Post-discharge after surgery Virtual Care with Remote Automated Monitoring-1 (PVC-RAM-1) technology versus standard care: randomised controlled trial

Michael H McGillion,[1,2] Joel Parlow,[3,4] Flavia K Borges,[2,5,6] Maura Marcucci,[5,6] Michael Jacka,[7] Anthony Adili,[8,9] Manoj M Lalu,[10,11] Carley Ouellette,[1] Marissa Bird,[1] Sandra Ofori,[2,12] Pavel S Roshanov,[13] Ameen Patel,[5,14] Homer Yang,[15,16] Susan O'Leary,[14,17] Vikas Tandon,[5,9] Gavin M Hamilton,[10,11] Marko Mrkobrada,[13] David Conen,[2,5,6] Valerie Harvey,[2] Jennifer Lounsbury,[1,14] Rajibul Mian,[2] Shrikant I Bangdiwala,[2,6] Ramiro Arellano,[3,4] Ted Scott,[14] Gordon H Guyatt,[5,6] Peggy Gao,[2] Michelle Graham,[18] Rahima Nenshi,[8,9] Alan J Forster,[11,19] Mahesh Nagappa,[15,16] Kelsea Levesque,[1] Kristen Marosi,[20] Sultan Chaudhry,[5] Shariq Haider,[5] Lesly Deuchar,[21] Brandi LeBlanc,[9] Colin J L McCartney,[10] Emil H Schemitsch,[22] Jessica Vincent,[2] Shirley M Pettit,[14] Deborah DuMerton,[4] Angela Djuric Paulin,[14] Marko Simunovic,[8] David C Williams,[23] Samantha Halman,[11,19] John Harlock,[8] Ralph M Meyer,[14,24] Dylan A Taylor,[18] Harsha Shanthanna,[17] Christopher M Schlachta,[22] Neil Parry,[22] David R Pichora,[25] Haroon Yousuf,[5] Elizabeth Peter,[26] Andre Lamy,[2,8,14] Jeremy Petch,[14] Husein Moloo,[11,27] Herman Sehmbi,[13,15] Melissa Waggott,[28] Jessica Shelley,[4] Emilie P Belley-Cote,[25] P J Devereaux,[2,5,6] on behalf of the PVC-RAM-1 Investigators

For numbered affiliations see end of the article

Correspondence to:
P J Devereaux
philipj@mcmaster.ca
(ORCID 0000-0003-2935-637X)

Additional material is published online only. To view please visit the journal online.

Cite this as: *BMJ* 2021;374:n2209
http://dx.doi.org/10.1136/bmj.n2209

Accepted: 6 September 2021

ABSTRACT

OBJECTIVE

To determine if virtual care with remote automated monitoring (RAM) technology versus standard care increases days alive at home among adults discharged after non-elective surgery during the covid-19 pandemic.

DESIGN

Multicentre randomised controlled trial.

SETTING

8 acute care hospitals in Canada.

PARTICIPANTS

905 adults (≥40 years) who resided in areas with mobile phone coverage and were to be discharged from hospital after non-elective surgery were randomised either to virtual care and RAM (n=451) or to standard care (n=454). 903 participants (99.8%) completed the 31 day follow-up.

INTERVENTION

Participants in the experimental group received a tablet computer and RAM technology that measured blood pressure, heart rate, respiratory rate, oxygen saturation, temperature, and body weight. For 30 days the participants took daily biophysical measurements and photographs of their wound and interacted with nurses virtually. Participants in the standard care group received post-hospital discharge management according to the centre's usual care. Patients, healthcare providers, and data collectors were aware of patients' group allocations. Outcome adjudicators were blinded to group allocation.

MAIN OUTCOME MEASURES

The primary outcome was days alive at home during 31 days of follow-up. The 12 secondary outcomes included acute hospital care, detection and correction of drug errors, and pain at 7, 15, and 30 days after randomisation.

RESULTS

All 905 participants (mean age 63.1 years) were analysed in the groups to which they were randomised. Days alive at home during 31 days of follow-up were 29.7 in the virtual care group and 29.5 in the standard care group: relative risk 1.01 (95% confidence interval 0.99 to 1.02); absolute difference 0.2% (95% confidence interval −0.5% to 0.9%). 99 participants (22.0%) in the virtual care group and 124 (27.3%) in the standard care group required acute hospital care: relative risk 0.80 (0.64 to 1.01); absolute difference 5.3% (−0.3% to 10.9%). More participants in the virtual care group than standard care group had a drug error detected (134 (29.7%) *v* 25 (5.5%); absolute difference 24.2%, 19.5% to 28.9%) and a drug error corrected (absolute difference 24.4%, 19.9% to 28.9%). Fewer participants in the virtual care group than standard care group reported pain at 7, 15, and 30 days after randomisation: absolute differences 13.9% (7.4% to 20.4%), 11.9% (5.1%

WHAT IS ALREADY KNOWN ON THIS TOPIC

Non-elective surgery patients often utilise acute hospital care (readmission, emergency department or urgent care centre visits) in the 30 days after discharge

As hospitals cope with covid-19, there is a need to reduce surgical patients' post-discharge use of acute hospital care to ensure hospital capacity and facilitate management of the backlog of people waiting for elective surgeries

A strong rationale and preliminary evidence suggest that virtual care and remote automated monitoring (RAM) might decrease the need for acute hospital care in adults discharged after surgery

WHAT THIS STUDY ADDS

Virtual care and RAM did not significantly increase days alive at home compared with standard care, but significantly improved detection and correction of drug errors and decreased pain

In post hoc analyses of centres with high escalation of care that commonly led to changes in medical management, virtual care and RAM reduced the risk of acute hospital care, brief acute hospital care, and emergency department visits

to 18.7%), and 9.6% (2.9% to 16.3%), respectively. Beneficial effects proved substantially larger in centres with a higher rate of care escalation.

CONCLUSION
Virtual care with RAM shows promise in improving outcomes important to patients and to optimal health system function.

TRIAL REGISTRATION
ClinicalTrials.gov NCT04344665.

Introduction

Although many hospitals cancelled elective surgery at the start of the covid-19 pandemic, semi-urgent (eg, oncology), urgent (eg, hip fracture), and emergent (eg, abdominal aortic aneurysm rupture) surgeries continued. Patients discharged after non-elective surgeries often utilise acute hospital care (ie, readmissions or visits to emergency departments or urgent care centres) in the 30 days after discharge.[1 2] As hospitals cope with covid-19 and in many cases resume elective surgeries, a reduction in surgical patients' post-discharge use of acute hospital care is needed to ensure hospital capacity and facilitate management of the backlog of people waiting for elective surgeries.

Virtual care encompasses all the ways that healthcare providers remotely interact (eg, telephone, computer) with their patients. Remote automated monitoring (RAM) refers to use of technology to remotely obtain data on patients' biophysical variables, such as blood pressure. A strong rationale and preliminary evidence suggest that virtual care and RAM will decrease acute hospital care in adults discharged after surgery.[3]

Because of the covid-19 pandemic, virtual delivery of care and RAM has garnered the attention of healthcare providers and funders.[4] Although substantial investment has been made and great promise shown in this method, robust data are needed.[5] We undertook the Post discharge after surgery Virtual Care with Remote Automated Monitoring-1 technology (PVC-RAM-1) trial to determine whether virtual care with RAM compared with standard care increases days alive at home within 31 days of discharge after non-elective surgery in adults.

