PVC-RAM-2

Post discharge after surgery Virtual Care with Remote Automated Monitoring technology 2 Trial

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ACT Network: Perioperative care

RFA 3 – Canadian Biotech/RCTs

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Evaluating Canadian Biotech with RCTs

- Company: Cloud DX
- Device: Connected Health™ Kit
- Therapeutic area: VC-RAM

Background

- Global increase in the burden of surgery, push to shorten hospital stays, free up beds to deal with backlogs
- PVC-RAM-2
  - Iterative approach grounded in empirical evidence from prior research

	PVC-RAM-1	PVC-RAM-3	PVC-RAM-2
Study Population	Semi-Urgent Urgent Emergent 40 years or older	Elective, non-cardiac 18 years or older	Semi-Urgent Urgent Emergent 40 years or older
Study Size	905 participants	2500 participants	2000 participants
Primary Objective	Days alive at home	Length of index hospital stay	Use of acute care
Length of Intervention	30 days	14 Days	14 Days (standard) Up to 28 Days (incl. extensions)
Follow Up Period	31 days	30 Days	45 Days

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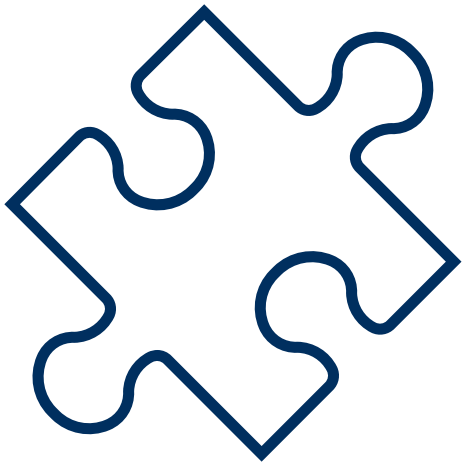
Research Question

- Among adults who have undergone semi-urgent (e.g., oncology), urgent (e.g., hip fracture), or emergency (e.g., ruptured abdominal aortic aneurysm) surgery, what is the effect of virtual care with RAM technology, compared to standard care, on acute-hospital care post-discharge following the index surgery, during the first 45 days after randomization?



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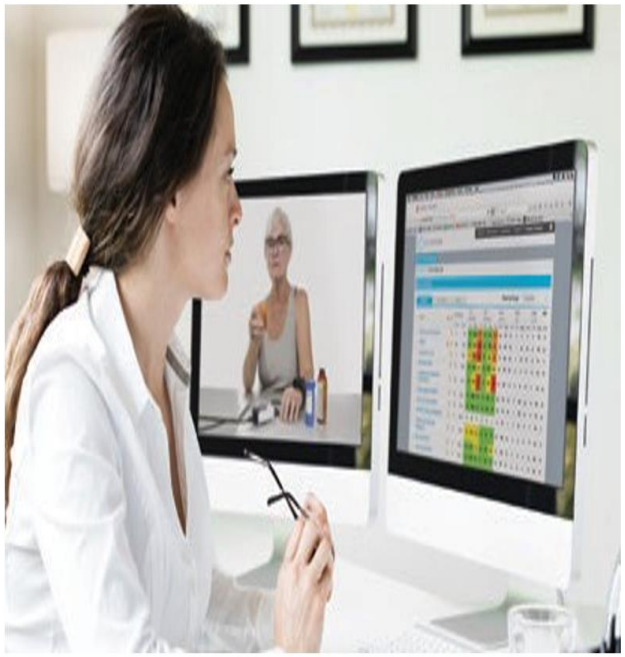
Design

THE CONNECTED HEALTH KIT

THE CLINICAL MONITORING DASHBOARD



Timelines

- **October 2024- January 2025**: Sites start up and activation
  - Train/retrain perioperative physicians and nurses
  - Obtain local ethics committees' approval
- **February 2025- February 2028**: recruit 2000 patients across 8 centers.
- **Following completion of recruitment**:
  - 45 days to complete final follow up visits
  - 3 months for data cleaning and adjudication
  - 3 months for analysis and validation of results
  - 2 months for manuscript preparation and submission, site close out activities, and preparation for results dissemination.

Updates

- Ethics approval obtained
- Trial open in 2 HHS sites
- “X” patients enrolled

Acknowledgements

- Dr PJ Devereaux, Dr M. McGillion
- The entire PVC-RAM study team, virtual nurses, co-investigators and collaborators