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The Second Heart Program: an intervention for individuals who have infective endocarditis who inject drugs

Submission date 25/11/2020	**Recruitment status** No longer recruiting	[_] Prospectively registered [X] Protocol
Registration date 13/01/2021	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 04/03/2024	**Condition category** Circulatory System	[_] Individual participant data [_] Record updated in last year

Plain English summary of protocol

Background and study aims

There are gaps in care after hospital discharge for people who inject drugs and who are admitted for infective endocarditis (an infection of the inner surface of the heart). Some of these gaps include access to care, access to social services (housing, transportation, security), the lack of harm reduction strategies talked about in a hospital setting, and stigma in the healthcare system around drug use. Researchers have developed a program called Second Heart. This program involves a healthcare team with the goal of addressing some of the medical, psychosocial, and health system challenges of people who inject drugs with infective endocarditis. This study aims to assess whether this program is feasible – so whether or not the program is possible to run in a healthcare setting. Some things the researchers are interested in understanding from this study are: the number of people who enroll in the program, complete the program, and the perceived strengths and weakness of the program for those enrolled, as well as program costs. The researchers can use the answers to some of these questions to decide whether or not to run the program on a wider scale and/or what would need to be changed in order for it to work better.

Who can participate?

Patients admitted to either St Joseph's Hospital or Hamilton General Hospital for infective endocarditis in the context of a history of substance use. They are over the age of 18, can speak English and live in the City of Hamilton.

What does the study involve?

Participants will be connected to the Second Heart Program, which includes access to four people:

1. A peer support worker is someone with substance use lived experience. A peer support worker will provide harm reduction education while participants are in the hospital. After hospital discharge, the peer support worker will connect them to harm reduction services, provide social support, and assist them in attending medical appointments. The peer support worker will initially make contact with them in the hospital, then connect weekly for the first month after discharge, and then every 2 weeks thereafter until 12 months after discharge. The

peer support worker is hired through the Canadian Mental Health Association (CMHA) in Hamilton, and has received standardized training and are coordinated through an organization.
2. A systems navigator is a person who assists patients in coordinating the health care and social services systems. The systems navigator will link them to community resources, addiction services, income support, transportation recourses and assist them in follow-up appointments. The system navigator will connect with patients in hospital every 2 weeks for the first 3 months after discharge, and monthly from 3-12 months, or upon request.
3. An addiction medicine physician is part of the hospital's Inpatient Addiction Service. This is something that is currently standard of care in the Hamilton General Hospital and St. Joseph's Healthcare Hamilton. This person may offer medication-assisted treatment if indicated. If treatment is initiated, a transfer of care will be arranged to appropriate community-based addictions care upon discharge. A consultation from the addiction physician is not a requirement for enrollment. If participants request an addiction consultation as an outpatient, they will be referred to the Rapid Access Addiction Medicine clinic or to a clinic of their preference in the community.
4. A primary care physician (family physician) provides primary care to people. If patients do not currently have a family physician, they will be connected to one following discharge from hospital. This person will coordinate their ongoing healthcare needs. If patients already have a family physician, the research team will seek to engage your physician as part of the treatment team. The family physician will be able to access the other members of the intervention team (peer support worker, systems navigator, addiction medicine physician) to assist them and maintain open communication throughout the study period.
While in the Second Heart program, data will be collected in order to understand how the program is working and is not working so as to improve the program next time. The research assistant will connect at 1, 3, 6, and 12 months after discharge to ask participants questions about their healthcare use and how the program is working for them. This will happen over the phone or in-person at David Braley Health Sciences Centre, depending on their preference. In addition, at 3 and 12 months the research assistant will conduct a one-on-one interview with participants to get a better understanding of how the program is working and is not working, and to understand their overall experience of the program. This interview is audio-recorded and takes about 30 minutes. In total it will take about 2 hours across the 12 months (two 30-minute interviews and four 15-minute check-ins).
In addition, the researchers will be collecting relevant data from electronic medical records. They are also requesting consent to link the data to provincial and federal administrative databases if required.

