3-month follow-up phone assessments. Participants will receive reminder phone calls prior

to these recording periods. Devices will be collected at follow-up appointments at the hospital. If no follow-up is scheduled, patients will be sent prepaid envelopes to ship the devices back to the hospital. A diagram outlining study procedures can be found in figure 1. On completion of the study and return of the device, patients will receive nominal monetary compensation for their participation.

On the day of surgery, research personnel will document information on the procedure, intraoperative care and postoperative disposition. While in hospital, personnel will also follow-up for complications, which will be assessed using the valid Postoperative Morbidity Survey and modified Clavien-Dindo Classification instrument.^{35 36}

Participants will be contacted by phone at three time-points after surgery: 1 week, 1 month and 3 months. To ensure high-quality standardised follow-up, posthospital discharge assessments will be performed centrally by the Applied Health Research Centre, the central coordination centre for the study. During these calls, research personnel will assess vital status, administer survey instruments (ie, 12-item WHODAS 2.0, SF-12, PROMIS), assess level-of-care needs and identify any new medical events that might impact on disability (eg, new surgery, stroke, heart failure, worsened cancer, hospital readmission, planned chemotherapy or radiotherapy). The exception to this will be that the WHODAS will not be administered at the 7-day follow-up call given the nature of the survey instrument (ie, it requires a 30-day look back period). Follow-up of patients will continue up until 1 year as part of the FIT After Surgery study.⁸

Sample size calculation

Based on budget, estimated recruitment and timing, we estimate that we will be able to recruit a total of 150 patients. A sample size of 150 subjects would provide 80% power at a 0.05 significance level to detect a change in disability from 12% to 20% when the continuous variable (activity level measured as number of steps) is decreased by one SD below the mean. An adjustment was made since a multiple regression of the independent variable of interest on the other independent variables in the logistic regression obtained an R^2 of 0.050.³⁷ Calculations were performed in PASS (NCSS, V.15).

Statistical analysis

The primary analysis will use linear regression mixed to quantify the association between preoperative measurements obtained from the wearable device and change in postoperative disability at 3 months while accounting for covariates including length of stay and correlation within hospital site. Measurements garnered from the device in the 3 to 7-day preoperative period will be summarised as mean values and treated as a continuous variable. Model checking techniques will determine the relationship between the exposure and outcome and non-linear techniques will be used if appropriate.

As a secondary analysis, the incremental benefit of using activity monitor data in predicting postoperative disability compared with other preoperative variables will be examined. Two models will be constructed: one with baseline covariates and another with baseline covariates plus data obtained from the activity monitor. The models will be compared using an F-test, root mean squared error and Akaike information criterion.

As a secondary analysis, will examine patterns of activity and sleep throughout the perioperative period. These patterns can be characterised using group-based trajectory models, which estimate changes over time in a repeatedly measured metric, and help identify individuals with similar longitudinal response patterns.³⁸ Latent class mixed models will be used to examine distinct groups of activity trajectories.³⁹ This method can determine the number of distinct trajectory types and model the trajectories continuously (including non-linearly) over time. Posterior probabilities will be used to assign subjects to the appropriate trajectory grouping. These groups will be characterised with respect to their preoperative, surgical and immediate postoperative (eg, complications) features.

ETHICS AND DISSEMINATION

Ethics approval

The POWERS study has been approved by the: Unity Health Toronto Research Ethics Board,. Through Clinical Trials Ontario, the Unity Health Toronto Research Ethics Board is responsible for ethics approval at all study sites in Ontario, Canada. Initial approval was provided on 1 August 2019. REB # 19-121 (CTO 1849). Renewal was granted on 19 May 2022. Experiments described in this study protocol performed were in accordance with the Declaration of Helsinki. Informed consent was obtained from all participants to participate in the study.

Dissemination

The results will be shared through publication in journals with a peer-reviewed submission process. Key results will be presented at international academic conferences. Our hope is to use end-of-grant knowledge translation strategies to identify key messages in the POWERS study for relevant audiences. Using the most up-to-date available evidence, influential and interested individuals or organisations will be identified to liaise the messages. Once the study has concluded, study authors will meet with relevant stakeholders such as members of the target population, scientists, physicians and governmental health policy politicians to further evaluate study results and finalise a robust strategy for knowledge translation.

CONCLUSION

We expect the POWERS study to help risk stratify patients based on perioperative activity levels and permit early identification of high-risk patients who may develop

postoperative disability; inform preoperative and encourage shared decision making between surgeon and patient by providing more information on treatment trajectory and immediate effect of surgery on patient life-style; lay the groundwork for future use of non-invasive personable wearables to aid clinical practice; and provide clarity on the relationship between perioperative activity/sleep levels and postoperative course. The POWERS study will substantially inform and improve the care of older adults who have major surgery worldwide every year.

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Contributors KSL, JL, DIM, JMV, GL, SE, JP-C, HC, MP, GRL and DNW contributed to the conception and design, as well as the acquisition, analysis, and interpretation of the data. JL wrote the first draft of the protocol, and KL revised it critically for important intellectual content. All authors have read and approved the final version of the manuscript to be published.

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Competing interests All investigators do not have any associations with commercial entities that provided support for the work reported in this manuscript or that could be viewed as having an interest in the general area of the submitted manuscript or have any similar financial associations involving family.

Patient and public involvement Patients and/or the public were involved in the design, or conduct, or reporting, or dissemination plans of this research. Refer to the Methods section for further details.

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