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Integrating Mental Health into Heart Failure Care: A Hybrid Type 1 Pretest-Posttest Feasibility Study of the FRAME Intervention

NCT #:

Principal/Qualified Investigator: Krystal Kehoe MacLeod

Contact Details: kmacleod@bruyere.org

Study Sponsor: Brain-Heart Interconnectome

Contact Details: ICC-BHI@uottawa.ca.

Study Funder: Canada First Research Excellent Fund (CFREF)

Contact Details: ICC-BHI@uottawa.ca.

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STUDY COLLABORATORS/CO-INVESTIGATORS:

Name: Vivian Welch

Title/Position: Research Scientist

Department/Institution: Bruyere Health Research Institute

Email Address: VWelch@bruyere.org

PROTOCOL SIGNATURE PAGE

I assume full responsibility for the scientific and ethical conduct of the study at my research site as described in this Protocol and supporting documentation (e.g. BREB), and agree to conduct this study in compliance with the Tri-Council Policy Statement 2: Ethical Conduct for Research Involving Humans; the International Conference on Harmonization – Good Clinical Practice: Consolidated Guideline; the provisions of the Personal Health Information Protection Act 2004, and the Food and Drug Act of Health Canada and its applicable regulations, and any other relevant regulations or guidelines endorsed by Bruyère Health, and the Bruyère Health Research Institute. I certify that all researchers and other personnel involved in this study at this institution are appropriately qualified and experienced or will undergo appropriate training and supervision to fulfill their role in this study.

☒ By checking here, I certify that I meet the requirements of a "Qualified Investigator" as defined by Health Canada.

Initial here: KKM

Principal Investigator Name (printed): Krystal Kehoe MacLeod

Principal Investigator Signature:

1. STUDY SUMMARY INFORMATION *(this section is intended to be brief and succinct)*

Study Title	*Integrating Mental Health into Heart Failure Care: A Hybrid Type 1 Pretest-Posttest Feasibility Study of the FRAME Intervention*
Study Design *(RCT, blinding, placebo, qualitative, etc.)*	This is a Hybrid Type 1 effectiveness-implementation design using a pretest–post-test mixed-methods design. The study evaluates the preliminary effectiveness of the FRAME intervention while concurrently assessing implementation processes across different healthcare settings within our pilot test sites. Quantitative data will be collected through patient surveys at two-time points (baseline and 6-month follow-up). Qualitative data will be collected through process mapping workshops with the site staff (e.g., site champion, care providers and administrative staff) either virtually or in-person following interview questions (see Appendix B) and optional semi-structured interviews with patients and caregivers. An interview guide will be developed in a later stage and will be submitted to the REB for review and approval prior to implementation, no randomization or blinding will be used.
Expected duration of Study	September 2025- December 2026
List all study locations/centres	1. Seaway Valley Community Health Centre 2. Winchester District Memorial Hospital 3. Centre de santé communautaire de l'Estrie 4. Orleans Cardiopulmonary Group 5. Carrefour santé Aline-Chrétien Health Hub Orleans 6. Équipe de sante familiale communautaire de l'Est d'Ottawa 7. United Counties Prescott and Russell Community Paramedicine Program 8. Cornwall Community Paramedicine Program 9. Montfort Hospital Emergency Department 10. University of Ottawa Heart Institute – Heart Function Clinic
Expected number of participants	Primary care settings (n = 5): Total estimated pool = 1,000 patients. Cardiac clinics (n = 3): Total estimated pool = 8,320 patients. Cardiac rehabilitation programs (n = 3): Total estimated pool = 300-600 patients. Emergency departments (n = 2): Total estimated pool = 240–480 patients
Study Objectives	**Primary Outcome Objectives**

	• Increase patient engagement in mental health conversations (with providers or loved ones) • Improve help-seeking behaviours, confidence in initiating mental health discussions, and awareness of mental health resources **Process Evaluation Objectives** • Identify implementation barriers and facilitators • Explore changes in clinical workflows related to mental health integration
Methodology	This study will use a pretest–posttest, mixed-methods design embedded within a Hybrid Type 1 implementation-effectiveness framework. Quantitative data will be collected via patient surveys administered at baseline and 6 months post-intervention to assess changes in mental health awareness, confidence, and help-seeking behaviours.The study will be conducted across 8–12 healthcare settings in Ontario, with procedures adapted to each site's operational context. **Quantitative Methods:** Surveys will be administered to patients before and after the intervention via QR code posters linking to the tool website, referrals from healthcare providers, and telephone/email recruitment methods to eligible patients from the patient roster in the site (only applicable for sites with a patient roster). Primary and secondary outcome measures will assess: • Frequency of mental health conversations • Engagement in help-seeking behaviours • Confidence discussing mental health • Awareness of mental health resources and supports in their community See Appendix A for surveys **Qualitative and Implementation Methods:**

	• 2-hour process mapping workshops with site staff pre- and post-implementation is a research method to visualize how a current clinical workflow works. Process mapping and evaluation workshops will be audio-recorded (with verbal and written consent) and focus on how mental health conversations are currently integrated into patient care and how FRAME was used during the intervention. These recordings will help identify facilitators and barriers to implementation. See Appendix B for the process mapping interview questions. • **Interviews**: Semi-structured inThis will be used as a comparison for pre- and post-intervention. The workshops with be audio-recorded and transcribed using PlayWrite. • 30-minute virtual monthly check-ins led by the research team with site champion and with site staff (if they wish to attend) during implementation phase to assess troubleshooting, facilitators and barriers of intervention. • Semi-structured interviews with a subset of patient and caregivers (n=12=15) post-intervention to explore their experiences with FRAME and its perceived impact (see Appendix B for interview guides). Note that interview guides are currently under development and will be submitted to the REB for review and approval prior to use. • Tool uptake tracking through QR code scans and digital metrics (e.g., website trafficking) Primary Endpoint: Change in the proportion of patients who report having mental health conversations with a healthcare provider or loved one in the past 6 months. Secondary Endpoints: (1) Change in patient engagement in mental health help-seeking behaviours. (2) Change in confidence in initiating mental health discussions with a healthcare provider or a loved one. (3)
Inclusion and Exclusion Criteria	**Inclusion Criteria** Patients (surveys and/or interviews): 1. Documented diagnosis with heart failure or on specific heart-failure related medications (used in the Emergency Department settings only). See section 5.1 for the medication list. 2. Receiving care at a participating pilot site

	3. Resides in Ontario or Quebec 4. Must be able to speak, read and understand English or French 5. Willing and able to provide informed consent and contact information for the administration of the follow-up survey (6 months post), for interviews (after the outcome survey) and compensation. Caregivers (interviews): 1. A caregiver of a patient with heart failure 2. Must be able to speak and understand English or French 3. Willing and able to provide informed consent to participate in the interview 4. Willing to provide contact information for compensation of the interview. Healthcare Providers / Administrative Staff: 1. Currently employed at a participating pilot site 2. Directly involved in patient care or clinic workflow 3. Willing and able to participate in process mapping workshops 4. Site champion willing to participate in monthly check-ins during the intervention phase **Exclusion Criteria** • Patients unable to provide informed consent (e.g., due to cognitive impairment or significant language barriers without available translated support) • Patients with no access to the internet as the tool is a web-based intervention
Study Intervention	The Heart x Mental Health FRAME (Foundation, Recognition, Awareness, Management and Engagement) tool is a multi-component, co-designed web tool created in collaboration with patient partners, caregivers, healthcare providers, Archipel Ontario Health Team and Great River Ontario Health Team. It is designed to improve recognition, awareness, management and support for mental health in patients with heart failure. There are three different versions: one for healthcare providers, one for caregivers and one for patients (see Appendix C-E). The intervention includes:

	• Educational material about heart failure and mental health • Conversational support to help facilitate discussions about mental health • Self-management activity maps (e.g., tips about nutrition and exercise) • Asset maps (i.e., displaying available resources in the community) • The provider-facing discussion tool to help initiate conversations about mental health and guide referrals or supports. FRAME was developed through a co-design process informed by the lived experiences of community partners and is intended to be adaptable to different healthcare environments. The intervention is low-burden and aims to normalize conversations about mental health in cardiac care settings.
Study Summary or Abstract	Heart failure is a high-risk, chronic condition that impacts patients' mental health. Approximately 50% of heart failure patients experience comorbid mental health conditions, such as stress, depression and anxiety, which affect their day-to-day lives. Despite this interconnection, the integration of mental health awareness and support into cardiac care remains limited. To address this gap, the FRAME (Foundation, Recognition, Awareness, Management, Engagement) intervention was co-designed by researchers, healthcare providers, health system decisionmakers, and patient partners. This pilot study evaluates the feasibility of implementing the FRAME intervention in pilot clinical sites within two health regions in Ontario, Canada, including team-based family medicine clinics, cardiac rehabilitation/specialist clinics, and emergency departments. Utilizing a pretest–posttest hybrid 1 model intervention design, this study evaluates process indicators and patient-focused outcomes through surveys and semi-structured qualitative interviews. Findings from this study will inform a future large scale cohort study and scalable integration of the FRAME tool into existing cardiac care pathways to enhance mental health awareness and support among heart failure patients.

2. BACKGROUND AND RATIONALE

Many mental health conditions and cardiovascular diseases, such as heart failure, share common mechanisms and can jointly contribute to poor health outcomes for patients (1). Individuals with heart failure are more likely

than others to experience symptoms of depression, anxiety, or stress, which are factors that can further exacerbate cardiovascular disease progression (1,2). Despite growing evidence of this relationship, treatment for brain-heart interconnected conditions remains fragmented. Distinct treatment pathways for mental health and cardiac conditions result in care gaps and reinforce silos both within the health system and between health and community care sectors. Knowledge about brain-heart interconnections has yet to be meaningfully integrated into care directives or health system reform initiatives aimed at addressing interconnected conditions.

Previous Work and the FRAME Intervention

Year 1 (April 2024 to March 2025) and the beginning of Year 2 of this project focused on understanding community needs and priorities and identifying care gaps. This was followed by the co-design of an intervention to address those needs in Eastern Ontario, in partnership with community research members and two Ontario Health Teams, Archipel and Great River. We triangulated data from (a) asset mapping, (b) consultations with patients, caregivers, clinicians and community service providers, (c) a rapid scoping review, and (d) collaborative co-design sessions. During this phase, we also built and strengthened relationships with decision makers at Ontario Health and the Ministry of Health, executives in Ontario Health Teams and Indigenous community leaders and advisors.

The intervention is called FRAME, which stands for Foundation, Recognition, Awareness, Management and Engagement. Our intervention targets heart failure patients who are experiencing or at risk of mental health challenges, as well as their caregivers and care providers. It is designed to improve awareness of the connections between brain and heart health and to increase understanding of the services and resources available in the community. It is structured across three audiences: provider facing, caregiver facing, and patient facing (See Appendix C, D, E). The intervention supports the development of knowledge about the connection between heart and mental health, promotes early recognition of emotional distress, and provides practical steps to encourage discussion about mental health, the adoption of self-management approaches and the use of community-based resources.

Heart Failure x Mental Health FRAME Intervention:

- **F**oundation helps build understanding of the link between mental and heart health
- **R**ecognition supports early identification of emotional challenges
- **A**wareness addresses the impact of heart failure on mood, identity, relationships and daily functioning
- **M**anagement equips individuals with self-management strategies for both mental and cardiac health
- **E**ngagement connects patients and caregivers to community resources and promotes proactive care

FRAME is both an educational and action-oriented intervention that aims to increase confidence and capacity among patients, caregivers and providers to recognize and respond to the mental health needs of individuals living with heart failure.

Rationale

To address interconnected brain and heart health issues, we are applying a Participatory Action Research approach (3,4). This ensures our research is community-led and action-oriented, with the goal of developing and evaluating interventions that support improved care for patients, caregivers, providers and decision makers. In collaboration with two Ontario Health Teams, Great River and Archipel, we will pilot and evaluate the FRAME intervention in three care settings: primary care, cardiology and emergency departments. These care settings represent the three most common touchpoints with the health care system for patients with heart failure – at their primary care provider, at the cardiologist, and at the emergency department

Pilot testing the intervention is a critical step to determine its feasibility, acceptability and potential for integration into real-world care settings. While the intervention was co-designed with local interest-holders and tailored to address known service gaps, it is essential to assess how it functions in practice. Following a Hybrid Type 1 implementation-effectiveness design (5,6) we will explore and evaluate how the FRAME intervention is received by patients, caregivers and providers, identify barriers to implementation, and refine tools and materials before broader scale-up.

Our proposed work also aligns with the Ministry of Health's healthcare reform priorities (7). Pillar Two emphasizes the need to improve access to timely care, especially for individuals with chronic illnesses. Supporting heart failure patients with mental health concerns by improving their awareness of available services and self-management options (such as exercise, nutrition, and social activation) can help ensure they have the knowledge and information (including cost, language, cultural fit and wait times) to make informed decisions about care within their communities. This study seeks to support communities in strengthening their existing care delivery systems to better address the overlapping needs of brain and heart health, specifically in the context of heart failure and mental health.

Context

The FRAME intervention will be pilot tested in 8 to 12 care settings, evenly distributed across two Ontario Health Team regions located in Eastern Ontario: Great River Ontario Health Team and the Archipel Ontario Health Team. These settings represent a mix of primary care, cardiac rehabilitation and specialization clinics, emergency services and community paramedic services where individuals with heart failure typically receive care.

The study will involve collecting data from three groups:

- ***Adult patients (40 years and older)*** who have a diagnosis of heart failure or are on a heart-failure-related medications (this will be at the emergency department only, see section 5.1 for medication list), and who are receiving care at one of the pilot sites.
- ***Care providers*** (e.g., clinicians, nurses, allied health professionals, paramedics) who serve our target patient population in one of the pilot sites.
- ***Caregivers*** who provide support for people with heart failure.

Participants must be able to provide informed consent and speak either English or French.

Setting Name	Setting Type (Primary, Cardiac, Emergency)
Great River Ontario Health Team	
Seaway Valley Community Health Centre	Primary Care Cardiac Rehabilitation Program
Cornwall Community Paramedic Program	Primary Care
Centre de santé communautaire de l'Estrie	Primary Care Cardiac Rehabilitation Program
Winchester District Memorial Hospital	Cardiac Imaging Emergency Department
Archipel Ontario Health Team	
Équipe de sante familiale communautaire de l'Est d'Ottawa	Primary Care
United Counties Prescott and Russell Community Paramedicine Program	Primary Care
Orleans Cardiopulmonary Group	Cardiac Clinic
Carrefour santé Aline-Chrétien Health Hub Orleans	Cardiac Rehabilitation Program
Montfort Hospital	Emergency Care

Known and Potential Risks and Benefits
While the intervention poses minimal risk, participants may experience emotional or psychological discomfort when discussing mental health. Benefits include increased mental health literacy and improved patient-provider communication around psychosocial concerns.

