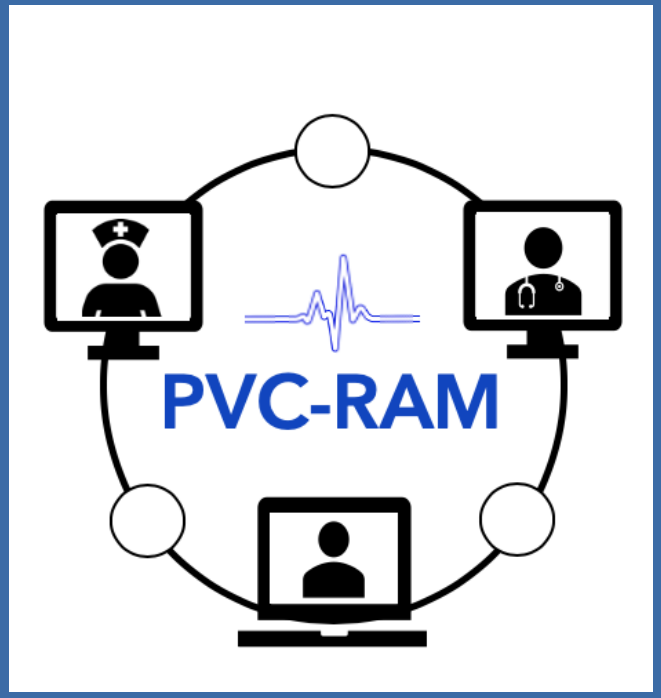

Post discharge after surgery Virtual Care with Remote Automated Monitoring technology (PVC-RAM) Trial

Co-Principal Investigators: Drs. PJ Devereaux and Michael McGillion

Population Health Research Institute
HEALTH THROUGH KNOWLEDGE

Hamilton Health Sciences

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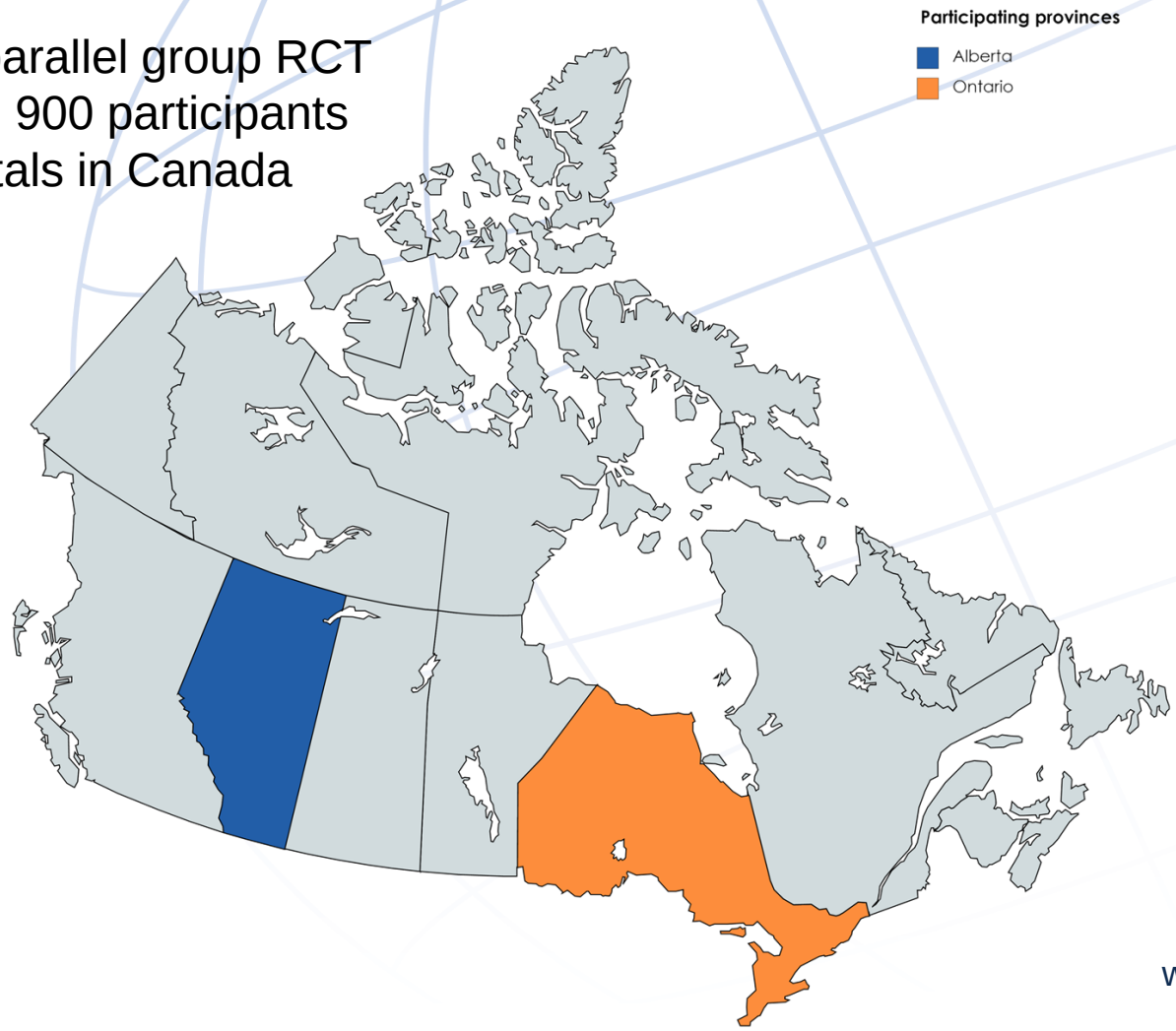
HEALTH SCIENCES