Methods

This investigator initiated, randomised, controlled trial was carried out at eight acute care hospitals in Canada. Supplementary file 1 provides details of the trial protocol and change summaries, and supplementary file 2 shows the statistical analysis plan. Details of the trial design and methods have been reported previously.[6] Centres obtained ethical approval before recruitment of participants. Study staff recruited participants from 23 April 2020 to 25 July 2020. Supplementary file 3 provides details of the trial investigators, coordinating centre, and committees.

Patient population

Eligible patients were aged ≥40 years, had undergone inpatient non-elective surgery, and the most responsible doctor had decided to discharge the patient home or patients had been discharged within 24 hours and not received acute hospital care since discharge, and provided informed consent to participate. Patients who underwent same day, non-elective surgery were eligible if the attending surgeon or anaesthetist believed these patients would normally have received inpatient surgery but received same day surgery because of the covid-19 pandemic.

We excluded patients who were discharged to rehabilitation or convalescent care for >7 days; were unable to communicate with research staff, complete study surveys, or undertake an interview using a tablet computer owing to a cognitive, language, visual, or hearing impairment; or resided in an area without mobile phone coverage.

Randomisation and blinding

Randomisation occurred after the most responsible doctor decided to discharge the patient home. Research staff randomised participants on a 1:1 basis to receive virtual care with RAM or standard care, using a 24 hour interactive web randomisation system, with block randomisation stratified by centre and type of surgery (cardiac versus non-cardiac). Randomly varying block sizes were used to ensure randomisation was balanced within participating centres and for concealment of randomisation; study staff and investigators were unaware of the block sizes. Owing to the nature of the intervention and follow-up procedures, participants, healthcare providers, and data collectors were aware of the group allocations. Outcome adjudicators were blind to group allocation.

Interventions

Research staff taught participants allocated to virtual care and RAM how to use the cellular tablet and RAM technology from Cloud DX (Kitchener, ON) (figure 1 in supplementary file 3). The RAM technology measured the biophysical variables blood pressure, heart rate, respiratory rate, oxygen saturation, temperature, and body weight. For 30 days, participants took biophysical measurements and completed a recovery survey daily; nurses reviewed these results (appendix 1 in supplementary file 3).

Participants interacted daily with a nurse virtually through the tablet on days 1-15 and every other day from days 16-30 after randomisation. On days without planned virtual visits, if participants' biophysical measurements or recovery survey responses exceeded predetermined thresholds or nurses identified another reason for concern, the nurses organised unscheduled virtual visits.

During virtual visits, nurses discussed participants' symptoms, evaluated participants' wounds and obtained pictures, reinforced principles of recovery after surgery and the need for physical distancing, and undertook drug review and reconciliation on days 1, 8, 15, 22, and 30 after randomisation. Nurses escalated care to preassigned doctors (perioperative doctors or surgeons) if participants' measurements

exceeded predetermined thresholds (appendix 2 in supplementary file 3), specific symptoms of concern were reported (eg, syncope), drug errors were identified, or they had concerns about participants' health that required a doctor's attention. Doctors could interact with participants virtually through the tablet, and they added or modified treatments as appropriate. In the virtual care group, participants had access to a nurse or doctor 24 hours a day, seven days a week. Appendix 3 in supplementary file 3 reports further details on how nurses and doctors delivered virtual care and how devices were returned.

In the standard care group, participants received post-hospital management according to the usual care at the hospital where they had surgery—PVC-RAM-1 did not require the surgeons' usual approach to post-discharge management to change for participants in the standard care group. Canada has a universal public payment system that covers the cost of hospital and doctor services, which alleviates cost as a barrier to these services in surgical patients after discharge. In Canada, standard care for most patients after non-elective surgery would include contact with a healthcare provider within 30 days of hospital discharge. Before this visit, the onus is on patients to connect with their surgeon should questions arise related to the appropriate use of drugs, or symptoms or signs of potential complications.

Outcomes and follow-up

The primary outcome was days alive at home within 31 days of hospital discharge. Secondary outcomes during 31 days of follow-up included acute hospital care, brief acute hospital care, hospital readmission, visit to emergency department or urgent care centre, hospital stay (days) for all causes, detection of a drug error, correction of a drug error, and death. Pain at 7, 15, and 30 days after randomisation was also a secondary outcome. We also captured pain interference scores at these times. A score of 0 represented no pain related interference and 10 represented complete interference with general activity, mood, walking ability, normal work, relations with other people, sleep, and enjoyment of life. We hypothesised that we would detect more drug errors and corrections in the virtual care group than standard care group, and a priori stated we would interpret this as an improvement in care.

Tertiary outcomes at 31 days of follow-up included costs related to utilisation of health services; patient level cost of recovery; reoperation; arrhythmia resulting in electrical cardioversion; acute renal failure resulting in dialysis; respiratory failure; infection; surgical site infection; life threatening, major, or critical organ bleeding; ileus; myocardial infarction; clinically important atrial fibrillation; symptomatic proximal venous thromboembolism; stroke; non-fatal cardiac arrest; *Clostridium difficile* associated diarrhoea; indwelling device inappropriately left in a patient; covid-19; delirium; surgeon, family doctor or specialist in-person clinic visit; surgeon, family doctor, or specialist virtual clinic visit; sepsis; and acute heart failure. Appendix 4 in supplementary file 3 reports the outcome definitions.

The day of randomisation was day 0 of follow-up, and the day after randomisation was day 1 of follow-up after randomisation, and so forth. As participants were followed from the day of randomisation until 30 days after randomisation, follow-up was for 31 days. Appendix 5 in supplementary file 3 presents the follow-up process.

Sample size

PVC-RAM-1 was designed to randomise 900 participants (appendix 6 in supplementary file 3). This sample size would provide ≥89% power if participants in the virtual care group were alive at home for ≥29.81 days, assuming participants in the standard care group would be alive at home on average 29.60 days, out of 31 potential days (two sided alpha of 0.05).

Changes to the protocol

Table 1 in supplementary file 3 reports major amendments to the trial and outcomes, and supplementary file 1 shows the change summaries of the protocol. Shortly after the trial started, we recognised the potential for a competing-outcomes issue between death and acute hospital care (appendix 8 in supplementary file 3). We therefore changed the primary outcome from acute hospital care to days alive at home during 31 days of follow-up. As a result of this change, we reordered acute hospital care as the first secondary outcome. Further amendments to the protocol included the addition of several outcomes as a result of perceived importance: brief acute hospital care, all cause hospital days, pain at six months, and indwelling device error. The following secondary outcomes were changed to tertiary outcomes to restrict secondary objectives to components of the primary outcome that the intervention had the most potential to affect: covid-19 infection; surgeon, family doctor, or specialist visit; sepsis; acute heart failure; and delirium.

