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.

ICF Version: October 1st 2024

RESEARCH INFORMED CONSENT FORM – INTAKE SURVEY

Study Title: Improving Care for Adults with Heart Failure and their Mental Well-Being

Version Date: 10-01-2024

REB # ****

This survey is being conducted by Dr. Krystal Kehoe MacLeod at the Bruyère Health Research Institute, working under the supervision of Dr. Vivan Welch. The study is funded by the Brain-Heart Interconnectome's Canada First Research Excellence Fund at the University of Ottawa.

Objectives and Summary:

We're testing a new approach called the FRAME intervention. The goal of this work is to improve healthcare settings such as primary care clinics, hospitals, or rehab programs, and support people with heart failure who also experience emotional or mental health challenges like anxiety, depression, or stress. Once you complete this survey, you will receive the FRAME intervention via email in January 2026. FRAME is designed to help people living with heart failure as well as their families and healthcare providers to better recognize, understand, and seek support for mental health concerns such as stress, anxiety, or depression. The tool includes materials such as tips and resources tailored to heart failure and mental health and suggestions for talking to your provider or caregiver about your needs. Since this is a pre-post intervention study, we will be contacting participants who complete this survey in 6-months to complete a follow-up survey and an optional interview to assess changes in experiences, confidence and behaviours of your mental health journey after exposure to the FRAME intervention. We expect that this survey will take about 5-15 minutes to complete. Your participation in this survey is completely voluntary, and you may choose not to take part, or not to answer any of the questions. If you decide to withdraw after you submit the survey, we will remove your responses from survey data if you notify the researcher by email at kmacleod@bruyere.org within two weeks after the submission of your survey.

Risks and Benefits:

You may find some of the questions to be of sensitive nature and may cause emotional or psychological discomfort when reflecting on personal mental health. You may skip any questions of the survey and withdraw from the study at any time without penalty.

By participating in this survey, you will receive a $5 Tim Hortons gift card by email and access to the FRAME tool in January 2026 and may have indirect benefits. No guaranteed direct benefit is offered. After exposure to the FRAME tool, you may:

- 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.

Confidentiality and Data Storage:

We will treat your personal information as confidential, although absolute privacy cannot be guaranteed. However, research records identifying you may be inspected by the Bruyère Health Research Ethics Board for the purpose of auditing the research. The results of this study may be published, but the data will be presented so that it will not be possible to identify you. De-identified data from this study may be shared with other researchers for verification, and to permit them to build upon our findings. All research data will be securely stored, and password protected at the Bruyère Health Research Institute SharePoint page and the RedCAP server (for survey data). Only authorized research personnel will access this data. After the study is completed, your data will be retained for a minimum period of 10 years for future research purposes, or legal orders.

Ethics Review and Contact Information:

This study has been reviewed and approved by the Bruyère Health Research Ethics Board as study #*****. If you have any ethical concerns about the study, or the way it is conducted, please contact the Bruyère Health REB: REB@bruyere.org.

Consent:

By clicking "I Agree" you agree to participate in the survey.
Would you like to receive a summary of the results from this study when they are available?

___Yes ___No
Email:_____

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

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Contact Details: ICC-BHI@uottawa.ca.

Study Funder: Canada First Research Excellent Fund (CFREF)

Contact Details: ICC-BHI@uottawa.ca.

ICF Version: October 1st 2024

WRITTEN RESEARCH INFORMED CONSENT FORM – WORKSHOPS/MONTHLY-CHECK INS

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

Version Date: 10-01-2024

Name and Contact Information of Researchers

Supervisor and Contact Information: Krystal Kehoe MacLeod (kmacleod@bruyere.org)

Bruyère Health Research Ethics Board Approval

Date of Approval: July 31st, 2025
Study # M16-25-028

Invitation

You are invited to take part in a research study because you are healthcare provider, nurse, administrative staff and/or any relevant staff at a clinic/hospital/program that is involved in the care of heart failure patients. Your participation is entirely voluntary, and a decision not to participate will not be used against you in any way. As you read this form, and decide whether to participate, please ask all the questions you might have, take whatever time you need, and consult with others as you wish.

What is the purpose of the study?

