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Supplemental Trial Groups and Investigators

Participating centres and investigators – *Kingston Health Sciences:* Darrin Payne, Rachael DaCunha, Sunil Patel, Michael Yacob, Siddhartha Srivastava, Lisa Nguyen, Curtis Nickel, Tyler Hands, Elorm Vowotor, Emile Peponoulas, Angela Webster, Tammy Doyle; *Hamilton Health Sciences, Hamilton General Hospital*: Kajenny Srivaratharajah, Dave Szalay, Deborah Bedini, Victor Chu, Jason Busse, Sandra Carroll, Jeremy Petch, Duane Bender, Dina Brooks, Krysten Gregus, Patricia Power, Dale Williams; *Hamilton Health Sciences, Juravinski Hospital and Cancer Centre*: Amitabha Chakroborty, Samir Raza, Amna Ahmed, Kelly Lawrence, Derek Hunt, David Cowan, Jehonathan Pinthus, David Wilson, Clare Reade, Leslie Gauthier, Stephen Kelly, Kirsten Krull, Kim Alvarado, Susan Reid, Mohit Bhandari; *University of Alberta Hospital*: Derek Dillane, James Greene, David Bigam, Ryan Snelgrove, Brian Buchanan, Oleksa Rewa, Ronald Brisebois, Nadr Jomha, Bruce Ritchie, Sherry Reid, Adrian Fairey, Greg Hrynchyshyn; *St. Joseph's Healthcare Hamilton*: Bobby Shayegan, Christian Finley, Wendy Lim, Maria Tiboni, David Choi, Anne-Marie MacDonald, Deanna Burnette, Tom Stewart, Melissa Farrell, Carolyn Goss, Faraaz Quiraishi; *The Ottawa Hospital*: Daniel McIsaac, Sarah Tierney, Shawn Hicks, Kathryn Wheeler, Josh Robert, Colleen McFaul, Greg Krolczyk, Purnima Rao, Stephane Moffett, Dan Dubois, Catherine Code, Heather Clark, Melissa Rousseau, Catherine Gray, Dominique Yelle, Youssef Tawil, Babak Rashidi, Weiwei Beckerleg, Shipa Gupta, Sudhir Sundaresan, Suzanne Madore, Andrew Seely, Reece Bearnes, Dean Fergusson, Susan Madden, Jad Abou Khalil, John Sinclair, Moein Momtazi, Rodney Breau, Humberto Vigil, James Chan; Freddy Nguyen, *London Health Sciences (University and Victoria Hospitals)*: George Nicolaou, Yamini Subramani, Ashraf Fayad, Amit Garg, Cathy Vandersluis, Glen Kearns, Cheryl Churcher, Carla Cormack, Brenda Maxwell, Johana Halabi, James Calvin, Douglas Naudie, Melfort Boulton, Stephanie Handsor, Heather Whittle, Charlotte Kenning.

Population Health Research Institute Coordinating Centre: Lori Blake, Sanela Dragic-Taylor, Arielle Fernandez, Peggy Gao, Valerie Harvey, Peter Koh, Louise Mastrangelo, John Liu, Yan Yun Liu, Rajibul Mian, Wesley Tong, Jessica Vincent, Heidi Wilton.

Event Adjudication Committee: Flavia K Borges (Chair), Sandra Ofori, Michael Wang, James Khan, Rahima Nenshi, Maura Marcucci.

Data Monitoring Committee: Victor M. Montori (Chair), Finlay McAlister, Kristian Thorlund. The members of the Data Monitoring Committee had expertise in clinical trials, perioperative care, virtual care, and statistics.

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APPENDIX 1A. Sample consent form

Informed Consent Form for Participation in a Research Study

Study Title: Post discharge after surgery Virtual Care with Remote Automated Monitoring technology (PVC-RAM) Trial

Study Doctor: Dr. X

Co-Investigator: Dr. Y

Sponsor/Funder(s): Population Health Research Institute (PHRI)

INTRODUCTION

You are being invited to participate in a clinical trial (a type of study that involves research). You are invited to participate in this trial because you are aged 40 or older and have recently had urgent or emergency surgery. This consent form provides you with information to help you make an informed choice. Please read this document carefully and ask any questions you may have. All your questions should be answered to your satisfaction before you decide whether to participate in this research study.

The study staff will tell you about the study timelines for making your decision.

Taking part in this study is voluntary. You have the option to not participate at all or you may choose to leave the study at any time. Whatever you choose, it will not affect the usual medical care that you receive outside the study.

You will not be able to participate if you are unable to communicate with research staff, complete study surveys, or undertake an interview using a tablet computer due to a cognitive, language, visual, or hearing impairment; and/or reside in an area without cellular network coverage.

IS THERE A CONFLICT OF INTEREST?

There are no conflicts of interest to declare related to this study.

WHAT IS THE BACKGROUND INFORMATION FOR THIS STUDY?

Surgery is done to improve survival and quality of life. Unfortunately, complications like pain and infection can be a problem for some people during their recovery after surgery. Your risk of

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wound infection, hospital readmission, or need to go to an emergency department or urgent care centre, is greatest in the first 30 days following your surgery. You may not see your surgeon, cardiologist or family doctor for several days or weeks after surgery. For example, it is common to wait up to 4 to 6 weeks to begin cardiac rehabilitation after cardiac surgery. Many complications, such as infection, pain, and medication errors can happen in the first few days following discharge home. If these problems are not dealt with fast enough, people can end up being readmitted to hospital or going to the emergency room. With the current pandemic of COVID-19, there may be COVID-19 positive patients in the hospital and it is important to reduce the risk of COVID-19 transmission to surgery patients if they need treatment or care from a nurse or doctor. We need to evaluate better ways of managing people's care after surgery, which helps prevent problems and helps people recover safely at home, and, at the same time, is sustainable for the healthcare system.

The standard or usual follow up timeline after surgery is a follow up visit or call from your surgeon. Depending on the type of surgery you have had, this follow up could be a telephone call or visit within a few days of your surgery, or up to 8 weeks after your surgery. During the COVID-19 pandemic, these timelines may be even longer.

WHY IS THIS STUDY BEING DONE?

The purpose of this study is to evaluate the use of hospital-to-home care tools to monitor recovery safely at home after surgery and to determine if home monitoring can prevent hospital readmission, emergency department or urgent-care centre visits, or other new admissions to healthcare facilities (e.g. rehabilitation centres), by catching and managing health related issues before they become larger problems for you.

WHAT OTHER CHOICES ARE THERE?