Statistical analyses

The data monitoring committee reviewed the data at two time points and recommended continuation of the trial. This included a safety review when the first 100 participants completed 31 days of follow-up, and the first interim efficacy review when 50% of participants completed 31 days of follow-up. The data monitoring committee used the modified Haybittle-Peto rule of 4 standard deviations (alpha=0.00006) for the first efficacy interim analysis. The second interim analysis was scheduled to occur when 75% of the participants had completed 31 days of follow-up, but the analysis did not occur because the last 25% of participants were recruited before the first 75% of participants completed 31 days of follow-up.

The operations committee wrote and finalised the statistical analysis plan before analyses were undertaken or any investigator was unblinded to the trial results. Participants were analysed in the

groups to which they were randomised, regardless of compliance. Participants lost to follow-up without having had the outcome of interest were censored on the last day their outcome status was known.

We used modified Poisson regression with robust variance estimator accounting for clustering by study centre, to estimate the 31 day effect of virtual care and RAM compared with standard care on the primary outcome of days alive at home.[7] In this model, we adjusted for type of surgery (cardiac versus non-cardiac) and pre-randomisation variables known to be associated with acute-hospital care after discharge post-surgery (appendix 7 in supplementary file 3). Treatment effects were also assessed in prespecified subgroups using tests for interactions in the modified Poisson regression models; interaction P values inform whether subgroup effects are likely due to chance.

For the secondary and tertiary outcomes, we compared the effect of virtual care and RAM using modified Poisson regression. We considered a two sided P value <0.05 to be statistically significant. All analyses were performed in SAS, version 9.4.

Patient and public involvement

A panel of four patient partners reviewed the daily symptom survey for clarity and perceived ease of use. Given rules on social distancing and limitations to in-person meetings, all feedback was provided by email. Patients were not involved in the trial design or analyses and did not contribute to the paper.

Results

Overall, 905 participants were randomised: 451 to virtual care and RAM and 454 to standard care (fig 1). Follow-up was complete for 903 participants (99.8%). The baseline personal and surgical characteristics of the participants were similar between groups (table 1). Participants' mean age was 63.1 years, 495 (54.7%) were men, 505 (55.8%) had hypertension, and 309 (34.1%) had active cancer (ie, received treatment within the past six months). In total, 732 participants (80.9%) underwent non-cardiac surgery and 178 (19.7%) underwent cardiac surgery, with a few undergoing both. The timing of surgery was semi-urgent in 514 participants (56.8%), urgent in 320 (35.4%), and emergent in 71 (7.8%). Table 2 in supplementary file 3 reports the subtypes of surgery, which were similar between groups.

Table 3 in supplementary file 3 presents compliance with virtual visits, provision of wound photos, and use of RAM among participants in the virtual care group. Forty one participants (9.2%) discontinued using the tablet and RAM technology before completing 30 days of the intervention. Usual post-discharge follow-up was consistent for both trial groups: 349 participants (76.9%) in the standard care group and 348 (77.2%) in the virtual care group had an in-person or virtual follow-up visit with a non-study surgeon, family doctor, or specialist.

The primary outcome, days alive at home during 31 days of follow-up, was 29.7 in the virtual care group and 29.5 in the standard care group: relative risk 1.01 (95% confidence interval 0.99 to 1.02); absolute difference 0.2% (95% confidence interval −0.5% to 0.9%) (table 2). Overall, 99 participants (22.0%) in the virtual care group and 124 (27.3%) in the standard care group required acute hospital care (0.80, 0.64 to 1.01; 5.3%, −0.3% to 10.9%).

Results for five of the 12 prespecified secondary outcomes were statistically significant (table 2). More participants in the virtual care group than standard care group had a drug error detected (134 (29.7%) *v* 25 (5.5%); absolute difference 24.2%, 19.5% to 28.9%) and a drug error corrected (128 (28.4% *v* 18 (4.0%); 24.4%, 19.9% to 28.9%). Fewer participants in the virtual care group than standard care group had pain at 7, 15, and 30 days after randomisation: absolute differences 13.9% (7.4% to 20.4%), 11.9% (5.1% to 18.7%), and 9.6% (2.9% to 16.3%), respectively.

Among the 134 participants (29.7%) in the virtual care group with a drug error detected, there were 286 drug errors (a mean 2.1 drug errors for each participant), and among the 25 participants (5.5%) in the standard care group with a drug error detected, there were 44 (mean 1.8) drug errors (table 4 in supplementary file 3). Drug omission (ie, patients did not take a drug they were supposed to take) was the most common drug error. Detection of drug omission was more common in the virtual care group (n=82, 18.2%) than standard care group (n=16, 3.5%); absolute difference 14.7%, 10.7% to 18.6%), with 173 and 28 drug omission errors, respectively, among such participants. More participants in the virtual care group than standard care group had a drug error corrected by a doctor or nurse (102 (22.6%) *v* 6 participants (1.3%); absolute difference 21.3%, 17.3% to 25.3%); among these participants, 173 and nine drug errors were corrected by a doctor or nurse, respectively.

Table 5 in supplementary file 3 reports the most responsible person for drug errors and the reason for such errors. Participants were associated with 256 of the drug errors (77.6%), and the most common reasons were intentional (n=118; 46.1%), a mistake (n=58; 22.7%), forgetfulness (n=29; 11.3%), and financial barriers (n=22; 8.6%). Doctors and nurses were associated with 61 of the drugs errors (18.5%), and the most common reasons were failure to communicate clear instructions on what drugs should and should not be taken at home (n=33; 54.1%), failure to write a prescription for a new drug (n=21; 34.4%), and failure to provide an instruction to discontinue a drug (n=4; 6.6%). Pharmacists were associated with 12 of the drug errors (3.6%), and these errors were always related to a failure to provide the drug as prescribed.

Compared with participants in the standard care group, those in the virtual care group had less moderate to severe pain while laying down and while moving at 15 and 30 days after randomisation (table 6 in supplementary file 3). Participants in the virtual care group also reported lower moderate to severe pain related interference scores at 7 and 30 days after randomisation than participants in the standard