3. STUDY OBJECTIVES AND PURPOSE

The outcome evaluation will focus on three core outcomes:

1. **Frequency of Mental Health Conversations (primary)**
   This outcome measures if patients with heart failure report having a discussion about mental health after being introduced to FRAME.
2. **Engagement in Health Seeking Behaviours (secondary)**
   This outcome evaluates whether participants (patients) report accessing mental health-related support, following the FRAME intervention. Supports may include formal resources (e.g., referrals to psychological services), informal or community-based support (e.g., peer groups, faith-based programs), and self-management strategies (e.g., mindfulness, exercise, online tools).
3. **Confidence in Engaging in Mental Health Conversations (secondary)**
   This outcome assesses perceived knowledge of the interconnection between mental health and heart failure through self-reported confidence in initiating mental health discussions.

The process evaluation will focus on understanding how FRAME is implemented across our selected test sites and identifying contextual factors that influence its feasibility, acceptability and integration into heart failure care. Guided by the RE-AIM (Reach, Effectiveness, Adoption, Implementation, and Maintenance) framework (8–10), the process evaluation will observe the following areas:

1. Integration of FRAME into Clinical Workflows

This area will observe how the intervention is incorporated into everyday clinical processes. We will evaluate this through pre- and post-implementation 2-hour process mapping workshops with site staff such as care providers, administrators (11) This will help us assess how mental health conversations are or are not being addressed in clinical workflows, and how these processes changes following the FRAME intervention.

2. Barriers and Facilitators to Implementation

Throughout the intervention phase, site champions will provide feedback to the research team during 30-minute monthly check-in meetings. The purpose of the meetings will be to discuss troubleshooting, workflow compatibility, patient engagement. Other site staff (e.g., care providers or administrative staff) will be more than welcome to join the meetings as well to provide additional insights.

3. Engagement with FRAME

Digital analytics and passive data collection (e.g., number of QR code scans) will be used to monitor how often and where the patient and caregiver resources are access. This will provide an estimate of how much reach and visibility the intervention is receiving within each setting.

4. STUDY DESIGN & METHODOLOGY

4.1 Endpoints

This study will assess both outcome and process endpoints to evaluate the impact and implementation of the FRAME intervention across pilot healthcare sites.

- **Primary Endpoint: Change in the frequency of mental health conversations.**
  This will be self-reported by patients with heart failure before and after the exposure to the FRAME intervention. This will be measured by a self-reported survey questions asking whether the participant has discussed their mental health with a healthcare provider in the past 6 months.

The time points for this endpoint will be compared between pre-intervention (intake survey) and post-intervention (6-month follow-up survey). (see Appendix A for surveys)

- **Secondary Endpoints:**
  There are three secondary endpoints that will measure changes in broader behavioural and attitudinal outcomes. All secondary outcomes will be self-reported through two timepoints: an intake survey (baseline) and an outcome survey administered approximately six months later.

1. **Change in mental health help-seeking behavior (e.g., accessing community-based supports or self-management activities).**
   This will be self-reported by patients on the survey that will capture the use of self-management or community-based mental health supports. The outcome survey will repeat these questions to identify changes over time. The timepoint for this would be pre- and post-intervention.
2. **Change in patient confidence to discuss mental health**
   This will be self-reported by patients on the survey items assessing confidence levels in initiating mental health discussions either with a healthcare provider or a loved one (e.g., caregiver, friend, etc...). The time point would be pre- and post-intervention.
3. **Change in awareness of where to find mental health information or support.**
   This will be self-reported by patients assessing perceived knowledge of where and how to access mental health information and supports. This timepoint would be pre- and post-intervention.

   All of these outcomes will also be questioned in the interviews, should the patients/caregivers wish to participate (see Appendix B for the interview guides).

Process Evaluation Endpoints:

1. Integration of FRAME Into Clinical Workflows

Measurement: Pre- and post-intervention recorded virtual or in-person 2-hour process mapping workshops with site staff to assess changes in mental health care pathways in heart failure care.

2. Implementation Barriers and Facilitators

Measurement: Monthly 30-minute recorded check-ins with site champions and staff to document implementation challenges, and successes.

3. Patient Engagement with FRAME

Measurement: Quantitative metrics with number of QR code scans and webpage visits to assess usage of patient-facing resources.

4.2 Study Design

This study will use a Hybrid Type 1 effectiveness- implementation design, which is well-suited to for evaluating interventions in real-world healthcare settings where both clinical outcomes and implementation processes are focus areas. This design evaluates the effectiveness of an intervention while also collecting formative data to understand it's

implementation context, where we determine its feasibility, acceptability, barriers and facilitators to uptake to support future trials (12). These implementation science hybrid designs are increasingly used in health services research to improve the transition of evidence-based practices into routine care.

The primary aim of Hybrid Type 1 would be to determine whether an intervention is effective in improving targeted outcomes. In this case, our primary and secondary outcomes for patients with heart failure. The secondary aim is to explore the conditions that influence its successful implementation and to determine what adaptation are needed to enhance integration in future and larger-scale trials adaptations (12). This approach showcases recommendations from implementation science to evaluate what works from whom and under what circumstances (5,13,14). This design also prioritizes testing the delivery of outcomes of an intervention while also gathering formative data on implementation processes.

The FRAME intervention was co-designed with patient partners, caregivers, healthcare providers and researchers. It has a strong foundation in evidence, however, it has not yet been implemented or evaluated in clinical settings. This study will assess the preliminary effectiveness of FRAME on patient-reported mental health conversations, help-seeking behaviours and confidence in discussing mental health and the "implementability" of the tool, including how it is adopted and integrated into clinical workflows across three healthcare settings: primary care, cardiac care and emergency departments.

To guide implementation evaluation, our study will apply the RE-AIM framework (Reach, Effectiveness, Adoption, Implementation, Maintenance), which is a widely used implementation science model that supports comprehensive assessments of outcomes.

A mixed-methods approach will be used to collect and analyze both quantitative and qualitative data from patients, caregivers and site staff. This would include:

- Pre- and post-implementation surveys for patients
- Implementation tracking (e.g., the number of QR codes scanned, site champion check-ins)
- Pre- and post-implementation process mapping workshops with site staff to visualize changes in clinical workflows related to mental health integration

The decision to use a Hybrid Type 1 model was based on a reflection analysis after 10 years of effective-implementation hybrid studies had a guide of four questions to consider when selecting a hybrid study type (15). For example, one of the questions asks about how much the research team knows about implementation determinants for the intervention and suggests that if we do not know much, consider a type 1 design. After the consideration of similar questions, the hybrid type 1 design was the most appropriate, as it will allow us to assess the preliminary effectiveness of the tool in improving mental health awareness and support while identifying implementation facilitators, barriers, and contextual considerations across our pilot test sites to assist us refine the tool for future scalability. See Figure 1 for a visual overview of how the hybrid model has been adapted and operationalized for this study, with a timeline specification.