You do not have to take part in this study in order to receive treatment or care. Currently, home monitoring is not part of the standard of care after surgery. Your doctor will provide the best care for you.

HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY?

It is anticipated that about 900 people will take part in this study, from research sites located in Canada. This study should take less than one year to complete and the results should be known in about one year.

WHAT WILL HAPPEN DURING THIS STUDY?

ASSIGNMENT TO A GROUP

If you decide to participate then you will be "randomized" into one of the groups described below. Randomization means that you are put into a group by chance (like flipping a coin). There is no way to predict which group you will be assigned to. You will have an equal chance of being placed in either group. Neither you, the study staff, nor the study doctors can choose

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what group you will be in. After randomization, you will be told which group you are in. The study doctors, study nurses, and research teams will also know which group you are in.

WHAT IS THE STUDY INTERVENTION?

Group 1 (Virtual Care and remote monitoring): Standard care (contact or visit with your surgeon after discharge and within the usual timeframe determined by your surgeon), plus virtual care and remote automated monitoring. If you are randomized to this group you will be monitored at home by study nurses for 30 days after discharge. You will be provided with a hospital to home kit that contains the following technologies: tablet computer (with stand), wrist–based blood pressure cuff (for blood pressure, pulse and breathing rate), finger worn pulse oximeter (for measuring your oxygen levels), thermometer (for temperature) and weigh scale (to monitor your weight). Monitoring will include daily video visits with a nurse for the first 15 days of the program and every other day after this. These video visits will take between 20-30 minutes to start. As you recover and become more comfortable with the technologies, the visits may become shorter.

Prior to discharge, or shortly after discharge (by mail), you will receive the hospital to home kit which will include instructions on how to set up the devices, and the planned 30-day monitoring schedule. You will review the kit and follow up schedule with your virtual care nurse during your first video visit. You will be provided with training on how to use monitoring devices and the tablet application during the first video call. Study nurses will also answer any questions you have.

The measurements collected from the monitoring devices will be uploaded automatically to the companion tablet provided in the monitoring kit. The study nurse will then be able to review these measurements with you during your video visits. The frequency of daily biophysical measurements will be 3 times a day for the first 15 days, and then twice a day from day 16 until 30 days after your start the study. Weight will be measured daily in the morning before breakfast. Vital signs and weight measurement frequency can be adjusted according to your tolerance based on the virtual nurse's judgement or based on directions from the most responsible physician. It is expected that at least one full set of biophysical parameters will be recorded each day of the study. In addition to the vitals collection, each day, for 30 days, you will answer surveys about how you are feeling. Your answers will be uploaded to the study nurse for review and may be discussed with you during the video visit. During the video visit, the study nurse will also ask you questions about your pain level and take a photograph of your wound to look for signs of infection.

After the 30-day monitoring period has ended, you will be contacted by a member of the study team by phone at approximately 31 days and 6 months after hospital discharge and asked a few questions about your overall health, any complications you had during the follow up period, any time spent in a hospital or other health care facility, and medical related expenditures. You will be asked to package up the kit and prepare the kit for return using the prepaid slip and contacting the shipping company to confirm the kit is ready for pick up.

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Group 2 (<u>Standard Care</u>): Standard care (contact or visit with your surgeon after discharge and within the usual timeframe determined by your surgeon).

If you are randomized to this group you will receive the usual care provided for your recovery after surgery. You will be contacted by a study team member via telephone on approximately day 7, 15, 30, 31, and 6 months after you have been discharged from the hospital. The phone calls on days 7, 15 and 30 will last approximately 10 minutes. During these calls, you will be asked any pain you may be experiencing and if you have recently been to a hospital or other healthcare facility. During the 31-day call (approximately 31 days after discharge), you will be asked about any medications you are taking, if you have recently been to a hospital or other healthcare facility., any complications that happened during your recovery, pain, health and medical related expenditures. This call will take 20-30 minutes. The last call from the study team at approximately 6 months after your discharge will take 10 minutes. You will be asked about any medications you are taking, pain, and any time spent in a hospital or other healthcare facility since the last telephone call. This final call will take approximately 10 minutes.

WHAT ELSE DO I NEED TO KNOW ABOUT THE STUDY INTERVENTION?

If at any point the study nurse feels your condition has worsened or thinks that you may experience a complication based on your vitals and video interview, the study nurse will have access to a study doctor 24 hours a day/ 7 days a week, to escalate your care. The study doctor will be able to assess you through telephone or video conferencing, and or may make clinical decisions (e.g., add or modify any of your treatments, refer you to other specialists, etc.) as they deem appropriate.
Outside of the regularly scheduled video visits you will also have access to a study nurse, 24 hours a day/ 7 days a week, should you feel that a change in your condition requires urgent contact with a healthcare provider.
The at home monitoring system from CloudDX used in the PVC-RAM study has previously been approved by Health Canada as monitoring systems. The monitoring system is not being tested in this study. We are investigating the clinical workflow and clinical and patient application of these approved devices.

WHAT ARE THE RESPONSIBILITIES OF STUDY PARTICIPANTS?

If you choose to participate in this study, you will be expected to:

- Tell the study doctor about your current medical conditions;
- Tell the study doctor about all prescription and non-prescription medications and supplements, including vitamins and herbals, and check with the study doctor before starting, stopping or changing any of these;
- Tell the study doctor if you are thinking about participating in another research study; and
- Return the monitoring kit and all devices at the end of the follow up period.

HOW LONG WILL PARTICIPANTS BE IN THE STUDY?

The study intervention will last for about 30 days and total follow up is 6 months. The study team will collect information from your hospital chart relevant to your time in hospital for the surgery that made you eligible to participate in this trial. This may include items like your medical history prior to surgery, laboratory assessments performed as part of your routine care, details of your operation, and information on your recovery between surgery and hospital discharge.

No matter which group you are randomized to, and even if you stop the study intervention early, we would like to keep track of your health for up to 6 months after hospital to provide data on health system use and cost after surgery. We also require your permission to collect information on your clinical outcomes (e.g., hospitalizations). This will be done by linking information like your health card number, name, date of birth to health care databases held at the Institute for Clinical Evaluative Sciences (ICES). The ICES databases contain information about physician, hospital, home care services and medications that are paid for by the Ontario government. The linkage of your data with ICES databases will be done in order to evaluate the efficacy of the intervention and assess its long-term outcomes.

CAN PARTICIPANTS CHOOSE TO LEAVE THE STUDY?