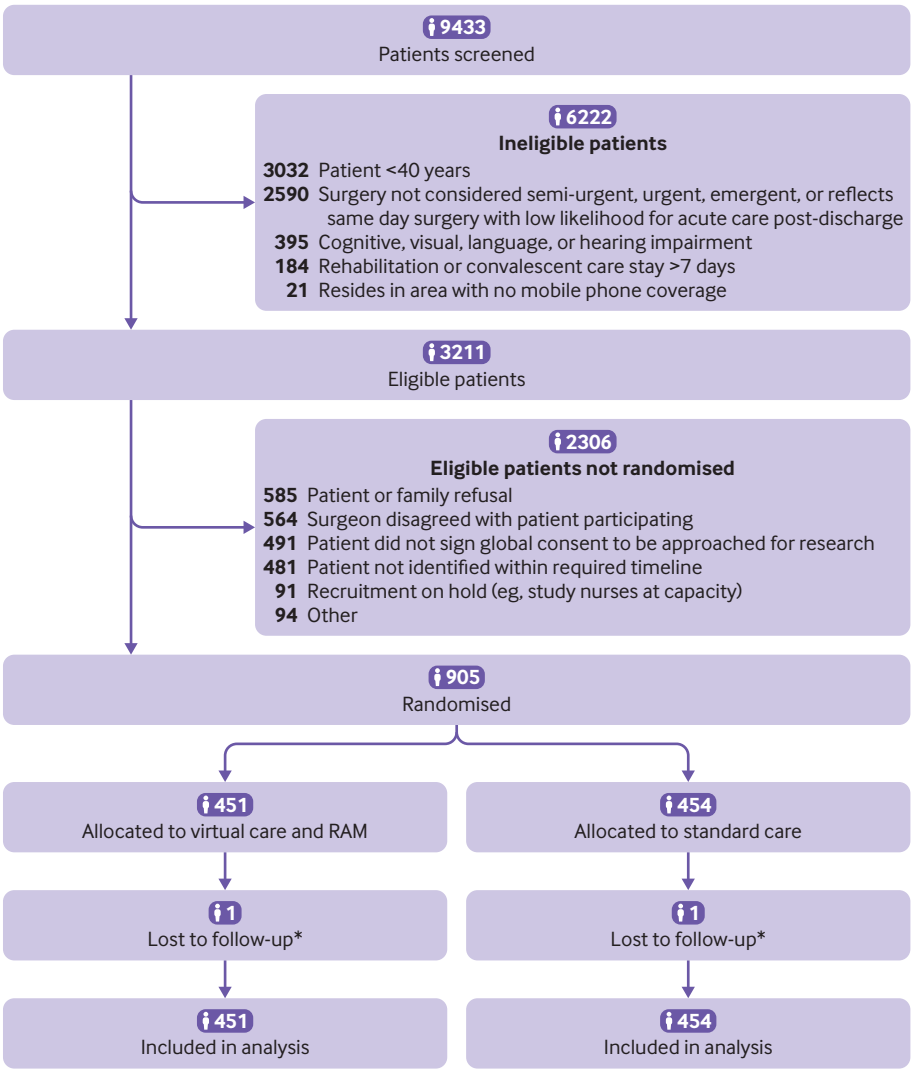

Fig 1 | Patient flowchart. *Data from two participants who withdrew from follow-up are included in the analysis and censored at time of last follow-up. RAM=remote automated monitoring

care group. Paracetamol (acetaminophen) was the analgesic for which relative usage between virtual care group versus standard care group changed over time (ie, usage before the index hospital admission, at discharge after surgery, and at 30 days after randomisation) (table 7 in supplementary file 3). More participants in the virtual care group than standard care group were taking paracetamol at 30 days after randomisation (absolute difference 25.2%, 18.8% to 31.6%).

Most tertiary outcomes (eg, sepsis, stroke, acute heart failure) at 30 days after randomisation were uncommon (table 8 in supplementary file 3). The results suggested that virtual care did not significantly affect any tertiary outcome. In the prespecified subgroup analyses for the primary outcome at 30 days after randomisation, the effects did not differ across the subgroups (figure 2 in supplementary file 3).

In the virtual care group, centres varied in the frequency with which nurses escalated care to a doctor (table 9 in supplementary file 3). Post hoc analyses evaluated results across the centres that had the highest (158 of participants (89.3%) had escalation of care), intermediate (n=103; 54.5%), and lowest escalation of care (n=29; 34.1%) (table 3). In the virtual care group, the total number of escalations and the mean escalations for each participant, respectively, was 758 (4.3) in the highest escalation centres, 227 (1.2) in the intermediate escalation centres, and 56 (0.7) in the lowest escalation centres. The total number and the mean escalations for each participant varied in the virtual care group for various triggers across centres. For example, the mean escalations for each participant for a biophysical variable trigger was 1.6 in the highest escalation of care centres, 0.4 in the intermediate, and 0.1 in the lowest.

Most escalations of care were to a perioperative doctor, with 747 occurrences in the highest escalation centres, 200 in the intermediate, and 43 in the lowest. The results of the escalation of care varied across centres. For example, the mean change in drug for each participant in the virtual care group was 1.3 in the highest escalation of care centres, 0.7 in the intermediate, and 0.3 in the lowest.

Table 1 | Baseline personal and surgical characteristics of participants by group allocation. Values are numbers (percentages) unless stated otherwise

Characteristics	Virtual care and RAM (n=451)	Standard care (n=454)
Mean (SD) age (years)	63.2 (10.4)	62.9 (11.2)
Men	259 (57.4)	236 (52.0)
History before randomisation:		
Hypertension	241 (53.4)	264 (58.1)
Active cancer*	153 (33.9)	156 (34.4)
Coronary artery disease	100 (22.2)	107 (23.6)
Diabetes	98 (21.7)	96 (21.1)
Smoked within 28 days before surgery	88 (19.5)	88 (19.4)
Obstructive sleep apnoea	74 (16.4)	75 (16.5)
Myocardial infarction	56 (12.4)	60 (13.2)
Atrial fibrillation	54 (12.0)	60 (13.2)
Chronic pain	52 (11.5)	50 (11.0)
Chronic obstructive pulmonary disease	41 (9.1)	39 (8.6)
Peripheral arterial disease	22 (4.9)	32 (7.0)
Stroke	22 (4.9)	17 (3.7)
Congestive heart failure	20 (4.4)	17 (3.7)
Transient ischaemic attack	18 (4.0)	15 (3.3)
Deep vein thrombosis	11 (2.4)	8 (1.8)
Pulmonary embolism	10 (2.2)	9 (2.0)
Need assistance with activities of daily living	9 (2.0)	7 (1.5)
Covid-19	0 (0)	1 (0.2)
Surgery type†:		
Non-cardi[a]c†	366 (81.2)	366 (80.6)
General	146 (32.4)	130 (28.6)
Urology/gynaecology	81 (18.0)	91 (20.0)
Orthopaedic	62 (13.7)	68 (15.0)
Neurosurgery	30 (6.7)	31 (6.8)
Vascular	22 (4.8)	25 (5.5)
Thoracic	23 (5.1)	17 (3.7)
Plastic	10 (2.2)	6 (1.3)
Other	10 (2.2)	15 (3.3)
Cardiac†	89 (19.7)	89 (19.6)
Coronary artery bypass grafting	69 (15.3)	75 (16.5)
Valve	28 (6.2)	19 (4.2)
Aortic	12 (2.7)	6 (1.3)
Other	12 (2.7)	13 (2.9)
Timing of surgery:		
Semi-urgent	241 (53.4)	273 (60.1)
Urgent	178 (39.5)	142 (31.3)
Emergent	32 (7.1)	39 (8.6)
Same day	28 (6.2)	42 (9.3)
Surgical approach†:		
Open	341 (75.6)	338 (74.4)
Minimally invasive	63 (14.0)	68 (15.0)
Endoscopic/endovascular	76 (16.9)	71 (15.6)
Anaesthesia†:		
General	435 (96.5)	436 (96.0)
Neuraxial	53 (11.8)	64 (14.1)
Regional block	22 (4.9)	15 (3.3)
Local	10 (2.2)	11 (2.4)
New diagnoses from start of surgery to randomisation:		
Bleeding	29 (6.4)	29 (6.4)
Myocardial injury after non-cardiac surgery	24 (6.6)	18 (4.9)
Infection	11 (2.4)	11 (2.4)
Delirium	5 (1.1)	4 (0.9)
Laboratory measurements before randomisation:		
Median (IQR) haemoglobin (g/L)	108 (94-124)	110 (95-124)
Median (IQR) creatinine (µmol/L)	69 (58-85)	71 (58-88)
Present at time of hospital discharge:		
Surgical drain	37 (8.2)	19 (4.2)
Stoma	22 (4.9)	17 (3.7)
Timing of hospital discharge relative to randomisation:		
Randomised before hospital discharge	358 (79.4)	361 (79.5)
Median (IQR) time from randomisation to discharge (days)	0.08 (0.04-0.17)	0.08 (0.04-0.17)
Randomised within 24 hours after hospital discharge	93 (20.6)	93 (20.5)