Background

- During the COVID-19 pandemic physicians are discharging all eligible patients and hospitals are cancelling elective surgeries to maximize bed availability, facilitate physical distancing, and reduce risk of COVID-19 transmission.
- Need remains for inpatient semi-urgent, urgent and emergency surgery.
- After hospital discharge post surgery, patients typically see a physician only after 2-4 weeks. These timelines may be longer during the COVID-19 pandemic and limited follow-up can result in delays in recognizing and managing complications.
- Patients discharged after non-elective surgeries are at substantial risk, in the 30 days following surgery, of hospital re-admission, presentation to emergency departments or urgent-care centres and death.
- Early identification and management of these complications has the potential to increase patient days alive and at home.

Trial Design

- Multicentre parallel group RCT
- Sample size: 900 participants
  - 8 hospitals in Canada



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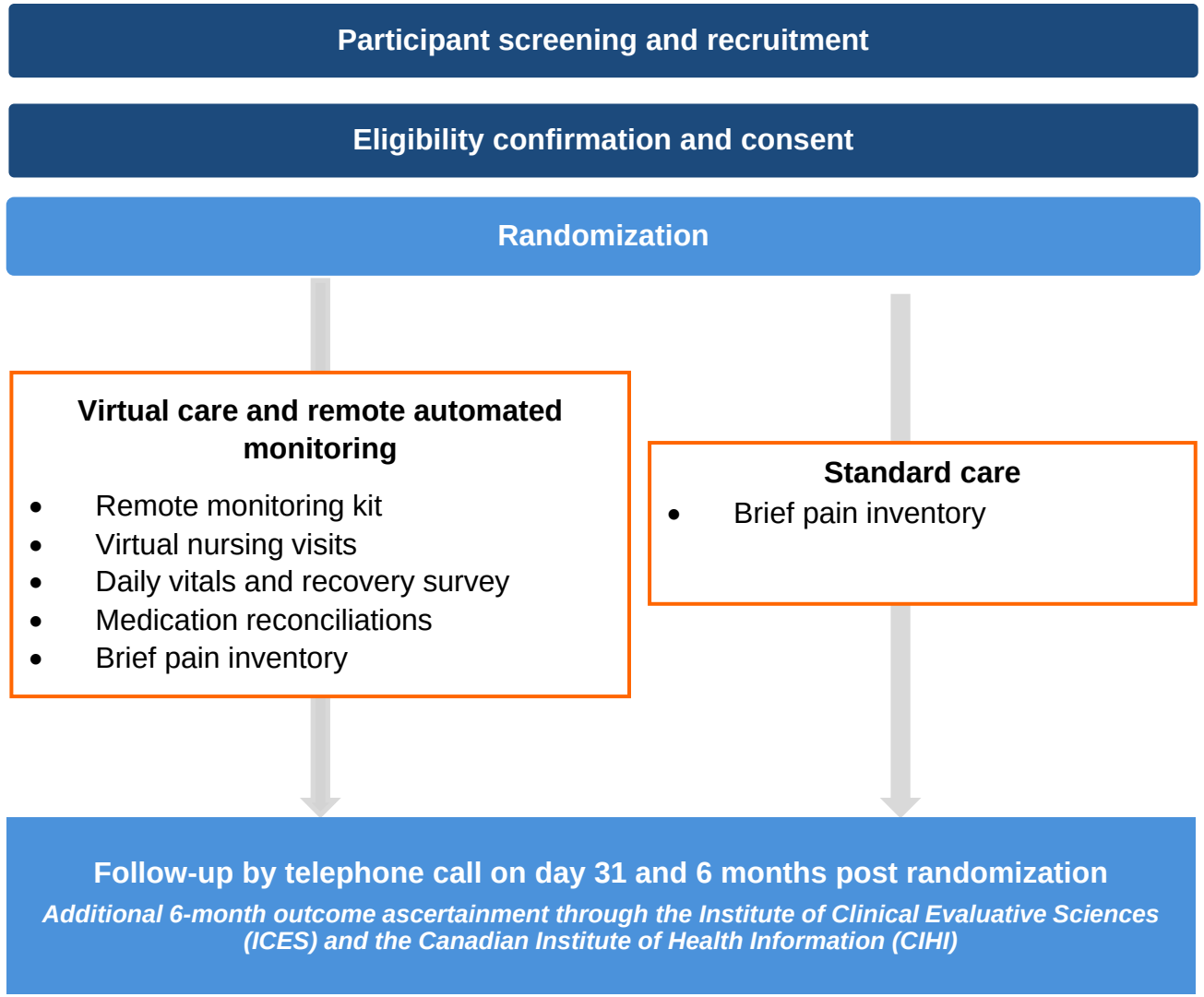
Intervention