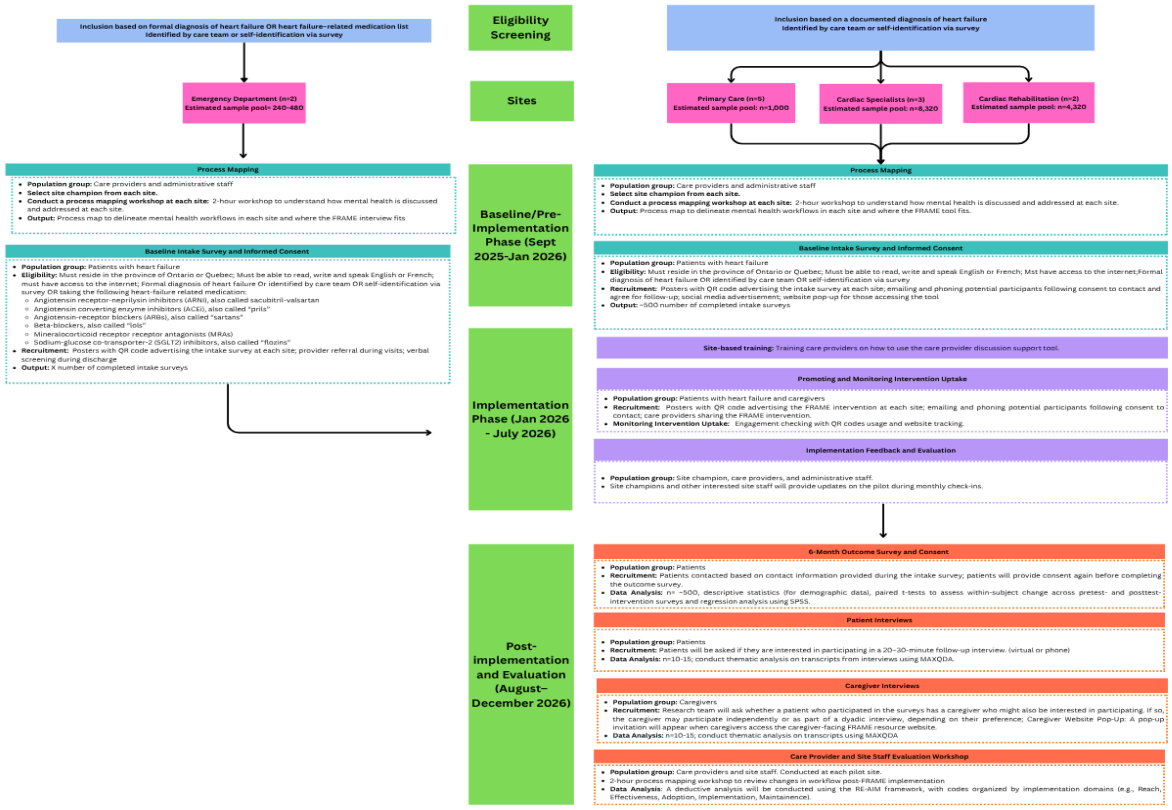

Figure 1. Adaptation of a Hybrid Type 1 Effectiveness-Implementation Design for the Heart Failure x Mental Health FRAME Intervention Feasibility Study. This figure illustrates how the FRAME intervention will be integrated using the Hybrid Type 1 design with timelines across different clinical pilot test sites, specifying the activities that occur per month and the implementation phase.

4.3 Study Measures

This study uses a Hybrid Type 1 effectiveness–implementation design to evaluate both patient-centred outcomes and implementation processes related to the FRAME intervention. Given the non-randomized nature of this feasibility study, efforts to reduce bias will include standardized data collection tools across all sites, training of research staff, use of validated survey items, and structured analytic approaches. No blinding or randomization will be used due to the exploratory nature of this study.

1. Outcome Evaluation

The outcome evaluation will assess the preliminary effectiveness of the FRAME intervention using patient-reported outcome measures. The focus is on evaluating changes in awareness, confidence, and engagement with mental health supports following exposure to the FRAME tool.

Primary Outcome Measure: Frequency of Mental Health Conversations

- **Description:** This outcome will be measuring patient behaviour change in the form of an increased number of mental health conversations after using the intervention.
- **Participants:** Patients with a documented diagnosis of heart failure or on heart-failure related medications.
  Timing: Pre-intervention (baseline) and 6 months post-intervention

Secondary Outcome Measures:

(1) Engagement in Health-Seeking Behaviours

- **Description:** This outcome will be measuring health-seeking behaviours in the form of whether they have accessed or know where to access mental health supports (e.g., community-based support) or information (e.g., self-management activities)
- **Participants:** Same as primary outcome
  Timing: Same as primary outcome

(2) Confidence in Engaging in Mental Health Conversations

- **Description:** This outcome will be measuring patient confidence in the form of initiating or participating in conversations about their mental health with a healthcare provider or loved one.
- **Participants:** Same as primary outcome
  Timing: Same as primary outcome

Measures and Data Collection:

- **Intake survey** (baseline): Self-administered questionnaires via RedCAP assessing the above outcomes.
- **Outcome survey** (post-intervention): Follow-up questionnaire with the same questions above in RedCAP to assess changes in the same domains 6 months after the intervention. The end of the survey will also include an invitation for an interview.
- **Survey Questions :** The questions were adapted from validated tools such as the Mental Health Literacy Scale (16) , Opening Minds Stigma Scale (17), and the General Self-Efficacy Scale (18).
- **Semi-structured interviews** (optional for patients and their caregivers): 20-30-minute interviews with a subsample of survey respondents' post-intervention to explore their experiences with FRAME resources and its influence on mental health engagement. We anticipate recruiting approximately n=12-15 patient participants for interviews, but will continue until data saturation is reached, defined as the point when no new themes are emerging (19). The final number may vary based on the diversity of participant experiences, and additional interviews may be conducted if needed to ensure broad representation.

See Appendix A for the surveys

Data Consolidation and Analysis:

Survey Data:
All survey responses will be self-administered by participants using REDCap and automatically stored on its secure server. Data will be exported for analysis using either SPSS or R. Descriptive statistics will be used to summarize demographic characteristics and baseline outcome measures.

To evaluate the primary endpoint and three secondary endpoints, we will conduct paired t-tests (or non-parametric equivalents if assumptions are not met) to examine within-subject changes between baseline and six-month follow-up. As multiple comparisons will be performed across related outcomes, we will control the overall family-wise error rate using the Holm-Bonferroni method (20). This approach ensures that statistical significance is not overstated due to the number of related hypothesis tests conducted. A p-value threshold adjusted via Holm-Bonferroni will be applied to determine significance across the four outcomes (one primary and three secondaries).

Interview Data:
Interviews will be audio-recorded or video-recorded (if conducted on Microsoft Teams) with participants' verbal and written consent. Interviews conducted virtually will be recorded through Microsoft Teams or by phone, and in-person interviews may use an encrypted recording device or PlayWrite. Recordings will be transcribed verbatim. Transcripts will be imported into MAXQDA 2022 for qualitative analysis. An inductive thematic analysis will be conducted following Braun and Clarke's six-phase approach(21), allowing themes to emerge from the data. Qualitative rigour will be supported using Lincoln and Guba's trustworthiness criteria (credibility, dependability, confirmability, and transferability) (22).