This study aims to evaluate the FRAME tool, a co-designed, web-based intervention developed to improve how mental health is recognized, discussed, and supported in patients with heart failure. While assessing its usefulness, we also aim to understand how it fits within different clinical environments.

What will I be asked to do?

If you agree to take part in the study, we will ask you to:

- A 2-hour process mapping workshop either virtually on Microsoft Teams or in-person at your clinic/hospital based on your preference *before* the FRAME tool is introduced, to help visualize how mental health is currently addressed in your clinical workflow. With your consent, this workshop will be audio-recorded (if in-person) and audio-recorded and video-recorded (if virtual). You may turn off your video if you wish not to be video-recorded.
- A training session (1–2 hours) in January 2026 with healthcare providers on how to use the FRAME tool. This session will occur virtually or in-person at your hospital/clinic based on your preference.
- A 2-hour evaluation workshop after the implementation phase to re-evaluate changes in workflow and practices. This workshop will occur virtually or in-person at your hospital/clinic based on your preference. With your consent, this workshop will be audio-recorded (if in-

person) and audio-recorded and video-recorded (if virtual). You may turn off your video if you wish not to be video-recorded.

- 30-minute monthly virtual check-ins to provide implementation feedback and address any troubleshooting issues during the implementation phase. This is for the site lead/champion only. Other staff in the process mapping workshop is more than welcome to attend these meetings if you wish. With your consent, this workshop will be audio-recorded and video-recorded. You may turn off your video if you wish not to be video-recorded.

Risks and Inconveniences

We do not anticipate any risks to participating in this study.

Possible Benefits

You may not receive any direct benefit. However, your participation may contribute to improving the integration of mental health support in heart failure care for others in the future.

No waiver of your rights

By signing this form, you are not waiving any rights or releasing the researchers from any liability.

Withdrawing from the study

You can withdraw at any time without providing a reason. If you withdraw, you may request that your data be removed from the study. Please notify the Principal Investigator within 2 weeks of your workshop/monthly check-in participation to request data removal.

Confidentiality

We will treat your personal information as confidential, although absolute privacy cannot be guaranteed. However, research records identifying you may be accessed by Bruyère Health Research Ethics Board for the purpose of auditing the research. The Research Ethics Board is responsible for monitoring the research. The audio- recordings will be transcribed by a company called PlayWrite. During the study, the recording and transcript will be held on US servers and subject to US laws and regulations. The company cannot use the recordings or transcriptions for any purpose other than this study. When the study is complete, the company will destroy the audio recordings and transcripts.

The results of this study may be published, but the data will be presented so that it will not be possible to identify any participants without their specific consent. De-identified data from this study may be shared with other researchers for verification, and to permit them to build upon our findings.

All research data will be password-protected at the Bruyère Health Research Institute. Everyone will be asked to respect the privacy of the other group members and asked not to disclose anything said within the context of the discussion. But it is important to understand that other people in the group with you may not keep all information private and confidential.

Data Retention

Your data will be stored and protected by the Bruyère Health Research Institute, in Canada but may be disclosed via a court order or data breach.
After the study is completed, your de-identified data will be retained for a minimum period of 10 years.

New information during the study

In the event that any changes could affect your decision to continue participating in this study, you will be promptly informed.

Ethics Review and Contact Information

This study has been reviewed and approved by the Bruyère Health Research Ethics Board as study # M16-25-028. If you have any ethical concerns about the study, or the way it is conducted, please contact the Bruyère Health REB: REB@bruyere.org

Statement of consent – print and sign name

I _____, have read the information given in this informed consent and all my questions have been answered to my satisfaction. I have had sufficient time to consider whether to participate in this study. I understand that my participation in this study is voluntary and that I may withdraw from the study at any time without penalty.
I voluntarily agree to participate in this study.

I would like you to send me a summary of results from this study when they are available.
___Yes ___No Email:_____

I agree to be contacted for quality improvement and/or feedback purposes by the study team and the Bruyère Health Research Institute.
___Yes ___No Email:_____

I agree to be contacted about future research studies at the Bruyère Health Research Institute.
___Yes ___No Email:_____

I agree to be (audio/video recorded/photographed …) ___Yes ___No

_____ _____
Signature of Participant Date

To the best of my knowledge, the information in this consent form, and the information that I, *(print name)* _____ have provided in response to any questions, fairly represents the study. I am committed to conducting this study in compliance with all the ethical standards that apply to studies that involve human participants. I will ensure that the participant receives a copy of this consent form.