Intervention

- Tablet computer and RAM technology
  - CloudDX Connected Health kit
- Biophysical measurements:
  - Blood pressure
  - Heart rate
  - Respiratory rate
  - SpO_2
  - Temperature
  - Weight
- Virtual video visits via cellular enabled tablet

Patient Population

Inclusion Criteria

1. Are ≥40 years of age
2. Have undergone same-day or inpatient semi-urgent, urgent, or emergency surgery and are being discharged home or are within 24 hours after discharge home, as long as they have not had acute-hospital care since their discharge
3. Provide informed consent to participate.

Exclusion Criteria

1. Underwent same-day surgery and the surgeon or anesthesiologist believes the case reflects a traditional same-day surgery case with a low likelihood of needing acute-hospital care
2. Went to rehabilitation or convalescent care for more than 7 days after undergoing surgery
3. 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
4. Reside in an area without cellular network coverage and no home wi-fi.

Outcomes

Primary Outcome

To determine, in adults being discharged after undergoing non-elective surgery, the effect of virtual care with RAM technology compared to standard care on days alive at home during the first 30 days after randomization.

Secondary Outcomes

- To determine, during the first 30 days after randomization, the effect of virtual care with RAM technology on the following secondary outcomes: 1. hospital re-admission; 2. emergency department visit; 3. urgent-care centre visit; 4. acute-hospital care (i.e., a composite of hospital re-admission and emergency department or urgent-care centre visit); 5. brief acute-hospital care (i.e., acute-hospital care that lasts <24 hours); 6. all-cause hospital days; 7. medication error detection; 8. medication error correction; and 9. death. An additional secondary objective is to determine the effect of virtual care with RAM technology on pain at 7, 15, and 30 days and 6 months after randomization, measured via the Brief Pain Inventory-Short Form.

Follow-up

Screening and recruitment

- Eligibility assessment
- Informed consent

Randomization and Baseline

- Demographics, medical history, medications and surgery details
- Baseline vitals and laboratory assessments

Hospital Discharge

- Discharge location
- CloudDX connected health kit delivered in hospital or via courier post-discharge (intervention arm only)

Follow-up

31 Day Follow-up

- Events since randomization
- Delirium assessment
- Ambulatory home care record

- **Virtual care and remote automated monitoring**
  - Virtual nursing visits days 1-15, and every other day on days 16-30
  - Daily vitals and health surveys
  - Brief pain inventory days 7,15,30
  - Medication reconciliation days 1, 8, 15, 22, 30 after randomization
  - Event escalations
  - Intervention compliance

- **Standard care**
  - Brief pain inventory days 7,15, 30
  - Medication reconciliation day 31

6 Month Follow-up

- Events since 31 day follow up
- Brief Pain Inventory