You can choose to end your participation in this research (called withdrawal) at any time without having to provide a reason. If you choose to withdraw from the study, you are encouraged to contact the study doctor or study staff and discuss the level of withdrawal. Information that was recorded before you withdrew will be used by the researchers for the purposes of the study, but no information will be collected or sent to the sponsor after you withdraw your permission.

CAN PARTICIPATION IN THIS STUDY END EARLY?

The study doctor may stop your participation in the study early, and without your consent, for reasons such as:

- You are unable to complete all required study procedures;
- The Sponsor decides to stop the study; or
- The Regulatory Authority/ies (for example, Health Canada) or research ethics board withdraw permission for this study to continue

If this happens, it may mean that you would not receive the study intervention for the full period described in this consent form. If you are removed from this study, the study doctor will discuss the reasons with you.

WHAT ARE THE RISKS OR HARMS OF PARTICIPATING IN THIS STUDY?

If you are randomized to the intervention, you will be required to use a wrist-based blood pressure monitor, and a wireless pulse oximeter. These devices may feel uncomfortable at times. You may discuss comfort of these devices with the virtual care nurse during your daily video visits.

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WHAT ARE THE BENEFITS OF PARTICIPATING IN THIS STUDY?

If you are randomized to the Virtual care and remote monitoring arm of the study you may benefit from the increased monitoring. Due to the increased monitoring, you will also have increased contact with study nurses compared to standard care. Study nurses may be able to identify health issues faster than usual. Your participation in this study may add to the medical knowledge about remote monitoring in patients after surgery.

HOW WILL PARTICIPANT INFORMATION BE KEPT CONFIDENTIAL?

If you decide to participate in this study, the study doctors and study staff will only collect the information they need for this study. Records identifying you at this centre will be kept confidential and, to the extent permitted by the applicable laws, will not be disclosed or made publicly available, except as described in this consent document.

Authorized representatives of the following organizations may look at your original (identifiable) medical/clinical study records at the site where these records are held, to check that the information collected for the study is correct and follows proper laws and guidelines.

- Population Health Research Institute, the Sponsor of this study
- The research ethics board who oversees the ethical conduct of this study in Ontario
- This institution and affiliated sites, to oversee the conduct of research at this location

Information that is collected about you for the study (called study data) may also be sent to the organizations listed above. Representatives of Clinical Trials Ontario, a not-for-profit organization, may see study data that is sent to the research ethics board for this study. Your name, address, email, or other information that may directly identify you will not be used. The records received by these organizations may contain your participant code, initials, sex, and date of birth.

The following organizations will also receive study data:

- Institute for evaluative clinical sciences (ICES)
- CloudDX Diagnostics Inc., technology service provider for in home monitoring and video follow up

Studies involving humans sometimes collect information on race and ethnicity as well as other characteristics of individuals because these characteristics may influence how people respond to different interventions. Providing information on your race or ethnic origin is voluntary.

This study requires the transfer of identifiable information to the Institute of Evaluative Clinical Sciences (ICES) for the purposes of longer term (6 month) follow up, health systems costs and health system use analysis.

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To do this we would like to gather more information about your medical care from the Institute for Clinical Evaluative Sciences (ICES). ICES is an independent research facility in Toronto, ON that studies the impact of health care and diseases in Ontario. ICES has special status under Ontario privacy law, allowing for the collection and use of patient data, including information about the use of physician services, hospitalizations, and prescriptions for patients residing in this province. In order to have this special status, ICES is required by law to have its policies and procedures, related to the security and privacy protection of data, reviewed and approved by the Information and Privacy Commissioner of Ontario every three years. All data are coded and kept in a secure environment, to maintain individual confidentiality.

Your study data will be entered into a password-protected database and kept in a secure location at the PHRI. This database can only be accessed by authorized members of our research team and will be used to study health outcomes related to surgery and use of health services during your hospitalization and up to 6 months after your participation in the trial began. The risks associated with allowing ICES to use your information are minimal, as the data at ICES are anonymized using unique identifiers and kept in a secure environment, and individuals are never identified.

By providing your consent to participate you are agreeing that the following information will be transferred:

- OHIP number
- Full first name
- Full last name
- Date of birth
- Sex
- Postal code

This information will be securely transferred from Population Health Research Institute (where the research is taking place) by or on behalf of the study investigators to the Institute for Clinical Evaluative Sciences (ICES) so the required linkages can be made to gather the information for the study. The study investigators will be permitted to access de-identified information only for analysis (i.e., any information that can directly identify a person like health card number or name will be removed or replaced with a code that is not known to the study investigators).

If the results of this study are published, your identity will remain confidential. It is expected that the information collected during this study will be used in analyses and will be published/ presented to the scientific community at meetings and in journals. This information may also be used as part of a submission to regulatory authorities around the world to support the approval of the study intervention.

The at-home system is not connected to the hospital. The Connected Health mobile application was designed by Cloud DX. The Cloud DX system will be receiving your personal data entered and it will be stored. Cloud DX will have access to your de-identified data for internal research, development, and regulatory filings. The Cloud DX Connected Health platform is a secure remote patient monitoring solution with all cloud data residing on secure Microsoft Azure servers. The cloud data storage resides entirely in Canada on servers physically located in

Toronto and Quebec (including all backup images), which meet HIPAA compliance for cloud services against ISO 27001 and SOC 2 certifications. During the study, your personal health information will be visible to research team members located across the participating hospital sites, and on restricted access by Cloud DX personnel for technical support. To ensure cybersecurity and patient privacy, the Samsung tablet supports cellular communications through Health Insurance Probability and Accountability Act (HIPAA)-compliant cloud infrastructure. Any data stored in the CloudDX cloud will be de-identified before exporting to our research database.

This study will use the CloudDX pulsewave platform to perform intervention/collect data, which is an externally hosted cloud-based service. A link to their privacy policy is available here (https://www.clouddx.com/#/privacy). Please note that whilst this service has been approved by the Hamilton Integrated Research Ethics Board for collecting data in this study, there is a small risk, as with any platform such as this, of data collected on external servers falling outside the control of the research team. Please talk to the researcher if you have any concerns.

WILL FAMILY DOCTORS/HEALTH CARE PROVIDERS KNOW WHO IS PARTICIPATING IN THIS STUDY?

Your surgeon and your family doctor/health care provider may be informed that you are taking part in a study so that you can be provided with appropriate medical care. If you do not want your family doctor/health care provider to be informed, please discuss this with the study team.