_____	_____
Name of person conducting the consent discussion	Date
_____	_____
Signature of person conducting the consent discussion	Date

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

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Study Funder: Canada First Research Excellent Fund (CFREF)

Contact Details: ICC-BHI@uottawa.ca.

ICF Version: October 1st 2024

WRITTEN RESEARCH INFORMED CONSENT FORM – INTERVIEWS

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

Version Date: 10-01-2024

Name and Contact Information of Researchers

Supervisor and Contact Information: Krystal Kehoe MacLeod (kmacleod@bruyere.org)

Bruyère Health Research Ethics Board Approval

Date of Approval: July 31st 2025
Study # M16-25-028

Invitation

You are invited to take part in a research study because you are either a patient or caregiver involved in heart failure care. The information in this form is intended to help you understand what we are asking of you so that you can decide whether you agree to participate in this study. Your participation is entirely voluntary, and a decision not to participate will not be used against you in any way. As you read this form, and decide whether to participate, please ask all the questions you might have, take whatever time you need, and consult with others as you wish.

What is the purpose of the study?

This study aims to evaluate the FRAME tool, a co-designed, web-based intervention developed to improve how mental health is recognized, discussed, and supported in patients, caregivers, and healthcare providers with heart failure. While assessing its usefulness, we also aim to understand how it fits within different clinical environments.

What will I be asked to do?

If you agree to take part in the study, we will ask you to:

- Participate in a 20–30-minute interview. The interview will explore your experience using the tool and its impact on mental health awareness and help-seeking. Interviews may be conducted individually or as a dyad (patient and caregiver together), depending on preference. This interview will take place by telephone or Microsoft Teams, depending on your preference.
- If the interview is by telephone, with your consent, the interview will be audio recorded, and once transcribed, the recording will be destroyed.
- If the interview is by Microsoft Teams, with your consent, the interview will be video, and audio recorded. Once transcribed, the recording will be destroyed. If you do not wish to be video recorded, you may turn off your video before the start of the interview or at any point during the interview.

Risks and Inconveniences

There are no medical risks to you if you join this study. Some questions or being recorded might make you feel uncomfortable, but you can skip any question or stop recording at any time.

Possible Benefits

You may not receive any direct benefit from your participation in this study. However, your participation may allow researchers to better understand the healthcare and mental health well-being of heart failure patients.

Compensation/Incentives

By completing the interview you will receive a $25 Amazon gift card, sent via email. If you are doing a dyad interview, you will each get a gift card. If you choose to withdraw from the study, you will still receive this compensation.

No waiver of your rights

By signing this form, you are not waiving any rights or releasing the researchers from any liability.

Withdrawing from the study

You can withdraw at any time without providing a reason. If you withdraw, you may request that your data be removed from the study. Please notify the Principal Investigator within 2 weeks of your interview participation to request data removal.

Confidentiality

We will treat your personal information as confidential, although absolute privacy cannot be guaranteed. However, research records identifying you may be accessed by Bruyère Health Research Ethics Board for the purpose of auditing the research. The Research Ethics Board is responsible for monitoring the research. The phone interview recordings will be transcribed by a company called PlayWrite. During the study, the recording and transcript will be held on US servers and subject to US laws and regulations. The company cannot use the recordings or transcriptions for any purpose other than this study. When the study is complete, the company will destroy the audio recordings and transcripts.

The results of this study may be published, but the data will be presented so that it will not be possible to identify any participants without their specific consent. De-identified data from this study may be shared with other researchers for verification, and to permit them to build upon our findings.

All research data will be password-protected at the Bruyère Health Research Institute. Everyone will be asked to respect the privacy of the other group members and asked not to disclose anything said within the context of the discussion. But it is important to understand that other people in the group with you may not keep all information private and confidential.

Data Retention

Your data will be stored and protected by the Bruyère Health Research Institute, in Canada but may be disclosed via a court order or data breach.
After the study is completed, your de-identified data will be retained for a minimum period of 10 years.

New information during the study

In the event that any changes could affect your decision to continue participating in this study, you will be promptly informed.