2. Process Evaluation

The process evaluation assesses how the FRAME intervention was implemented, its perceived feasibility, acceptability, and fit within each clinical context. It includes provider/staff perspectives.

Participants: Care providers, administrative staff, and site champions
Timing: Pre-intervention (baseline), during implementation, and post-intervention
Measures and Data Collection:

- **Process Mapping Workshops (pre/post):** Two-hour facilitated in-person or virtual workshops with care providers and staff to visualize clinical workflows and how/when mental health is addressed. A baseline process map will be developed and revisited post-implementation to identify changes. A secondary process map will be developed to visually represent the changes in workflow and practices before and after the intervention. Process Mapping workshops will be audio-recorded (with verbal and written consent), transcribed using PlayWright or Microsoft Teams transcription, and analyzed thematically using MAXQDA. Process mapping workshop recordings will inform the construction of visual process maps for each site pre- and post-intervention. Coding will follow an inductive approach to identify patterns in mental health within the specific clinic setting following Braun & Clarke's framework.
- **Implementation monitoring:** QR code usage and web traffic analytics for FRAME materials. Site champions will also provide monthly feedback during 30-minute check-ins for barriers, facilitators and any troubleshooting.

Data Consolidation and Analysis:

All data collected during process mapping workshops and monthly site champion check-ins will be audio-recorded with verbal and written consent and transcribed using PlayWright or Microsoft Teams transcription. These transcripts will be imported into MAXQDA 2022 for analysis. A deductive analysis approach will be used, guided by the RE-AIM

framework (Reach, Effectiveness, Adoption, Implementation, and Maintenance) (10). Transcripts will be coded according to predefined categories that reflect RE-AIM domains, allowing the research team to systematically assess how FRAME was implemented, adopted by staff, and maintained across different care settings.

Pre- and post-intervention process maps will be constructed for each site and visually compared to identify changes in workflow, conversation points, and mental health-related practices. A fidelity checklist will also be developed and used to document and monitor consistency in the implementation of FRAME activities across all participating sites (23). This checklist will be updated throughout the implementation period based on data from the monthly site check-ins and QR code and survey usage. Since this is a pre-post implementation study without randomization, there will be no allocation concealment or blinding. However, the accumulation of different data sources will enhance the validity of findings.

4.4 Drug/Device Trial Description *(for Health Canada regulated and non-regulated clinical trials)*

N/A

4.5 Study Duration

The study will run from **September 2025 to December 2026**, with the following phases:

Baseline / Pre-Implementation Phase (September to January 2026)

Each participating site will begin with a baseline data collection phase to understand how mental health is currently discussed, integrated and addressed within each care setting. This phase will also gather input directly from patients to assess current experiences and needs.

Data Collection

Process Mapping: As an initial step, each site will take part in a process mapping activity to examine how mental health is currently addressed within clinical workflows. Process mapping is a structured method used to visually represent and analyze the steps involved in healthcare delivery (24). It helps teams identify where, when and how mental health is, or is not, being addressed, and highlights opportunities for improvement. Benefits include improved understanding of local systems, identification of service gaps or redundancies, and the development of a shared perspective among team members. Care providers and administrative staff from each setting (n = 2-5) will be invited to attend a two-hour workshop to complete the process mapping activity collaboratively and then be sent the final process map to review and provide feedback. This session will be recorded for future reference to make the process map. See Appendix B for the interview guide.

Intake Survey: To capture patient perspectives on mental health in the context of heart failure care, a brief pre-intake survey will be made available (Appendix A). QR codes linking to the survey will be posted in each setting (see Appendix F), and providers who are willing will be invited to share the survey link with their patients by email or in person. The survey will assess patients' current mental health experiences, awareness of resources and any unmet needs. Patient name,

phone number and email will be collected to facilitate contact for the outcome survey after the pilot test period. Patients who complete the intake survey will receive early access to the FRAME intervention before it is fully advertised and publicly available during the implementation phase in January 2026.

Implementation Phase (January–July 2026):

Following baseline activities, each site will begin the implementation of the FRAME intervention, with training, site-specific adaptations and a six-month pilot period. This phase will focus on integrating the intervention into routine care practices through provider engagement. For providers, training will cover how to use the informational and discussion support tool (Appendix C). With providers and administrative staff, we will discuss and decide how to advertise the patient and caregiver-facing components of the FRAME intervention. Booklets and posters will be distributed to support both provider and patient engagement.

January – Training and Rollout Preparation
Training will be tailored to the needs and preferences of each site. A planning discussion will take place with site leads to determine preferred training modalities (e.g., in-person sessions, virtual modules, printed materials) during the pre-implementation phase. For providers, training will cover how to use the informational and discussion support tool (Appendix C). With providers and administrative staff, we will discuss and decide how to advertise the patient and caregiver-facing components of the FRAME intervention. Booklets and posters will be distributed to support both provider and patient engagement.

February to July – Pilot Testing the FRAME Intervention
The intervention will be implemented over six months at all participating sites. QR codes and posters will be displayed to connect patients with FRAME materials and support tools. Care providers will be encouraged to share FRAME resources during routine care interactions and begin initiating mental health conversations using the tool provided. Each site will identify a "site champion" to support internal coordination and communication. Monthly 30-minute virtual check-ins will be held with each site champion to monitor progress, troubleshoot challenges, and share insights across sites. These check-ins will be open to other site team members who wish to attend. All sessions will be recorded and transcribed to support the process evaluation.

Data Collection

Intervention Uptake Monitoring: Engagement with the intervention will be tracked by monitoring QR code usage and web traffic to patient- and caregiver-facing FRAME resources.

Implementation Feedback: Site champions will provide updates during monthly check-ins, including reflections on implementation progress, provider engagement, patient responses and any barriers or facilitators encountered.

Post-implementation and Evaluation (August–December 2026):

Following the six-month pilot period, the intervention will be evaluated using the RE-AIM framework (Reach, Effectiveness, Adoption, Implementation, Maintenance) to assess its impact on mental health discussion and engagement within each care setting. Evaluation activities will vary between patients and site staff (care providers and administrative staff).

Data Collection

Patient Evaluation:

Outcome Survey: To assess behaviour, change and engagement with mental health following exposure to the FRAME intervention, patients who completed the pre-intake survey will be invited to complete a follow-up survey six months after being exposed to the FRAME intervention. The research team will contact eligible patients by email to complete the outcome survey and attach the outcome survey poster (Appendix G). In addition, participating care providers may support recruitment by reaching out to patients who interacted with the FRAME intervention during the implementation phase. The follow-up survey will explore changes in awareness, comfort discussing mental health, and uptake of self-management strategies or resources (Appendix A).

Interviews: At the end of the outcome survey, patients will be invited to indicate whether they are interested in participating in a 20-30-minute interview with the research team. Those who express interest will be contacted by a member of the research team to schedule the interview by phone or email (this will be indicated by patient's preference on the survey). Interviews will be semi-structured and conducted either by phone or via Microsoft Teams, depending on the participant's preference. We anticipate recruiting approximately n=12-15 patient participants for interviews, but will continue until data saturation is reached, defined as the point when no new themes are emerging (19). The final number may vary based on the diversity of participant experiences, and additional interviews may be conducted if needed to ensure broad representation.