WILL INFORMATION ABOUT THIS STUDY BE AVAILABLE ONLINE?

A description of this clinical trial will be available on *https://clinicaltrials.gov*. This website will not include information that can identify you. You can search this website at any time.

WHAT IS THE COST TO PARTICIPANTS?

The virtual care and remote monitoring technologies will be supplied at no charge while you take part in this study. Participation in this study will not involve any additional costs to you or your private health care insurance.

ARE STUDY PARTICIPANTS PAID TO BE IN THIS STUDY?

You will not be paid for taking part in this study. In the case of research-related side effects or injury, medical care will be provided by the study investigator, to help you recover from the injury or refer you for appropriate treatment. Costs for medical care that you might incur for injuries or illnesses that are not a direct result of research activities will not be covered by the study.

WHAT ARE THE RIGHTS OF PARTICIPANTS IN A RESEARCH STUDY?

You will be told, in a timely manner, about new information that may be relevant to your willingness to stay in this study.

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You have the right to be informed of the results of this study once the entire study is complete. The results of this study will be available on the clinical trial registry (see the "Will information about this study be available online" section for more details).

Your rights to privacy are legally protected by federal and provincial laws that require safeguards to ensure that your privacy is respected.

By signing this form, you do not give up any of your legal rights against the study doctor, sponsor or involved institutions for compensation, nor does this form relieve the study doctor, sponsor or their agents of their legal and professional responsibilities.

You will be given a copy of this signed and dated consent form prior to participating in this study.

WHAT IF RESEARCHERS DISCOVER SOMETHING ABOUT A RESEARCH PARTICIPANT?

During the study, the researchers may learn something about you that they didn't expect. For example, the researchers may find out that you have another medical condition that was not previously diagnosed. If any new clinically important information about your health is obtained as a result of your participation in this study, it may be shared with your family doctor at your discretion. Should a new medical condition be identified that requires treatment, your care will be directed by study doctors. See the "What else do I need to know about the study intervention?" section for more details.

WHOM DO PARTICIPANTS CONTACT FOR QUESTIONS?

If you have questions about taking part in this study, or if you suffer a research-related injury, you can talk to your study doctor, or the doctor who is in charge of the study at this institution. That person is:

Dr. X XXX XXX XXXX ext XXXXX

If you have questions about your rights as a participant or about ethical issues related to this study, you can talk to someone who is not involved in the study at all. That person is:

Name	Telephone
Office of the Chair of the X Integrated Research Ethics Board	XXX-XXX-XXXX ext. XXXXX

SIGNATURES

- All of my questions have been answered,
- I understand the information within this informed consent form,
- I allow access to medical records and related personal health information as explained in this consent form,

- I do not give up any legal rights by signing this consent form,
- I understand that my family doctor/health care provider may be informed of study participation
- I agree to take part in this study.

Signature of Participant	PRINTED NAME	Date/Time
Signature of Person Conducting the Consent Discussion	PRINTED NAME & ROLE	Date/Time

OR

Verbal Consent obtained	PARTICIPANT'S PRINTED NAME	Date/Time
Signature of Person who obtained verbal consent	PRINTED NAME & ROLE	Date/Time

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APPENDIX 1B. RAM technology components, validation, testing, and security features, and nurse and physician training to use this technology

The Cloud DX Connected Health Kit supports virtual care through remote vital sign monitoring, patient surveys, and configurable notifications. The kit contains an Android tablet pre-programmed with the companion application, blood pressure monitor, thermometer, pulse oximeter, and weight scale. The cellular tablet comes with a data plan to support all communications and data transfer required for the duration of the trial.

The Cloud DX platform includes the Clinician Portal, a secure online dashboard for patient monitoring and management. Within the dashboard the nurses and physicians see vital sign metrics, patient survey responses and measures of care plan compliance. Two-way communication via secure text messaging and video enables feedback loops to patients (e.g. reminder notifications) that facilitate intervention adherence. Notifications such as vital signs triggers are highlighted to allow for easy triage of large patient groups. Multiple dashboard reports (vital signs, survey results) can be exported via PDF or (in a full integration) via the application interface and downloaded into a hospital or clinic electronic medical record. For the duration of the trial, patient data were housed on Microsoft Azure cloud computing infrastructure and will be downloaded to secure data holdings at the Population Health Research Institute.

User testing data support ease of use of the Connected Health Kit by seniors without prior experience with computers. In an e-clinic pilot usability study conducted at Dalhousie Medicine New Brunswick, ten healthy participants (67±6 years) consented to a 6-month qualitative assessment of the Cloud DX Pulsewave vital sign device with a Physician-Portal™ and a Medeo™ video conferencing platform. Despite citing concerns over a lack of computer

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experience, all participants stated the Pulsewave® vital sign device was easy-to-use, and all could readily connect with the secure web portal and take their vital signs reading.[1]

The vital sign monitors included in the Connected Health Kit are licensed by Health Canada and cleared for accuracy by the United States (US) Food and Drug Administration. The devices are International Standards Organization certified (#13485:2016) for Quality Management and are compliant with US and Canada privacy requirements. Personal health data is encrypted and stored in Canada, within the Microsoft Azure cloud.

Trial nurses and perioperative physicians received standardized training in virtual care pertaining to their respective clinical roles as well as the Connected Health Kit remote automated monitoring (RAM) technology and clinician dashboard interface. Nurses received 1.5 days of training on virtual care clinical protocols and RAM technology. Virtual care training focused on the daily/weekly routines for patient video visits, including: head-to-toe postoperative patient assessment, vital signs interpretation and care escalation triggers, ongoing patient monitoring protocols, interpretation of daily patient symptom surveys, daily wound monitoring and photography, and medication reconciliation. RAM technology training covered the following: set up and enablement of Bluetooth connection between vital signs monitors and the tablet computer; patient training on vital signs monitors and related trouble shooting; RAM technology care and handling, and navigation and use of the clinician dashboard interface and software for clinical documentation; review of patient vital signs and information; and clinical communication features (e.g., nurse-physician real time video consultations).

Clinical training for physicians included standardized postoperative review of patient systems, drug reconciliation, and diagnosis and management of potential postoperative symptoms and complications. Physicians were also trained in standardized procedures for daily

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virtual clinical rounds with trial nurses (at their respective hospital sites), as well as video consultations for direct medical management of patients. Physicians received similar training to nurses with respect to the RAM technology clinician dashboard interface and software.