RAM=remote automated monitoring; IQR=interquartile range; SD=standard deviation.
*Defined as patients with a diagnosis of cancer (not non-melanoma skin cancers) who were receiving or had received active treatment (eg, chemotherapy, radiation, or surgery) within the past six months.
†Sums of subtypes of surgery, surgical approach, and anaesthesia exceed total number of patients because some patients had more than one type.

Table 2 | Outcomes within 31 days of hospital discharge by group allocation. Values are numbers (percentages) unless stated otherwise

Outcome	Virtual care and RAM (n=451)	Standard care (n=454)	Relative risk* (95% CI)	Absolute difference, % (95% CI)†	P value
Primary outcome					
Mean (SD) No of days alive at home	29.7 (3.9)	29.5 (3.8)	1.01 (0.99 to 1.02)	0.2 (−0.5 to 0.9) ^	0.53
Secondary outcomes					
Acute hospital care	99 (22.0)	124 (27.3)	0.80 (0.64 to 1.01)	5.3 (−0.3 to 10.9)	0.06
Brief acute hospital care	62 (13.7)	82 (18.1)	0.75 (0.56 to 1.02)	4.4 (−0.4 to 9.2)	0.07
Hospital readmission	43 (9.5)	58 (12.8)	0.77 (0.53 to 1.11)	3.3 (−0.8 to 7.4)	0.16
Emergency department visit	89 (19.7)	111 (24.4)	0.81 (0.64 to 1.04)	4.7 (−0.7 to 10.1)	0.10
Urgent care centre visit	4 (0.9)	9 (2.0)	NR‡	1.1 (−0.5 to 2.7)	0.26
Median (IQR) all cause hospital days	0 (0-0)	0 (0-0)	0.89 (0.59 to 1.35)	0.1 (0.0 to 0.2)§	0.59
Death	3 (0.7)	3 (0.7)	NR‡	0	1.00
Detection of drug error	134 (29.7)	25 (5.5)	5.29 (3.52 to 7.93)	24.2 (19.5 to 28.9)	<0.001
Correction of drug error	128 (28.4)	18 (4.0)	7.01 (4.36 to 11.52)	24.4 (19.9 to 28.9)	<0.001
Pain after randomisation (days)¶:					
7	227/386 (58.8)	309/425 (72.7)	0.81 (0.73 to 0.90)	13.9 (7.4 to 20.4)	<0.001
15	193/402 (48.0)	248/414 (59.9)	0.80 (0.71 to 0.91)	11.9 (5.1 to 18.7)	<0.001
30	144/411 (35.0)	184/413 (44.6)	0.80 (0.67 to 0.94)	9.6 (2.9 to 16.3)	<0.008

RAM=remote automated monitoring; IQR=interquartile range; NR=not reported; SD=standard deviation.
*Using modified Poisson model.
†Calculated from crude proportions.
‡A stable relative risk estimate based on a modified Poisson regression was not possible because of too few events.
§Based on normal approximation to Poisson.
¶In the virtual care group 85.6%, 89.1%, 91.1% of patients provided data at 7, 15, and 30 days after randomisation, respectively. In the standard care group 93.6%, 91.2%, 90.9% of patients provided pain data at 7, 15, and 30 days after randomisation, respectively.

Table 3 | Nurse escalation of care of participants in virtual care and remote automated monitoring group*

	Total No of patients (n=451)	Patients in centres with highest escalation of care (n=177)	Patients in centres with intermediate escalation of care (n=189)	Patients in centres with lowest escalation of care (n=85)	P value
No (%) of patients with escalation of care	290 (64.3)	158 (89.3)	103 (54.5)	29 (34.1)	<0.001
Total No of escalations	1041	758	227	56	
Mean No of escalations per patient in virtual care group	2.3	4.3	1.2	0.7	
Trigger of escalation of care (No):					
Onset/change of sign or symptom	481	353	86	42	
Biophysical variable	366	278	78	10	
Drug issue	152	98	50	4	
Other	42	29	13	0	
Mean No of triggers of escalation of care per patient in virtual care group:					
Onset/change of sign or symptom	1.1	2.0	0.5	0.5	
Biophysical variable	0.8	1.6	0.4	0.1	
Drug issue	0.3	0.6	0.3	0.1	
Other	0.1	0.2	0.1	0	
No of escalations of care to study doctor† (No):					
Perioperative medicine doctor	990	747	200	43	
Surgeon	55	29	22	4	
Mean No of escalations of care to study doctor per patient in virtual care group:					
Perioperative medicine doctor	2.2	4.2	1.1	0.5	
Surgeon	0.1	0.2	0.1	0.1	
Result of escalation of care (No):					
Change in drug	385	237	124	24	
Virtual visit	316	234	61	21	
Continue to monitor with no immediate action	329	295	31	3	
Outpatient diagnostic testing‡	79	38	29	12	
Nurse to educate patient§	73	67	4	2	
Patient to follow-up with non-study doctor	49	35	11	3	
Other	53	28	16	9	
Mean results of escalation of care per patient in virtual care group:					
Change in drug	0.9	1.3	0.7	0.3	
Virtual visit	0.7	1.3	0.3	0.3	
Continue to monitor with no immediate action	0.7	1.7	0.2	<0.1	
Outpatient diagnostic testing‡	0.2	0.2	0.2	0.1	
Nurse to educate patient§	0.2	0.4	<0.1	<0.1	
Patient to follow-up with non-study doctor	0.1	0.2	0.1	<0.1	
Other	0.1	0.2	0.1	0.1	

*Escalation of care to doctor per patient at centre.
†Sums of perioperative medicine doctors and surgeons exceeds total number of patients as some patients had escalation of care to both.
‡Outpatient diagnostic testing included blood and urine tests, imaging, and electrocardiography.
§Nurses educated patient about, for example, drug dosing and monitoring wound.