A formal interview guide will not be developed at this stage. Instead, interviews will be designed to explore emerging trends from the intake and outcome survey data. This flexible, responsive approach will allow the research team to probe more deeply into trends or complexity shown in the collected quantitative survey data. This ensures that qualitative data collected from the interview enriches the interpretation of the quantitative survey results. An REB amendment will be submitted beforehand with the attached interview guide.

Care Provider and Site Staff Evaluation Workshop: To evaluate implementation outcomes and provider experiences, we will conduct a two-hour evaluation workshop with approximately n=2-5 staff members per site. Participants may include care providers, site champions, and administrative staff involved in implementation. Interviews will explore whether the provider-facing FRAME tool was useful and relevant, how it was integrated into the workflow, and whether it contributed to increased discussion and engagement around mental health in the context of heart failure care. The initial process map created during the pre-intervention phase will be revisited during the post-implementation period to facilitate discussion about how mental health care pathways have changed as a result of the intervention. A secondary process map will be developed to visually represent the changes in workflow and practices before and after the intervention. This updated map will be shared with each pilot site as a resource to support ongoing maintenance of the changes beyond the pilot period. No long-term follow-up is planned post-pilot and evaluation phase.

Caregivers Interviews: Caregivers will be recruited through two pathways during the pilot phase. First, when scheduling interviews with patients, the research team will ask whether the patient has a caregiver who may be interested in participating in an interview. They participate either independently or as part of a dyadic interview, depending on the preferences of the patient and caregiver. Second, caregivers who interact with the caregiver-focused webpage on the FRAME site will see a pop-up invitation offering the opportunity to share their contact information if they are interested in being interviewed.

Caregivers who express interest will be contacted by the research team to schedule a 15- to 20-minute interview, conducted by phone, in person, or via Microsoft Teams, based on their preference. The interviews will follow a grounded theory approach (25) and begin with two open-ended prompts (Appendix B), allowing themes to emerge naturally. This approach is intended to create space for caregivers to share their experiences in their own words.

4.6 Study Stopping Rules/Termination

As this study poses minimal risk to participants, stopping rules are limited to practical and ethical concerns. The study or a portion of it will be discontinued if:

For intake and outcome survey:

- Participants can close the browser if they change the mind about participating and if after filling out survey. Participants may also click on the withdrawal button at the bottom of the survey.
- Ethical concerns arise during the study that warrant a temporary pause or complete stop, as determined by the principal investigator and/or Research Ethics Board.
- Participants may withdraw at any time without consequence, and incomplete survey data will be excluded from analysis if the participant requests removal.

For interviews:

- Participants may withdraw from the study at any time during the interview without consequence. Incomplete interviews will be excluded from the analysis if the participant requests removal.

4.7 Drug or Investigational Product Accountability Procedures

N/A

4.8 Randomization and Blinding

N/A

4.9 Data Records

N/A

5. SELECTION AND WITHDRAWAL OF STUDY PARTICIPANTS

5.1 Inclusion Criteria

Inclusion Criteria:

Patients (Surveys and Optional Interviews)

1. Patients with a formal diagnosis of heart failure
2. Patients on the following list of medications (26):

- Angiotensin receptor-neprilysin inhibitors (ARNI), called sacubitril-valsartan
- Angiotensin converting enzyme inhibitors (ACEi), called “prils”
- Angiotensin-receptor blockers (ARBs), called “sartans”
- Beta-blockers, called “lols”

- Mineralocorticoid receptor receptor antagonists (MRAs)
- Sodium-glucose co-transporter-2 (SGLT2) inhibitors, called "flozins"

3. Receiving care at one of the participating pilot test sites or if they found their way to the tool website
4. Willing and able to provide informed consent and name, email address and phone number for follow-up contact (for survey and interview)

Caregivers (Optional interviews):

1. Caregivers who support adult(s) with heart failure.

Healthcare Providers and Site Staff

1. Healthcare provider (e.g., physician, nurses, allied health professionals, pharmacists, community paramedics) currently working at one of the participating pilot test sites
2. Involved in care or coordination of care for patients with heart failure (e.g., administration, executive staff)
3. Willing to participate in pre- and post-intervention process mapping workshops

5.2 Exclusion Criteria

Patients

1. Inability to provide informed consent (e.g., due to cognitive impairment or language barriers without translated support)
2. Participants that do not have access to the internet will not be able to use the web-tool.

Healthcare Providers

1. Providers that are not involved in the care of heart failure patients

5.3 Reasons for a Participant Being Withdrawn, or Withdrawing, from the Study

Participants may be withdrawn or choose to withdraw from the study for the following reasons:

- The participant withdraws consent at any time.
- The participant is no longer reachable (i.e., lost to follow-up).
- The participant is non-compliant with the study procedures (e.g., does not complete the survey despite reminders).
- The participant no longer meets the inclusion criteria (e.g., if they move out of the participating care setting).
- A protocol violation occurs that necessitates the removal of the participant.
- The participant passes away during the course of the study.

Participant Replacement:

Participants who withdraw will not be replaced. Data will be analyzed only from completed surveys and interviews.

Withdrawal Process:

If a participant chooses to withdraw, no further data will be collected. Any previously collected data will be retained and de-identified unless the participant requests that their data be removed, in which case all identifiable data will be deleted.

The participant must contact the principal investigator by email within two weeks from their submission of the survey and/or interview in this case and will be written on the consent form.

5.4 Study Stopping/Termination Rules

The study may be suspended or terminated early for any of the following reasons:

- It becomes clear that the study will not reach its primary outcome or recruitment targets.
- Unanticipated risks to participants arise (e.g., participants experience distress at a level that outweighs the minimal risk profile of the study).
- Persistent non-compliance with the protocol by study sites or staff.
- Infrastructure issues (e.g., loss of site partners, withdrawal of funding, or changes in Ontario Health Team capacity to participate).
- Pandemic restrictions or similar external events affect the feasibility or safety of continuing the study.

6. STUDY MEASURES AND PARTICIPATION

6.1 Treatment of Participants for Drug/Device Trials

N/A

6.2 Treatment of Participants for all other Studies

Participants will not receive any drug or physical treatment. Study procedures involve:

- Patients complete surveys at two time points (baseline and 6-months post-intervention). This survey will take about 10-15 minutes to complete.
- Optional 30-minute semi-structured interviews with a subsample of patients and caregivers who indicate on the outcome survey they wish to participate.
- Clinic staff at participating pilot sites will participate in two 2-hour process mapping workshops (pre- and post-intervention)

There are no restrictions to food, drink, medications or physical activity for participation in the study.

6.3 Monitoring Participant Compliance

Compliance monitoring will be minimal due to the nature of the study:

- Surveys: Completion will be monitored through the survey platform for both the intake and outcome surveys. Email reminders can be sent to patients who did not complete the survey but started it via the automated system sent from the platform. No follow-up is required after the survey unless the participant expresses interest in having an interview. An e-gift card will be sent via email after the completion of the intake survey and after the outcome survey.
- Interviews: Scheduled based on participant availability and confirmed by the research team; no follow-up is required after the interview is completed, other than providing the compensation via email.
- No diaries, bloodwork, or physiological measures are required.

Participants are considered compliant if they complete the survey or attend the interview after consent. There are no long-term participation requirements beyond the post-intervention period.