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APPENDIX 1C. Biophysical measurements and recovery survey

Based on a schedule developed by a virtual nurse, the tablet prompts patients to measure their biophysical parameters. The frequency of daily biophysical measurements is 3 times a day for the first 15 days, and then twice a day from day 16 until 30 days after randomization. Weight is measured daily in the morning before breakfast. Measurement of biophysical parameters can be adjusted according to a patient's acuity and tolerance, based on the virtual nurse's judgement or directions from a physician. Patients record at least one full set of biophysical parameters each day of the study. The tablet prompts patients daily to complete the recovery survey. The recovery survey consists of questions related to infection, bleeding, pain, dehydration, ileus, and cardiovascular and respiratory complications.

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APPENDIX 1D. Example of vital sign thresholds and nurse and physician actions

Systolic blood pressure measurement	Flag to nurse	Nurse action	Physician action
110-115 mm Hg	Mild	Nurse to contact and assess patient during scheduled video call. Advise patient to re-check measurement. Nurse to update perioperative care physician, at daily rounds.	Rule out precipitating factors (e.g. sepsis, volume depletion, bleeding, heart failure). Review medication and fluid intake. Decrease blood pressure medication dosage accordingly. Order back to virtual nurse and coordinate follow up with virtual nurse. Reassess in 24 hours.
86-99 mm Hg	Medium	Nurse to contact and assess patient within 30 minutes. Advise patient to re-check measurement. If unresolved, nurse will inform perioperative care physician within 1 hour	All of the above and the following. Withhold anti-hypertensives till SBP >100 mmHg if patient with no HFrEF. Assess volume status. Order back to virtual nurse and coordinate follow up. Reassess in 4-6 hours
<85 mm Hg	High	Contact and assist patient immediately. Advise patient to re-check measurement. If unresolved, nurse will inform perioperative care physician within 15 minutes	Assess patient for symptoms If patient is asymptomatic then all of the above and the following. Withhold anti-hypertensives. Consider video call with patient. Consider clinic assessment. Order back to virtual nurse and coordinate follow up

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	If patient is symptomatic then all of the above and consider emergency room assessment.

mmHg - millimeters of mercury; HFrEF – heart failure reduced ejection fraction; SBP – systolic blood pressure.

APPENDIX 1E. Rationale for changing the primary outcome

The initial primary outcome was acute-hospital care. One of the first patients randomized to the virtual care group was an elderly male who was detected to have significant bradycardia based on his RAM data, on day 2 post randomization. When the virtual nurse attempted to contact the patient, the patient's wife answered and indicated that the patient had told her that he was exhausted and wanted to be left alone to sleep all day. The virtual nurse escalated care to the perioperative physician who contacted the wife and insisted on talking to the patient. Upon interacting with the patient, the perioperative care physician recognized the patient had a decreased level of consciousness and facilitated having an ambulance bring the patient to the hospital. The patient was brought to the hospital and was found to be in complete heart block and received an emergency pacemaker. This case made us recognize that our detection and management of this patient resulted in an acute-hospital care event. In contrast, if a similar patient in the control group died at home, this would create a competing outcomes problem in that this patient would not meet the primary outcome. We therefore decided to change the primary outcome to days alive at home to avoid the potential competing outcomes problem that this case identified was possible.

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APPENDIX 1F. Tertiary outcomes

Tertiary outcomes during the first 30 days after randomization include: 1. health services utilization-related costs; 2. patient-level cost of recovery; 3. re-operation; 4. arrhythmia resulting in electrical cardioversion; 5. acute renal failure resulting in dialysis; 6. respiratory failure; 7. infection; 8. surgical site infection; 9. life-threatening, major, or critical-organ bleeding; 10. ileus; 11. myocardial infarction; 12. clinically important atrial fibrillation; 13. symptomatic proximal venous thrombo-embolism; 14. stroke; 15. non-fatal cardiac arrest; 16. clostridium difficile-associated diarrhea; 17. indwelling device inappropriately left in a patient; 18. COVID-19 infection; 19. delirium; 20. surgeon, family physician, or specialist in-person clinic visit; 21. surgeon, family physician, or specialist virtual clinic visit; 22. sepsis; and 23. acute heart failure. Additional tertiary outcome during the first 6 months after randomization include: 1. the secondary outcomes; 2. COVID-19 infection; 3. surgeon, family physician, or specialist in-person clinic visit; and 4. surgeon, family physician, or specialist virtual clinic visit.

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APPENDIX 1G. Outcome definitions

Outcome	Definition
Days alive at home[1]	Days alive at home are the number of days patients spend at their usual residence – be it a house or apartment, a group home or shelter, a seniors' residence, or a nursing home – or at a community residence of a relative, friend, or acquaintance without, during that day, being admitted to a hospital or visiting an emergency department or urgent-care centre. Thus, patients lose days alive at home if 1. patients go to an emergency department or urgent-care centre; 2. they become inpatients at a hospital or rehabilitation or convalescence-care facility; or 3. they die. More specifically, our approach to calculating days alive at home follows. If a patient visits an emergency department or urgent-care centre anytime between midnight and 23:59 on a given day, they will lose that day as a day alive at home. If a patient visits an emergency department or urgent-care centre anytime between midnight and 23:59 on a given day and they remain in the emergency department or urgent-care centre past midnight into the next day, then they lose 2 day alive at home. If a patient is admitted to the hospital or rehabilitation or convalescence-care facility anytime between midnight and 23:59 on a given day, they will lose that day as a day alive at home. They will continue to lose days alive at home until the day in which they are home and out of an acute-hospital care or a rehabilitation or convalescence-care facility from midnight for an entire day. Patients randomized before hospital discharge do not lose this day alive at home unless after their discharge they die or visit an emergency department or urgent-care centre on the day of their discharge. Patients randomized before hospital discharge will lose this day alive at home if their discharge is ultimately delayed and they do not go home on their day of randomization. Because patients are followed until day 30 after randomization and the day of randomization is day 0, if a patient is discharged home after randomization and remains at home until death on day 2 after randomization (i.e., they survived at home on the day of randomization and day 1 after randomization, but died on the subsequent day) they would be counted as having had 2 day alive at home, and lose 29 of the possible 31 days alive at home.
Hospital re-admission[2]	Patient admission to an acute-care hospital.
Emergency department visit[2]	Patient visit to an emergency department.