In the subgroup analyses based on centres with the highest, intermediate, and lowest escalation of care, the interaction P values were 0.05 for acute hospital care, 0.06 for brief acute hospital care, 0.03 for visit to an emergency department, and 0.54 for hospital readmission (fig 2). These analyses suggested participants in the highest escalation centres had a lower risk of acute hospital care (relative risk 0.56, 0.38 to 0.82; absolute difference 14.1%, 5.3% to 23.0%), brief acute hospital care (0.47, 0.27 to 0.80; 11.0%, 3.6% to 18.3%), and emergency department visit (0.54, 0.37 to 0.81; 14.2%, 5.4% to 22.9%) with virtual care than with standard care.

Table 10 in supplementary file 3 reports the effects of virtual care with RAM on tertiary six month outcomes. No impact was found on days alive at home at six months.

Discussion

Virtual care and RAM did not significantly increase days alive at home within 31 days of discharge from hospital after surgery. Virtual care and RAM did, however, result in significantly more participants having a drug error detected and corrected. In addition, fewer participants in the virtual care group than standard care group had pain at 7, 15, and 30 days after randomisation. Post hoc analyses suggested that virtual care and RAM reduced the risk of acute hospital care, brief acute hospital care, and visits to an emergency department compared with standard care in centres with high escalation of care but not in centres with lower levels of escalation.

Strengths and limitations of this study

In our study we randomised 905 patients in eight centres and obtained follow-up on 99.8% of participants. Among those in the virtual care group, escalation of care varied substantially across centres. Our post hoc analyses suggest that this variation might have influenced the results. Participants were aware of their treatment allocation and this could have affected the reporting of pain. We did, however, find increased usage of appropriate analgesics, reductions in moderate to severe pain, and reductions in moderate to severe pain related interference scores in the virtual care group, supporting the results for a reduced burden of pain with virtual care. If doctors and participants knew immediately after surgery that the patient had been randomised to virtual care with RAM after discharge rather than standard care, this knowledge could have facilitated earlier hospital discharges in the former group. Because patients were randomised after

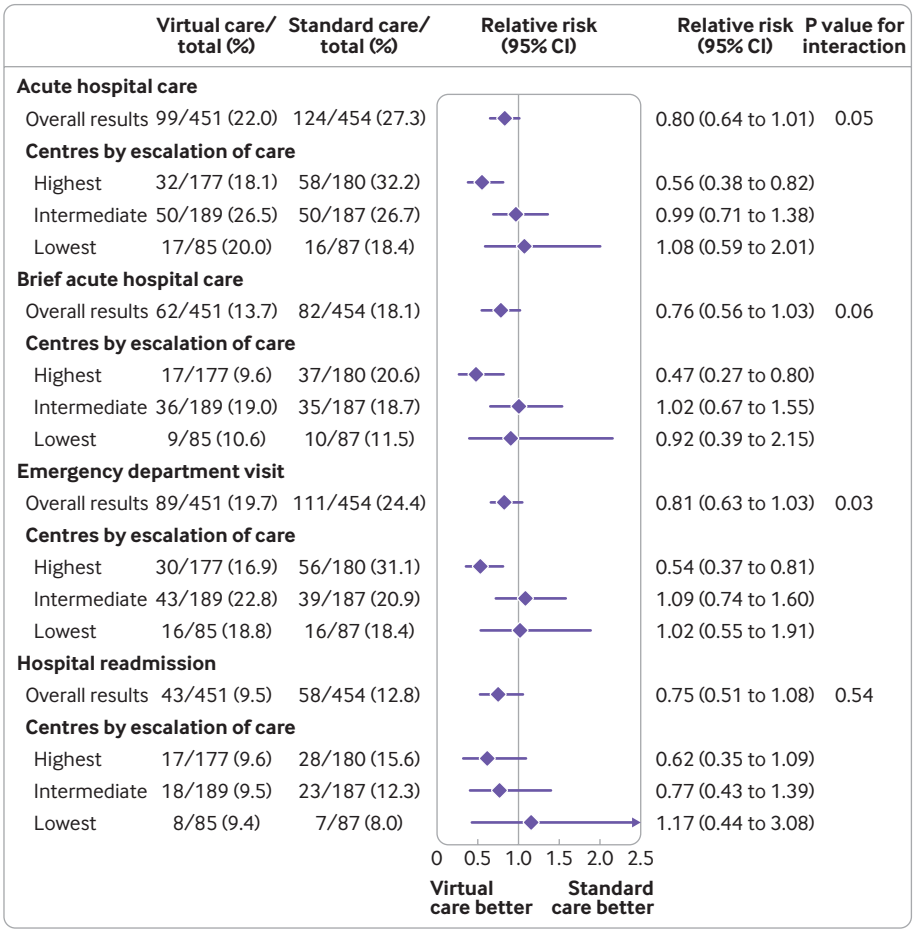

Fig 2 | Subgroup analysis based on centres' escalation of care for 31 day outcome of acute hospital care, brief acute hospital care, emergency department visit, and hospital readmission

the most responsible doctor had decided to discharge them home, we were not able to inform this issue. We did not ascertain if participants viewed days alive at home as an important outcome. Also, we do not have documentation on how the usual standards of care (eg, discharge protocols) changed at participating centres during the covid-19 pandemic. Although baseline variables, including the subtypes of surgery, appear balanced between the two treatment groups, we cannot exclude the possibility of a baseline imbalance of prognosis in this moderately sized randomised controlled trial. We did not assess the impact of the intervention on quality of life.

Comparison with other studies

An observational study of 20 patients discharged after oesophagostomy showed participants' use of virtual care with RAM after discharge was feasible and well received by all patients.[8] A study compared 54 orthopaedic surgery patients—who had postoperative home monitoring of blood pressure, heart rate, oxygen saturation, and pain scores four times a day for four days after discharge with specified alert protocols to a healthcare provider—with 107 orthopaedic surgery patients who received standard care after hospital discharge.[3] This observational study reported an 80% relative risk reduction in the composite of hospital readmission and emergency department visit at 30 days. A systematic review that evaluated virtual care in the recovery of surgical patients after hospital discharge showed that investigators have thus far conducted only small observational studies with a high risk of bias; the three randomised controlled trials included a total of only 153 patients.[9] Although the findings of this review require cautious interpretation, the studies suggest the acceptability of virtual care by patients and doctors, the potential to save patients' time and money from travelling to clinics and missing work, and providing hospital clinic space for new patients. Among eligible patients in our trial, about 18% refused to participate, and 18% of surgeons did not agree to patients participating. Moreover, only 9% of participants discontinued virtual care and RAM before completing the trial. Although we found that most patients and surgeons were agreeable to the trial and compliant with the intervention, further research is needed to establish the barriers to virtual care with RAM after surgery and participation in clinical trials for patients and surgeons.