7. ASSESSMENT OF EFFICACY

Primary and secondary outcomes will be assessed using pre- and post-intervention surveys administered to patients during the following timeframes:

Assessment Methods:

Baseline / Pre-Implementation Phase (September to December 2025)

Survey Data: All patient intake survey data will be collected via REDCap, a secure, web-based platform. Surveys will capture demographics, current mental health engagement, awareness of services, and confidence in discussing mental health. Data will be exported into SPSS or R for analysis. Descriptive statistics will be used to summarize participant characteristics and baseline responses across sites. These baseline measures will serve as a reference point for comparison with follow-up responses after the intervention.

Process Mapping Workshops: Workshops will be audio-recorded with verbal consent and transcribed using Microsoft Teams or PlayWrite. Transcripts will be imported into MAXQDA 2022. A deductive analysis will be conducted using the RE-AIM framework, with codes organized by implementation domains (e.g., Reach, Adoption, Implementation). The findings from the workshop will also inform the construction of baseline visual process maps for each site. These maps will help document existing mental health pathways and serve as a comparison point for post-implementation changes.

Implementation Phase (January to July 2026)

Implementation Monitoring: Intervention uptake will be tracked using analytics such as QR code scans and web traffic for FRAME resources. A fidelity checklist will be created to document which components of the FRAME intervention were implemented at each site, including training completion, distribution of materials, and resource sharing. Monthly check-ins with site champions will be recorded and transcribed. Feedback from these sessions will be coded using the RE-AIM framework to assess implementation progress, emerging barriers, and facilitators. Feedback from providers and site champions during monthly check-ins will be used to monitor real-time implementation trends. These discussions will be deductively coded using the RE-AIM framework and used to update the fidelity checklist and track variation in intervention delivery across settings.

Post-Implementation and Evaluation Phase (August to December 2026)

Survey Data (Outcome Survey):
Patients who completed the intake survey will be invited to complete a follow-up survey six months after FRAME exposure. Data will again be collected in REDCap. Paired t-tests (or non-parametric equivalents, such as the Wilcoxon signed-rank test) will be conducted to examine changes in:

- Frequency of mental health discussions
- Engagement in mental health-related supports
- Confidence in discussing mental health with providers

Regression models may also be applied to explore the association between intervention exposure and outcomes, adjusting for demographic or site-level differences.

Patient Interviews: Approximately n=12–15 patient interviews will be conducted, with flexibility to continue until data saturation is reached. Interviews will be recorded, transcribed, and thematically analyzed in MAXQDA 2022 using Braun & Clarke's six-phase method. This inductive analysis will explore patient experiences with the FRAME intervention, including its usefulness and impact on behavior. Interview content will also help contextualize survey findings. Rigor will be supported using Lincoln & Guba's criteria for trustworthiness (credibility, dependability, confirmability, and transferability).

Caregiver Interviews: Caregivers will be recruited through patients or directly from the FRAME website. They will participate in 15–20-minute interviews, individually or as part of a dyad. Interviews will follow a grounded theory approach, starting with two open-ended prompts (Appendix B) to allow themes to emerge naturally. Transcripts will be analyzed inductively in MAXQDA to build theory about caregiver experiences, challenges, and support needs in relation to heart failure and mental health.

Provider and Staff Evaluation Workshops: Follow-up workshops with 2–5 staff per site will revisit the original process maps created during the pre-implementation phase. Post-implementation process maps will be developed collaboratively during the session to visualize changes in workflow. These recordings will be transcribed and analyzed deductively using the RE-AIM framework, and maps will be compared to assess workflow improvements or gaps. These final process maps will be left with each site to support sustainability beyond the pilot period.

8. POTENTIAL BENEFITS, RISKS AND SAFETY

8.1 Potential Benefits

Patients having access to the tool may indirectly benefit from increased attention to mental health in their heart failure care journey. No guaranteed direct benefit is offered to participants. Participants could:

- Gain awareness about the connection between heart health and mental health
- Learn about resources available in the community and have access to guides that will help they self-manage their heart failure and mental well-being.
- Feel empowered to engage in conversations about mental health with their healthcare providers.

8.2 Risks

- Emotional or psychological discomfort when reflecting on personal mental health due to the sensitive nature of the topic.
- Confidentiality breach: minimal risk due to the use of identifiable contact information

Mitigation Strategies:

- A list of free and accessible mental health resources will be provided to all participants in the consent form and before interviews begin.
- Participants may skip any survey and interview questions they do not wish to answer.
- Interviews will be scheduled at participants' convenience, and they can pause or end the interview at any time.
- Participants will be reminded they can withdraw without any consequence.
- Personal information of participants will be stored securely in RedCAP and Bruyere Health Research Institute SharePoint.
- All identifiable information will be de-identified prior to analysis.

These risks and mitigation strategies will be outlined clearly in the informed consent form (ICF).

8.3 Safety

As this study does not involve a medical or therapeutic intervention, serious adverse events are unlikely. However, some adverse events may occur:

- Any Adverse Events, such as participant distress during interviews, will be documented and discussed with the principal investigator.
- No Adverse Drug Reactions are applicable.

9. RECRUITMENT

Sample Size Pool and Recruitment Estimates

Based on preliminary discussions with participating pilot sites, we estimate a total recruitment pool of approximately 7,060 to 7,300 patients across the 8–12 participating care settings during the six-month intervention period. Estimates are stratified by setting type, accounting for site volume, focus of care, and potential overlap:

- Primary care settings (n = 5): Each site is expected to see approximately 200 eligible patients over six months, based on weekly estimates provided by participating providers. **Total estimated pool = 1,000 patients.**
- Cardiac clinics (n = 3): From two of our community sites, we expected to see approximately 2,160 unique patients over six months, given the high focus on heart failure. We expect the pool from the University of Ottawa Heart Institute site to be bigger, approximately 4,000 unique patients. **Total estimated pool = 8,320 patients.**
- Cardiac rehabilitation programs (n = 3): While these programs may include repeat visits, each site is expected to have approximately 100-200 unique patients over the course of six months. **Total estimated pool = 3,00-600 patients.**
- Emergency departments (n = 2): Each site is estimated to contribute 120–240 eligible patients over six months, depending on volume and fluctuations. **Total estimated pool = 240–480 patients.**

Overall, **this results in a projected recruitment pool of approximately 10,100 to 10,400 eligible patients**, with minimal anticipated overlap across care settings. Some overlap may occur with emergency department visits.

Sample size estimates were calculated based on a paired t-test design, which reflects the study's pre-post structure, comparing patient-reported outcomes before and after exposure to the FRAME intervention. To control for the increased

risk of Type I error due to multiple hypothesis tests (one primary and three secondary outcomes), a Bonferroni correction was applied. This adjusted the significance level (alpha) from 0.05 to 0.0125 per test. A desired statistical power of 0.80 was used to ensure adequate sensitivity to detect meaningful change.

- **Small effect (Cohen's *d* = 0.1):** 1,118 participants pre and post
- **Small-to-moderate effect (Cohen's *d* = 0.15):** 499 participants pre and post
- **Moderate effect (Cohen's *d* = 0.2):** 282 participants pre and post

The actual effect size to use will be guided by the expected impact of the intervention based on similar prior studies and the minimal clinically important difference for the outcomes being assessed. Given the total projected recruitment pool of 10,100 to 10,400 eligible patients, we anticipate that it will be feasible to meet sample size requirements for detecting even small-to-moderate changes

Sample size was calculated using a paired t-test model to compare pre- and post-intervention survey scores. We applied a Bonferroni correction for four outcome measures (one primary and three secondary), adjusting alpha to 0.0125. A power of 0.80 was selected.