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Urgent-care centre visit[2]	Patient visit to an urgent-care centre.
Acute-hospital care[2]	Acute-hospital care is a composite outcome of hospital re-admission and emergency department or urgent-care centre visit
Brief acute-hospital care[2]	Acute-hospital care that last <24 hours from the time of arrival to the time of discharge home.
All-cause hospital days[2]	If a patient is admitted to the hospital for any reason anytime between midnight and 23:59 on a given day, this will count as a day in hospital. Study personnel will determine the total number of days in the hospital for any reason. Patients randomized before hospital discharge do not have this day counted as a hospital day unless after their discharge they are re-admitted to the hospital on the day of their discharge. Patients randomized before hospital discharge will have this day counted as a hospital day if their discharge is ultimately delayed and they do not go home on their day of randomization.
Medication error detection[2]	Medication errors include mistakes in medication prescribing, transcribing, dispensing, administering, or monitoring due to preventable events or actions taken by a patient, caregiver, or healthcare worker. Medication errors include: drug omission (i.e., patient did not take a drug they were supposed to take), drug commission (i.e., patient taking a drug they were not supposed to take), duration error, dosing error, frequency error, route error, and timing error. We will record all drug errors identified and also report whether they resulted in harm. We will use the following definitions for harm: 1. no harm – error that does not cause any clinically appreciable harm to the patient; 2. minor harm – error that leads to event resulting in minor treatment or extra monitoring to ensure significant harm is avoided (e.g., mild symptoms or minimal loss of function; one day of symptoms; laboratory abnormality not requiring emergency department or urgent-care centre visit); 3. moderate harm – error that leads to event requiring treatment or extra monitoring and causes temporary but not permanent harm (e.g., laboratory abnormality, symptoms, or condition requiring emergency department or urgent-care centre visit); 4. severe harm – error that leads to event that requires treatment or extra monitoring and results in significant or permanent harm (e.g., permanent disability or loss of function; near-death event [e.g., anaphylaxis, cardiac arrest]; serious laboratory abnormality, symptom, or condition requiring intervention to sustain life or leading to prolonged hospitalization); and 5. death – error leading to loss of life.
Medication error correction[2]	Any medication error that is corrected.

Death[3]	The definition of death is all cause mortality.
Pain[4]	Study personnel will collect pain data through administration of the Brief Pain Inventory Short Form (BPI-SF), which captures pain intensity as well as pain-related interference with daily activity related to their surgery. The BPI-SF includes four 11-point numeric rating scales (NRS) of pain intensity, which measure "average", "least", and "worst" pain intensity in the past 24 hours (hrs.), respectively, as well as pain intensity "now" (0= no pain, 10= pain as bad as you can imagine). The BPI-SF interference subscale will also be used, which measures the degree to which pain interferes with general activity, mood, walking, work, relations with others, sleep, and enjoyment of life (NRS for each item; 0=does not interfere, 10=completely interferes). A total interference score is determined by calculating the sum of these 7 items. The BPI-SF has strong psychometric properties with well-established reliability and validity across divergent surgical groups.
Re-operation[2]	Re-operation refers to any surgical procedure undertaken for any reason (e.g., wound dehiscence, infection)
Arrhythmia resulting in electrical cardioversion	Any arrhythmia that leads to electrical cardioversion.
Acute renal failure resulting in dialysis[5]	This outcome is defined as acute renal failure that results in dialysis (i.e., use of hemodialysis machine or peritoneal dialysis apparatus) in a patient who was not on chronic dialysis before randomization.
Respiratory failure[2]	Patient intubated or put on bilevel positive airway pressure (BiPAP).
Infection[3]	Infection is defined as a pathologic process caused by the invasion of normally sterile tissue, fluid, or body cavity by pathogenic or potentially pathogenic organisms.
Surgical site infection[2]	Surgical site infection is an infection that occurs within 30 days after surgery and involves the skin, subcutaneous tissue of the incision (superficial incisional), or the deep soft tissue (e.g., fascia, muscle) of the incision (deep incisional).
Life-threatening bleeding[6]	Life-threatening bleeding is bleeding that is fatal, or leads to: significant hypotension that requires inotrope or vasopressor therapy, urgent (within 24 hours) surgery (other than superficial vascular repair), or intracranial hemorrhage.

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Major bleeding[7]	Major bleeding is defined as bleeding that is not specified under "life-threatening bleeding" and results in at least one of the following: 1. a postoperative hemoglobin ≤ 70 g/L; 2. a transfusion of ≥1 unit of red blood cells; or 3. leads to one of the following interventions: embolization, superficial vascular repair, nasal packing.
Critical-organ bleeding[8]	Critical-organ bleeding is bleeding that is intracranial, intraocular, intraspinal, pericardial, retroperitoneal, or intramuscular with compartment syndrome.
Ileus[9]	Ileus is a physician diagnosis of functional obstruction of the gastrointestinal tract in the absence of an alternative diagnosis that leads to postoperative decreased bowel activity. The definition requires the following criteria: 1. inability to pass flatus or stool for >24 hours; and 2. persistence of one or more of the following signs and symptoms for >24 hours: abdominal distention; diffuse abdominal pain; or nausea or vomiting.
Myocardial infarction[10]	The diagnosis of myocardial infarction requires one of the following criteria: 1. Detection of a rise or fall of a cardiac biomarker (preferably troponin) with at least one value above the 99th percentile of the upper reference limit (URL) together with evidence of myocardial ischemia with at least one of the following: A. ischemic signs or symptoms (i.e., chest, arm, neck, or jaw discomfort; shortness of breath, pulmonary edema); B. development of pathologic Q waves present in any two contiguous leads that are ≥ 30 milliseconds; C. new or presumed ECG changes indicative of ischemia (i.e., ST segment elevation [≥ 2 mm in leads V_1, V_2, or V_3 OR ≥ 1 mm in the other leads], ST segment depression [≥ 1 mm], or symmetric inversion of T waves ≥ 1 mm) in at least two contiguous leads; D. new LBBB; or E. new cardiac wall motion abnormality on echocardiography or new fixed defect on radionuclide imaging F. identification of intracoronary thrombus on angiography or autopsy 2. Cardiac death, with symptoms suggestive of myocardial ischemia and presumed new ischemic ECG changes or new LBBB, but death occurred before cardiac biomarkers were obtained, or before cardiac biomarker values would be increased. 3. Percutaneous coronary intervention (PCI) related myocardial infarction is defined by elevation of a troponin value (>5 x 99th percentile URL) in patients with a normal baseline troponin value (≤99th percentile URL) or a rise of a troponin measurement >20% if the baseline values are elevated and are stable or falling. In addition, either (i) symptoms suggestive of