Policy implications

We changed our primary outcome to days alive at home because of a case that identified the potential for death to be a competing outcomes problem with our original primary outcome, acute hospital care. As only three deaths occurred in each trial group, relevant competing outcomes proved inconsequential. Virtual care and RAM did not significantly affect days alive at home but raised the possibility of a reduction in acute hospital care (22.0% virtual care *v* 27.3% standard care; relative risk 0.80, 95% confidence interval 0.64 to 1.01), brief acute hospital care (13.7% *v* 18.1%; 0.75, 0.56 to 1.02), hospital readmission (9.5% *v* 12.8%; 0.77, 0.53 to 1.11), and emergency department visit (19.7% *v* 24.4%; 0.81, 0.64 to 1.04). During the covid-19 pandemic, when patients might want to avoid post-discharge acute hospital care,[10] our finding that more than one in four patients in the standard care group sought acute hospital care highlights the magnitude of the problem. Although our trial occurred during the covid-19 pandemic, the insights from our trial are probably also relevant in non-pandemic settings.

Drug errors during discharge after surgery were common (29.7% of virtual care participants, with a mean 2.1 drug errors per patient). Virtual care showed large absolute benefits in detecting (24.2%) and correcting drug errors (24.4%). Detection and correction of drug errors have the potential to improve both short term and long term health. Compared with standard care, virtual care also showed substantial absolute benefits in reducing pain; reducing moderate to severe pain, including with movement; and reducing moderate to severe pain related interference scores. Patients are likely to consider these absolute differences important.[11] Our finding of a substantial increase in paracetamol usage at 30 days after randomisation in the virtual care group (absolute difference 25.2%) suggests that healthcare providers can, through virtual care, increase patients' use of this well tolerated drug and substantially improve pain during discharge from hospital after surgery.

It is only credible to expect virtual care with RAM to impact outcomes if these interventions identify problems and lead to changes in management. Across centres in the virtual care group, noticeable variations were found in the proportions of participants with care escalated by a nurse to a doctor, the number of escalations, the frequency in which biophysical variables and onset or change in signs or symptoms triggered escalation of care, and the result of the escalation of care, such as change in drugs. In post hoc analyses, in the highest escalation of care centres, virtual care and RAM was associated with a lower risk of acute hospital care (relative risk 0.56, 0.38 to 0.82), brief acute hospital care (0.47, 0.27 to 0.80), and visits to an emergency department (0.54, 0.37 to 0.81) than standard care.

Although we established predetermined thresholds for biophysical measurement in which nurses were to escalate care to a doctor, nurses and doctors could adjust the frequency of biophysical measurements and variables for alerts. Moreover, nurses could decide whether patients' health required a doctor's attention. These results suggest virtual care and RAM can have substantial effects on lowering the risk of acute hospital care, brief acute hospital care, and visits to an emergency department, if compliance with predetermined biophysical thresholds is rigorous, escalation of care to a doctor is frequent, and doctors appropriately modify care.

Our study provides proof of concept that virtual care with RAM can improve outcomes following hospital discharge after non-elective surgery. Further trials are needed to improve the efficiency (eg, not all patients need to interact with a nurse on days 1-15 and every other day from days 16-30 after hospital discharge) and cost effectiveness of virtual care with RAM in this setting. Qualitative research might also inform how to optimise adherence to intervention and surgeon participation.

Centres in high income countries could implement our virtual care with RAM intervention. Key factors for centres to consider before introducing our intervention include ensuring an adequate supply of dedicated and committed nurses and doctors so that patients receive care 24 hours a day; procuring reliable and reusable virtual care and RAM technology, such as the Cloud DX technology we used in this study; establishing if the patient population resides in areas with mobile phone coverage; and ensuring adequate funding. Although some might question whether virtual care with RAM is viable in patients discharged after surgery in low income countries, given that the dominant cost of this intervention is for staff, which is often more affordable in lower income countries, and that many low income countries have extensive mobile phone coverage, it is possible that such countries could surpass high income countries in the use of this technology. More research, including in low income countries, is needed to inform the potential and cost effectiveness of virtual care with RAM in patients discharged after surgery.

Conclusions

Virtual care and RAM did not significantly affect days alive at home but was associated with a significant increase in detection and correction of drug errors and a decrease in pain. In post hoc analyses of centres with high escalation of care that commonly led to changes in medical management, virtual care and RAM reduced the risk of acute hospital care, brief acute hospital care, and visits to an emergency department.

AUTHOR AFFILIATIONS

[1]School of Nursing, McMaster University, Hamilton, Ontario, Canada
[2]Population Health Research Institute, Hamilton, Ontario, Canada
[3]Department of Anesthesiology and Perioperative Medicine, Queen's University, Kingston, Ontario, Canada
[4]Department of Anesthesiology and Perioperative Medicine, Kingston Health Sciences Centre, Kingston, Ontario, Canada
[5]Department of Medicine, McMaster University, Hamilton, Ontario, Canada
[6]Department of Health Research Methods, Evidence, and Impact, McMaster University, Hamilton, Ontario, Canada
[7]Departments of Critical Care and Anesthesiology, University of Alberta, Edmonton, Alberta, Canada
[8]Department of Surgery, McMaster University, Hamilton, Ontario, Canada
[9]St Joseph's Healthcare Hamilton, Hamilton, Ontario, Canada
[10]Department of Anesthesiology and Pain Medicine, The University of Ottawa and The Ottawa Hospital, Ottawa, Ontario, Canada
[11]The Ottawa Hospital Research Institute, Ottawa, Ontario, Canada
[12]Department of Internal Medicine, University of Port Harcourt, Port Harcourt, Nigeria, West Africa
[13]Department of Medicine, Schulich School of Medicine, University of Western Ontario, London, Ontario, Canada
[14]Centre for Data Science and Digital Health, Hamilton Health Sciences, Hamilton, Ontario, Canada
[15]Department of Anesthesia and Perioperative Medicine, Schulich School of Medicine, University of Western Ontario, London, Ontario, Canada
[16]Department of Anesthesia & Perioperative Medicine, London Health Sciences Centre, London, Ontario, Canada
[17]Department of Anesthesia, McMaster University, Hamilton, Ontario, Canada
[18]Department of Medicine, University of Alberta, Edmonton, Alberta, Canada
[19]Department of Medicine, The University of Ottawa and The Ottawa Hospital, Ottawa, Ontario, Canada
[20]Department of Medicine, Queen's University, Kingston, Ontario, Canada
[21]Alberta Health Services, Alberta, Canada
[22]Department of Surgery, University of Western Ontario and London Health Sciences Centre, London, Ontario, Canada
[23]Department of Surgery, University of Alberta, Edmonton, Alberta, Canada
[24]Department of Oncology, McMaster University, Hamilton, Ontario, Canada
[25]Department of Surgery, Queen's University and Kingston Health Sciences Centre, Kingston, Ontario, Canada
[26]Lawrence S Bloomberg Faculty of Nursing, University of Toronto, Toronto, Ontario, Canada
[27]Department of Surgery, The University of Ottawa and The Ottawa Hospital, Ottawa, Ontario, Canada
[28]The Ottawa Hospital, Ottawa, Ontario, Canada

The site investigators are listed in supplementary file 3.