Ethics Review and Contact Information

This study has been reviewed and approved by the Bruyère Health Research Ethics Board as study # M16-25-028. If you have any ethical concerns about the study, or the way it is conducted, please contact the Bruyère Health REB: REB@bruyere.org

Statement of consent – print and sign name

I _____, have read the information given in this informed consent and all my questions have been answered to my satisfaction. I have had sufficient time to consider whether to participate in this study. I understand that my participation in this study is voluntary and that I may withdraw from the study at any time without penalty.
I voluntarily agree to participate in this study.

I would like you to send me a summary of results from this study when they are available.
___Yes ___No Email:_____

I agree to be contacted for quality improvement and/or feedback purposes by the study team and the Bruyère Health Research Institute.
___Yes ___No Email:_____

I agree to be contacted about future research studies at the Bruyère Health Research Institute.
___Yes ___No Email:_____

I agree to be audio-recorded (telephone interview) and/or video-recorded (virtual interview) ___Yes ___No

_____ _____
Signature of Participant Date

To the best of my knowledge, the information in this consent form, and the information that I, _____ have provided in response to any questions, fairly represents the study. I am committed to conducting this study in compliance with all the ethical standards that apply to studies that involve human participants. I will ensure that the participant receives a copy of this consent form.

_____	_____
Name of person conducting the consent discussion	Date
_____	_____
Signature of person conducting the consent discussion	Date

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Study Funder: Canada First Research Excellent Fund (CFREF)

Contact Details: ICC-BHI@uottawa.ca.

ICF Version: October 1st 2024

RESEARCH INFORMED CONSENT SCRIPT FOR VERBAL CONSENT – WORKSHOPS AND MONTHLY-CHCEK-INS

Study Title: Improving Care for Adults with Heart Failure and their Mental Well-Being

Version Date:
10-01-2024

Hello, my name is (insert name) and I am a [researcher at Bruyère Health Research Institute]. I am working under the supervision of Dr. Krystal Kehoe MacLeod. Thank you for joining us today.

You are being invited to participate in a research study called Integrating Mental Health into Heart Failure Care: A Hybrid Type 1 Pretest-Posttest Feasibility Study of the FRAME Intervention because of your clinic/hospital/program is part of the care of heart failure patients.

For process mapping workshop:

The purpose of this workshop is to help us understand how mental health is currently addressed in your clinic's workflow, and to explore how the FRAME tool might be integrated into this process. Participation today involves a 1.5 to 2-hour virtual or in-person workshop. The session will be audio-recorded to help us accurately document your feedback, but your name and any identifying information will be kept confidential in our notes and reports.

For monthly check-ins (in implementation phase only, will be with same participant(s) as workshops):

The purpose of this meeting is to check-in on any facilitators or barriers you are facing with the FRAME tool, address any troubleshooting issues and receive your feedback. Participation today involves a 30-minute virtual check-in meeting. The sessions will be audio-recorded to help us accurately document your feedback, but your name and any identifying information will be kept confidential in our notes and reports.

Your participation is entirely voluntary. You are free to choose not to answer any questions, and you may stop participating at any time without penalty. There are no known risks to participating, and your insights will help inform improvements to mental health care in your setting.

We will treat your personal information as confidential, although absolute privacy cannot be guaranteed. However, research records identifying you may be accessed by Bruyère Health Research Ethics Board for the purpose of auditing the research. The Research Ethics Board is responsible for monitoring the research. The audio-recordings will be transcribed by a company called PlayWrite. During the study, the recording and transcript will be held on US servers and subject to US laws and regulations. The company cannot use the recordings or transcriptions for any purpose other than this study. When the study is complete, the company will destroy the audio recordings and transcripts.

The results of this study may be published, but the data will be presented so that it will not be possible to identify any participants without their specific consent. De-identified data from this study may be shared with other researchers for verification, and to permit them to build upon our findings.

All research data will be password-protected at the Bruyère Health Research Institute. Everyone will be asked to respect the privacy of the other group members and asked not to disclose anything said within the context of the discussion. But it is important to understand that other people in the group with you may not keep all information private and confidential.

Your data will be stored and protected by the Bruyère Health Research Institute, in Canada but may be disclosed via a court order or data breach.After the study is completed, your de-identified data will be retained for a minimum period of 10 years.