	myocardial ischemia or (ii) new ischemic ECG changes or (iii) angiographic findings consistent with a procedural complication or (iv) imaging demonstration of new loss of viable myocardium or new regional wall motion abnormality are required. 4. Stent thrombosis associated with myocardial infarction when detected by coronary angiography or autopsy in the setting of myocardial ischemia and with a rise and/or fall of cardiac biomarker values with at least one of value above the 99th percentile URL. 5. Coronary artery bypass grafting (CABG) related myocardial infarction is defined by elevation of cardiac biomarker values (>10 x 99th percentile URL) in patients with a normal baseline troponin value (≤99th percentile URL). In addition, either (i) new pathological Q waves or new LBBB, or (ii) angiographic findings consistent with a procedural flow-limiting complication such as coronary dissection, occlusion of a major epicardial artery or graft, side-branch occlusion-thrombus, disruption of collateral flow or distal embolization, or (iii) imaging evidence of new loss of viable myocardium or new regional wall motion abnormality. 6. For patients who are believed to have suffered a myocardial infarction within 28 days of a MINS event or within 28 days of a prior myocardial infarction, the following criterion for myocardial infarction is required: Detection of a rise or fall of a cardiac biomarker (preferably troponin) with at least one value above the 99th percentile of the upper reference limit (URL) and 20% higher than the last troponin measurement related to the preceding event together with evidence of myocardial ischemia with at least one of the following: A. ischemic signs or symptoms (i.e., chest, arm, neck, or jaw discomfort; shortness of breath, pulmonary edema); B. development of pathologic Q waves present in any two contiguous leads that are $\geq$ 30 milliseconds; C. new or presumed new ECG changes indicative of ischemia (i.e., ST segment elevation [$\geq$ 2 mm in leads V_1, V_2, or V_3 OR $\geq$ 1 mm in the other leads], ST segment depression [$\geq$ 1 mm], or symmetric inversion of T waves $\geq$ 1 mm) in at least two contiguous leads; D. new LBBB; or E. new cardiac wall motion abnormality on echocardiography or new fixed defect on radionuclide imaging F. identification of intracoronary thrombus on angiography or autopsy
Clinically important atrial fibrillation[3]	The definition of clinically important atrial fibrillation requires the documentation of atrial fibrillation or atrial flutter on a 12 lead electrocardiogram, or confirmed atrial fibrillation or atrial flutter (e.g., rhythm strip) that results in angina, congestive heart failure, symptomatic

	hypotension, or requires treatment with a rate controlling drug, antiarrhythmic drug, or electrical cardioversion.
Symptomatic proximal venous thrombo-embolism[8]	Venous thromboembolism that includes symptomatic pulmonary embolism or symptomatic proximal deep vein thrombosis.
Symptomatic pulmonary embolism[8]	The diagnosis of symptomatic pulmonary embolism requires symptoms (e.g., dyspnea, pleuritic chest pain) and any one of the following: 1. A high probability ventilation/perfusion lung scan; 2. An intraluminal filling defect of segmental or larger artery on a helical CT scan; 3. An intraluminal filling defect on pulmonary angiography; or 4. A positive diagnostic test for DVT (e.g., positive compression ultrasound) and one of the following: A. non-diagnostic (i.e., low or intermediate probability) ventilation/perfusion lung scan, or B. non-diagnostic (i.e., subsegmental defects or technically inadequate study) helical CT scan
Symptomatic proximal deep venous thrombosis[8]	The diagnosis of symptomatic proximal deep venous thrombosis (DVT) requires: 1. symptoms or signs that suggest DVT (e.g., leg pain or swelling), 2. thrombosis involving the popliteal vein or more proximal veins for leg DVT OR axillary or more proximal veins for arm DVTs Any of the following defines evidence of vein thrombosis: A. a persistent intraluminal filling defect on contrast venography (including on computed tomography); B. noncompressibility of one or more venous segments on B mode compression ultrasonography; or C. a clearly defined intraluminal filling defect on doppler imaging in a vein that cannot have compressibility assessed (e.g., iliac, inferior vena cava, subclavian).
Stroke[9]	Stroke is defined as either: 1. a new focal neurological deficit thought to be vascular in origin with signs or symptoms lasting ≥24 hours or leading to death; or 2. a new focal neurological deficit thought to be vascular in origin with signs or symptoms lasting <24 hours with positive neuroimaging consistent with a stroke.
Non-fatal cardiac arrest[6]	Non-fatal cardiac arrest is defined as successful resuscitation from either documented or presumed ventricular fibrillation, sustained ventricular tachycardia, asystole, or pulseless electrical activity requiring cardiopulmonary resuscitation, pharmacological therapy, or cardiac defibrillation.

Clostridium difficile-associated diarrhea[8]	This outcome requires diarrhea as a symptom with laboratory documentation of Clostridium difficile.
Indwelling device inappropriately left in a patient	An indwelling device (e.g., drain, catheter, pacemaker wire) inappropriately left in patient is defined as an indwelling device inappropriately being left in a bodily organ or passage longer than it was intended.
COVID-19 infection[11]	For COVID-19 infection, we will accept any laboratory confirmed evidence of COVID-19 infection.
Delirium[12,13]	For the diagnosis of delirium within 30 days after randomization, any one of the following criteria is required: 1. Patient meets the criteria for ongoing delirium on day 31 at the in-person or telephone 3D-CAM administered on day 31; OR 2. Patient is unable to complete the telephone interview on day 31 because they are too confused. This criterion is significant for an acute decline in their cognition when patients are able to complete telephone interviews at baseline, which is consistent with one of our eligibility criteria; OR 3. Positive history of delirium in the 30 days after randomization as assessed through a telephone interview with a family member/caregiver using the FAM-CAM on day 31; OR 4. Positive history of delirium in the 30 days after randomization based on the review of electronic hospital health records
Surgeon, family physician, or specialist in-person clinic visit	Patient in-person visit to a surgeon's, family physician's, or specialist's clinic.
Surgeon, family physician, or specialist virtual clinic visit	Patient has a virtual clinical visit with a surgeon, family physician, or specialist.
Sepsis[14]	Our definition of sepsis is based on the Third International Consensus Definitions for Sepsis and Septic Shock (Sepsis-3). Sepsis requires a quick Sequential Organ Failure Assessment (qSOFA) Score ≥2 points due to infection. The qSOFA includes the following items and scoring system: 1. altered mental status (1 point); 2. systolic blood pressure ≤100 mm Hg (1 point); and 3. respiratory rate ≥22 breaths per minute (1 point).