Estimated minimum sample sizes:

- Small effect (Cohen's d = 0.1): 1,118 participants
- Small-to-moderate effect (Cohen's d = 0.15): 499 participants
- Moderate effect (Cohen's d = 0.2): 282 participants

Given a projected total eligible patient population of 10,100–10,400 across participating sites during the study period, we anticipate being able to recruit the sample needed to detect even small-to-moderate effects.

Breakdown of anticipated research participants:

- **Patients:** Up to 1,200 for pre-post surveys; all will be invited for follow-up interviews but only 12-15 interviews will be conducted.
- **Caregivers:** Estimated 10–20, based on patient consent and availability; only those who express interest will be invited for interviews.
- **Healthcare providers/clinic staff:** Up to 80 participants total (~6–10 per site), depending on site size. These individuals will take part in the process mapping workshops, training sessions, monthly check-ins, and the evaluation workshop. They will be recruited based on initial meetings with site staff.

Recruitment of patients will stop once target pre-post survey completion is achieved (n = ~500–1,200) and interviews are completed (n=~12-5). The research team has sufficient staff support to meet the demands of the 6-month data collection period.

Recruitment Methods:

1. *Patient Recruitment*

Survey Recruitment
Eligible patients will be recruited to complete the intake and outcome surveys (Appendix A) through the following methods:

- **Clinic-Based Posters with QR Codes:** Posters will be displayed in high-traffic areas within each participating site (e.g., waiting rooms, exam rooms, reception desks). Each poster will include a QR code that links directly to the intake or outcome survey (Appendix F and G), depending on the pilot phase and the survey will be hosted on REDCap.
- **Email and Phone Outreach:** Participating site staff will identify eligible patients and contact them via email or phone to introduce the study. If a patient expresses interest, the intake survey will be shared by either the site staff or the research team. This email will include a secure link to the intake survey as well as access to the FRAME tool after completion of the survey. See Appendix H for all recruitment texts.
- **During the Intervention Phase:** Care providers will share the FRAME tool directly with patients during routine clinical interactions. As part of this interaction, patients will be informed about the study and asked if they consent to be contacted later by the research team for the outcome survey. If patients agree, their contact information will be collected at that point and sent to the research team.
- **Outcome Survey Distribution:** At the time of completing the intake survey, patients will be asked to provide their name, email, and/or phone number so they can be contacted to complete the outcome survey. This will be clearly explained at the end of the intake survey. Six months after a patient has completed the intake survey and received the FRAME tool, the research team will reach out via the contact information provided to invite them to complete the outcome (post-intervention) survey. Follow-up will be conducted through email and/or phone, based on the patient's stated preference.
- **Patient Website Pop-Up:** Patients accessing the online FRAME tool will receive a pop-up message inviting them to participate in the outcome survey.
- **Social media recruitment:** Study posters and survey links will be shared via social media platforms and communication channels managed by Brain-Heart Interconnectome, our Ontario Health Teams, and their communication channels. This includes posts on platforms such as Instagram, Facebook as well as promotion through newsletters and community-facing websites to increase visibility and engagement with eligible patients.

Interview Recruitment
At the end of the outcome survey, patients will be asked if they are interested in participating in a 20–30-minute follow-up interview. The research team will reach out to those who express to schedule the interview. Interviews will be conducted by phone or Microsoft Teams based on participant preference. Participants who complete the interview will receive a $25 Amazon gift card.

2. Caregiver Recruitment

Caregivers will be recruited through two pathways.

- **Patient Referral (Dyadic or Individual Participation):** When scheduling patient interviews, the research team will ask whether the patient has a caregiver who might also be interested in participating. If so, the caregiver may participate independently or as part of a dyadic interview, depending on their preference.

- **Caregiver Website Pop-Up:** A pop-up invitation will appear when caregivers access the caregiver-facing FRAME resource website. Those interested in participating will be invited to share their contact information. The research team will follow up to schedule a 15–20-minute interview via phone, Microsoft Teams, or in person. Caregivers who participate in interviews will receive a $25 gift card.
- **Social media recruitment:** Study posters and survey links will be shared via social media platforms and communication channels managed by Brain-Heart Interconnectome, our Ontario Health Teams, and their communication channels. This includes posts on platforms such as Instagram, Facebook as well as promotion through newsletters and community-facing websites to increase visibility and engagement with eligible patients.

3. Healthcare providers and administration staff

Site Champion Selection:
Each site will nominate one staff member to act as a site champion, responsible for coordinating local activities and participating in monthly check-in meetings with the research team. Site champions will be identified during early planning discussions with each clinic.

Process Mapping and Evaluation Workshops:
All participating sites will identify relevant care providers and administrative staff to take part in the process mapping workshops. Recruitment will occur through direct discussion with site leads during the planning phase to identify appropriate staff (e.g., clinician, nurses, social workers, receptionists, clinic managers) who are actively involved in patient care and/or clinic workflows.

- **Pre-Implementation (Process Mapping Workshops):** A two-hour workshop will be scheduled at each site with invited staff to map out the current workflow for addressing mental health in heart failure care.
- **Post-Implementation (Evaluation Workshop):** Following the intervention period, the same or additional staff will be invited to participate in a second workshop to review how workflows have changed and to provide feedback on the intervention.

4. Site Compensation

Each participating site will receive financial compensation to support the time and resources required to implement and evaluate the FRAME intervention. This funding is intended to offset the operational costs associated with participating in the pilot and will include support for:

- Training time for care providers and staff involved in implementing the FRAME tool.
- Attendance at workshops, including the baseline process mapping and post-implementation evaluation sessions.
- Remuneration for site champions, who will lead local coordination and attend monthly check-ins.
- Funds for printing and distributing posters and FRAME-related patient materials.
- Hourly remuneration for staff time spent supporting recruitment, such as emailing or calling eligible patients to invite participation in the survey.

Care providers will not receive compensation for using the provider-facing FRAME tool as part of routine care. Compensation is limited to time spent in training or other research-specific activities. See budget attachment for a detail description.

10. CONSENT AND SCREENING

Consent Procedures:

- Survey participants will review an informed consent via RedCAP before continuing the survey for both the intake and outcome surveys (see Appendix I and J)
- Interview participants will provide verbal and written consent before the interview by phone/Microsoft Teams (see Appendix K and L).
- Participants will receive a digital copy of the consent form.
- Workshop/monthly-check in participants will review a written consent form and provide verbal consent before each session occurs.
- There are no screening procedures beyond confirming participants' eligibility (see Appendix A, questions 5-6 in primary care/cardiac rehabilitation/cardiac specialist and questions 5-7 in the Emergency Department for screening eligibility)

Time commitment:
Surveys: ~10-15 minutes

Process Mapping Focus Groups: 4 hours (2 hours pre-implementation and 2 hours post-implementation)

Reoccurring Team Meetings with Sites during the implementation phase: 30-minute monthly check-ins.

Substitute decision-makers:
Not applicable. All participants must be capable of consenting.

10.1 Ongoing Consent/Assent

- Ongoing verbal confirmation of consent will be obtained at the start of each interview.
- Participants will be reminded that they can stop at any time without penalty.
- For surveys, participants may stop at any point and skip questions as they choose.

11. SPECIMEN COLLECTION, STORAGE AND ANALYSIS

N/A

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