If you decide to withdraw after the workshop/check-in, your responses will be removed if you notify the researcher or principal investigator at kmacleod@bruyere.org within two weeks of the workshop/check-in date.

Ethics Review and Contact Information

This study has been reviewed and approved by the Bruyère Health Research Ethics Board as study #*****. If you have any ethical concerns about the study, or the way it is conducted, please contact the Bruyère Health REB: REB@bruyere.org.

You can also reach me at [interviewer contact information]. You may contact my supervisor at kmacleod@bruyere.org

Do you have any questions about this study or need any clarification?

Do I have your permission to begin? Yes___ No___

Do you agree to be audio recorded? Yes___ No___

Do you agree to be contacted with a summary of results from this study when they are available? Yes___ No___ Email:_____

Do you agree to be contacted if you are eligible for future studies? Yes___ No___

Do you agree for de-identified data collected in this study to be used for secondary data analysis? For example, if we want to compare results from this study to another study. Yes___ No_

Participant's Name/Pseudonym/Initials: _____

_____ _____

Name of person conducting the consent discussion Date

_____	_____
Signature of person conducting the consent discussion	Date

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Study Funder: Canada First Research Excellent Fund (CFREF)

Contact Details: ICC-BHI@uottawa.ca.

ICF Version: October 1st 2024

RESEARCH INFORMED CONSENT FORM – OUTCOME SURVEY

Study Title: Improving Care for Adults with Heart Failure and their Mental Well-Being

Version Date: 10-01-2025

REB # M16-25-028

We are inviting you to complete this survey because you are a patient with heart failure, or on heart-failure related medications or have completed the intake survey. This survey is being conducted by Dr. Krystal Kehoe MacLeod at the Bruyère Health Research Institute, working under the supervision of Dr. Vivan Welch. The study is funded by the Brain invite you to complete this survey because you are a patient with heart failure, are currently taking heart-failure-related medications, or have already -Heart Interconnectome's Canada First Research Excellence Fund at the University of Ottawa.

Objectives and Summary:

We're testing a new approach called the FRAME intervention. The goal of this work is to improve healthcare settings such as primary care clinics, hospitals, or rehab programs, and support people with heart failure who also experience emotional or mental health challenges like anxiety, depression, or stress. Once you complete this survey, you will be asked if you wish to participate in a 20–30-minute optional interview to assess changes in experiences, confidence and behaviours of your mental health journey after exposure to the FRAME intervention. You will be compensated for your time following the interview. We expect that this survey will take about 5-15 minutes to complete. Your participation in this survey is voluntary, and you may choose not to take part, or not to answer any of the questions. If you decide to withdraw after you submit the survey, we will remove your responses from survey data if you notify the researcher by email at kmacleod@bruyere.org within two weeks after the submission of your survey.

Risks and Benefits:

You may find some of the questions to be of sensitive nature and may cause emotional or psychological discomfort when reflecting on personal mental health. You may skip any questions of the survey and withdraw from the study at any time without penalty.

By participating in this survey, you will receive a $5 Tim Hortons gift card by email. No guaranteed direct benefit is offered. After exposure to the FRAME tool, you may:

- 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.

Confidentiality and Data Storage:

We will treat your personal information as confidential, although absolute privacy cannot be guaranteed. However, research records identifying you may be inspected by the Bruyère Health Research Ethics Board for the purpose of auditing the research. The results of this study may be published, but the data will be presented so that it will not be possible to identify you. De-identified data from this study may be shared with other researchers for verification, and to permit them to build upon our findings. All research data will be securely stored, and password protected at the Bruyère Health Research Institute SharePoint page and the RedCAP server (for survey data). Only authorized research personnel will access this data. After the study is completed, your data will be retained for a minimum period of 10 years for future research purposes, or legal orders.

Ethics Review and Contact Information:

This study has been reviewed and approved by the Bruyère Health Research Ethics Board as study #*****. If you have any ethical concerns about the study, or the way it is conducted, please contact the Bruyère Health REB: REB@bruyere.org.

Consent:

By clicking "I Agree" you agree to participate in the survey.
Would you like to receive a summary of the results from this study when they are available?

___Yes ___No
Email:_____