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Acute heart failure[3]	The definition of acute heart failure requires at least one of the following clinical signs (i.e., elevated jugular venous pressure, respiratory rales or crackles, crepitations, or presence of S3) with at least one of the following: 1. radiographic findings of vascular redistribution, interstitial pulmonary edema, or frank alveolar pulmonary edema, OR 2. heart failure treatment with a diuretic and documented clinical improvement.

[1]Myles PS, Shulman MA, Heritier S, Wallace S, McIlroy DR, McCluskey S, Sillar I, Forbes A. Validation of days at home as an outcome measure after surgery: a prospective cohort study in Australia. BMJ Open. 2017;7:e015828.
[2] McGillion M, Yost J, Turner A, Bender D, Scott T, Carroll S, et al. Technology-Enabled Remote Monitoring and Self-Management — Vision for Patient Empowerment Following Cardiac and Vascular Surgery: User Testing and Randomized Controlled Trial Protocol. JMIR Res Protoc 2016;5(3):e149
[3]Vascular Events in Noncardiac Surgery Patients Cohort Evaluation (VISION) Study Investigators, Spence J, LeManach Y, Chan MTV, Wang CY, Sigamani A, et al. Association between complications and death within 30 days after noncardiac surgery. CMAJ. 2019;191(30):E830-E837.
[4]Cleeland CS, Ryan KM. Pain assessment: global use of the Brief Pain Inventory. Ann Acad Med Singapore 1994;23:129-38.
[5]HIP ATTACK Investigators. Accelerated surgery versus standard care in hip fracture (HIP ATTACK): an international, randomised, controlled trial. Lancet. 2020;395(10225):698-708
[6]Devereaux PJ, Mrkobrada M, Sessler DI, Leslie K, Alonso-Coello P, Kurz A, et al. Aspirin in Patients Undergoing Noncardiac Surgery. NEJM. 2014;370(16):1494-503.
[7]Roshanov PS, Eikelboom JW, Sessler DI, Kearon C, Guyatt GH, Crowther M, et al. Bleeding Independently Associated with Mortality after Noncardiac Surgery (BIMS): an International Prospective Cohort Study Establishing Diagnostic Criteria and Prognostic Importance. British J Anaesth. 2020;S0007-0912(20):30536-5.
[8]Devereaux PJ, Duceppe E, Guyatt G, Tandon V, Rodseth R, Biccard BM. Dabigatran in patients with myocardial injury after non-cardiac surgery (MANAGE): an international, randomised, placebo-controlled trial. Lancet. 2018:391:2325-34.
[9]Borges FK, Nenshi R, Devereaux PJ. Fast track pathway to accelerated cholecystectomy versus standard of care for acute cholecustitis (FAST) Pilot trial protocol. Forthcoming 2021.
[10]Thygesen K, Alpert JS, Jaffe AS, Simoons ML, Chaitman BR, White HD, the Writing Group on behalf of the Joint ESC/ACCF/AHA/WHF Task Force for the Universal Definition of Myocardial Infarction. Third Universal Definition of Myocardial Infarction. Eur Heart J. 2012;33(20):2251-67.
[11]Ontario Ministry of Health and Long-Term Care [Internet]. Toronto: The Government of Ontario; c2020 [cited 2020 Dec 21]. Case Definition – Coronavirus Disease (COVID-19). Available from: http://www.health.gov.on.ca/en/pro/programs/publichealth/coronavirus/docs/2019_case_definition.pdf
[12]Marcantonio ER, Ngo LH, O'Connor M, Jones RN, Crane PK, Metzger ED, Inouye SK. 3D-CAM: derivation and validation of a 3-minute diagnostic interview for CAM-defined delirium: a cross-sectional diagnostic test study. Ann Intern Med. 2014;161(8):554-61.
[13]Mailhot T, Darling C, Ela J, Malyuta Y, Inouye SK, Saczynski J. Family Identification of Delirium in the Emergency Department in Patients With and Without Dementia: Validity of the Family Confusion Assessment Method (FAM-CAM). J Am Geriatr Soc. 2020;68(5):983-990.
[14]Singer M, Deutschman CS, Seymour CW, Shankar-Hari M, Annane D, Bauer M, et al. The Third International Consensus Definitions for Sepsis and Septic Shock (Sepsis-3). JAMA. 2016;315(8):801-10.

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APPENDIX 1H. Follow-up process

Study personnel will contact all study patients in both treatment groups at 31 days and 6 months after randomization and collect data on the following outcomes: 1. days alive at home; 2. hospital re-admission; 3. emergency department visit; 4. urgent-care centre visit; 5. all-cause hospital days; 6. delirium; 7. sepsis; 8. acute heart failure; 9. death; 10. patient-level cost of recovery; 11. arrhythmia resulting in electrical cardioversion; 12. acute renal failure resulting in dialysis; 13. respiratory failure; 14. infection; 15. surgical site infection; 16. life-threatening, major, or critical-organ bleeding; 17. ileus; 18. myocardial infarction; 19. clinically important atrial fibrillation; 20. symptomatic proximal venous thrombo-embolism; 21. stroke; 22. non-fatal cardiac arrest; 23. clostridium difficile-associated diarrhea; and 24. indwelling device inappropriately left in patient. Study personnel will also collect pain data through the Brief Pain Inventory-Short Form (BPI-SF) in all study patients in both treatment groups at 6 months after randomization.

Study personnel will contact patients in the standard-care group and collect data on the following outcomes: 1. BPI-SF on days 7, 15, and 30; and 2. medication error detection and medication error corrections on day 31 after randomization. For patients in the virtual care and RAM group, virtual nurses will collect data on the following outcomes: 1. the BPI-SF on days 7, 15, and 30 after randomization; and 2. medication error detection and medication error corrections on days 1, 8, 15, 22, and 30 after randomization. Through the Institute for Clinical Evaluative Sciences (ICES) and the Canadian Institute of Health Information (CIHI), we will collect data on the following outcomes up to 6 months after randomization: 1. acute-hospital care; 2. COVID-19 infection; 3. re-operation; 4. surgeon, family physician, or specialist clinic visit; and 5. health services utilization-related costs.

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REFERENCES

1. Ouellete N, Melville S, Brunt KR, Lutchmedial S. Qualitative assessment of a non-invasive vital sign monitor with secure home-based video conferencing, patient engagement platform: The e-Clinic Pilot Study. . 7th Annual New Brunswick Health Research Conference. Saint John, New Brunswick2015.

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