Contributors: MHM, JP, FKB, MM, MJ, AA, MML, CO, MB, SO, PSR, AP, HY, SOL, VT, GMH, MM, DC, VH, JL, RM, SIB, RA, TS, GHG, PG, MG, RN, AJF, MN, KL, KM, SC, SH, LD, BL, CJLM, EHS, JV, SMP, DD, ADP, MS, DCW, SH, JH, RMM, DT, HS, CMS, NP, DRP, HY, EP, AL, JP, HM, HS, MW, JS, EPBC, and PJD conceived and designed the study and designed the protocol. All authors contributed to critical revisions of the manuscript and approved the version for submission. PJD and MHM are the guarantors. The corresponding author attests that all listed authors meet authorship criteria and that no others meeting the criteria have been omitted.

Funding: This trial was supported by a Roche innovation challenge application grant, McMaster covid-19 research fund grant, the Research Institute of St Joseph's Healthcare Hamilton grant, and covid-19 innovation funding grant from the Ottawa Hospital Academic Medical Association (TOHAMO), and Queen's University Department of Anaesthesiology award and Department of Medicine Research award to help fund the trial at Kingston Health Sciences. This trial received in-kind support to cover the salaries of the virtual nurses from the Hamilton Health Sciences, Kingston Health Sciences, London Health Sciences, St Joseph's Healthcare Hamilton, the Ottawa Hospital, and the University of Alberta Hospital. MHM holds the Heart and Stroke Foundation/Michael G DeGroote endowed chair in cardiovascular nursing. CO and SO received internship funding from Mitacs Accelerate to support work on the PVC-RAM-1 trial. FKB and MM hold McMaster University Department of Medicine career research awards. DC holds a McMaster University Department of Medicine mid-career research award. PJD holds the McMaster University/Hamilton Health Sciences chair in perioperative care and a tier 1 Canada research chair in perioperative medicine. The funders had no role in considering the study design or in the collection, analysis, interpretation of data, writing of the report, or decision to submit the article for publication.

Competing interests: All authors have completed the ICMJE uniform disclosure form at http://www.icmje.org/disclosure-of-interest/ and declare: support from Roche, McMaster University, the Research Institute of St Joseph's Healthcare Hamilton, Ottawa Hospital Academic Medical Association, Queen's University, Hamilton Health Sciences, Kingston Health Sciences, London Health Sciences, St Joseph's Healthcare Hamilton, the Ottawa Hospital, and the University of Alberta Hospital for the submitted work; a financial relationship with Cloud Diagnostics Canada for purchase of devices and data plans used in this trial; and a relationship with Cloud Diagnostics Canada, which undertook training sessions for virtual nurses and perioperative doctors and surgeons on how to use their technology.

Ethical approval: Ethical approval was obtained for all participating sites in Ontario through Clinical Trials Ontario, Hamilton Integrated Research Ethics Board (#2172) and from the University of Alberta Hospital Health Research Ethics Board (#Pro00100098). We attest that we have obtained appropriate permissions and paid any required fees for use of copyright protected materials.

Data sharing: The Population Health Research Institute (PHRI) is the sponsor of this trial. The PHRI believes the dissemination of clinical research results is vital and sharing of data is important. PHRI prioritises access to data analyses to researchers who have worked on the trial for a substantial duration, have played important roles, and have participated in raising the funds to conduct the trial. PHRI balances the length of the research study, and the intellectual and financial investments that made it possible with the need to allow wider access to the data collected. Data will be disclosed only upon request and approval of the proposed use of the data by a review committee. Data are available to the journal for evaluation of reported analyses. Although data sharing agreements prohibit the Institute for Clinical Evaluative Sciences (ICES) from making the ICES dataset publicly available, access can be granted to those who meet prespecified criteria for confidential access, available at www.ices.on.ca/DAS.

The corresponding author affirms that the manuscript is an honest, accurate, and transparent account of the trial. The funders of the trial had no role in data collection, data analyses, data interpretation, or writing of the manuscript. The corresponding author had full access to all of the data and had final responsibility for the decision to submit for publication.

Dissemination to participants and related patient and public communities: We will disseminate the results of our trial through a BMJ blog and "Reducing Global Perioperative Risk" (http://perioperative-risk.amjmed.com/), a web based, multimedia resource centre we developed in partnership with Elsevier (funded by the Canadian Institutes of Health Research). Linked to Elsevier's worldwide readership, this resource centre is designed for global scale knowledge "push" and uses opt-in email blasts for mass knowledge dissemination. We will also present the results at high impact international and national scientific meetings.

Provenance and peer review: Not commissioned; externally peer reviewed.

1 Glance LG, Kellermann AL, Osler TM, et al. Hospital readmission after noncardiac surgery: the role of major complications. *JAMA Surg* 2014;149:439-45. doi:10.1001/jamasurg.2014.4
2 Canadian Institutes of Health Information. All-cause readmission to acute care and return to the emergency department, 2012. https://publications.gc.ca/collections/collection_2013/icis-cihi/H118-93-2012-eng.pdf
3 Yang H, Dervin G, Madden S, et al. Postoperative home monitoring after joint replacement: Retrospective outcome study comparing cases with matched historical controls. *JMIR Perioper Med* 2018;1:e10169. doi:10.2196/10169
4 Thornton J. The "virtual wards" supporting patients with covid-19 in the community. *BMJ* 2020;369:m2119. doi:10.1136/bmj.m2119
5 Perakslis E, Ginsburg GS. Digital Health-The Need to Assess Benefits, Risks, and Value. *JAMA* 2021;325:127-8.
6 McGillion MH, Parlow J, Borges FK, et al, PVC-RAM Investigators. Post Discharge after Surgery Virtual Care with Remote Automated Monitoring Technology (PVC-RAM): protocol for a randomized controlled trial. *CMAJ Open* 2021;9:E142-8. doi:10.9778/cmajo.20200176
7 Zou G. A modified poisson regression approach to prospective studies with binary data. *Am J Epidemiol* 2004;159:702-6. doi:10.1093/aje/kwh090
8 Breteler MJM, Numan L, Ruurda JP, et al. Wireless Remote Home Monitoring of Vital Signs in Patients Discharged Early After Esophagectomy: Observational Feasibility Study. *JMIR Perioper Med* 2020;3:e21705. doi:10.2196/21705
9 Gunter RL, Chouinard S, Fernandes-Taylor S, et al. Current Use of Telemedicine for Post-Discharge Surgical Care: A Systematic Review. *J Am Coll Surg* 2016;222:915-27. doi:10.1016/j.jamcollsurg.2016.01.062
10 Sharma M, Lioutas VA, Madsen T, et al. Decline in stroke alerts and hospitalisations during the COVID-19 pandemic. *Stroke Vasc Neurol* 2020;5:403-5. doi:10.1136/svn-2020-000441
11 Gilron I, Kehlet H, Pogatzki-Zahn E. Current status and future directions of pain-related outcome measures for post-surgical pain trials. *Can J Pain* 2010;3:36-43. doi:10.1080/24740527.2019.1583044.

Supplementary information: supplementary file 1
Supplementary information: supplementary file 2
Supplementary information: supplementary file 3