What are the possible benefits and risks of participating?
The researchers do not anticipate that there will be any harm from taking part in this study. Some people may feel uncomfortable sharing their opinions or talking about their drug use. There are no direct benefits to participants aside from contributing to the scientific community.

Where is the study run from?
McMaster University (Canada)

When is the study starting and how long is it expected to run for?
February 2020 to March 2024

Who is funding the study?
Hamilton Academic Health Sciences Organization (Canada)

Who is the main contact?
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Contact information

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Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
Nil known

Study information

Scientific Title
The Second Heart Program: a peer-focused, multidisciplinary harm reduction intervention to improve outcomes for people who inject drugs after admission for infective endocarditis

Acronym
Second Heart

Study objectives
The overall objective of this study is to assess the feasibility of the Second Heart Program. For the following research questions, the category of consideration based on recommendations for feasibility studies.
1. What is the enrollment, completion and drop-out rate of participants?
2. What are the reasons for drop-out among participants?
3. What is the perceived acceptability of the process of the intervention to eligible participants? (process)
4. What is the number and nature of unintended (or negative) outcomes?
5. How often do peer support workers and systems navigator connect with participants? (resources)
6. What is the nature of the supports/contact points provided by peer support workers and system navigator?
7. What are the program costs (i.e., cell phones, human resources, travel)?
8. What is the number and nature of challenges in the collection of data throughout study? (management)
9. What is the reinfection, readmission, and reintervention rates for participants?
10. What is the mortality rate 1-year post-hospitalization for IE?
11. What is the number of touch points with cardiovascular surgery, cardiology, infectious disease, systems navigator, primary care physician, addictions services in hospital and 1-year post-discharge?
12. What are the perceived strengths (impacts), weaknesses (challenges), opportunities, and threats of the program from the perspective of patients, peer support workers, healthcare providers?

Ethics approval required

Old ethics approval format

Ethics approval(s)
Approved 05/02/2020, Hamilton Integrated Research Ethics Board (293 Wellington Street North, Suite 102, Hamilton ON, L8L 8E7; +1 (0)905 521 2100 x70014; erebhelpdesk@hhsc.ca), Project # 7012

Study design
Convergent mixed-methods study design

Primary study design
Interventional

Study type(s)
Other

Health condition(s) or problem(s) studied
People who inject drugs after admission for infective endocarditis

Interventions
The proposed innovation (Second Heart Program) is a peer-focused, multidisciplinary harm reduction intervention strategy to address gaps in the current management of PWID with IE. The Second Heart Program is a novel clinical program intended to address the medical, psychosocial, and health system challenges encountered by PWID with IE. The unique multidisciplinary model of addiction medicine physicians, peer support workers with lived experience, a system navigator, and a primary care physician is intentionally designed to serve the needs of PWID with IE. The Second Heart Program is the first program specifically designed to transition PWID and IE from hospital to community utilizing a multidisciplinary team.

Participants will be connected to the Second Heart Program, which includes access to four people:
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In addition, the researchers will be collecting relevant data from electronic medical records. They are also requesting consent to link the data to provincial and federal administrative databases if required.

Intervention Type
Other

Primary outcome(s)
1. Recruitment rate recorded as the number of eligible participant who consent to participate in the study by 12 months
2. Attrition rate recorded as the number of participants who consent to participate that remain in the study until the end of follow up at 12 months

Key secondary outcome(s))
1. Patient information (including descriptive demographic data, social determinants of health, medical history, substance use history, access to harm reduction and community resources, and treatment plan and patient goals) will be collected by a combination of self-report and electronic medical record chart review at baseline and 12-months post-discharge
2. Resource feasibility outcomes (number and nature of connections with the peer support worker and systems navigator) will be tracked in an appointment tracking file with every contact they come into with patient. Program costs will be extracted from financial reports yearly
3. Management feasibility outcomes (number and nature of challenges in data collection) will be recorded by a memo note ongoing throughout the study
4. Scientific feasibility outcomes (reinfection, readmission, and reintervention rate at 1, 3, 6, and 12-months, 1-year post-discharge mortality rate, number of touch points with cardiovascular surgery, cardiology, infectious disease, systems navigator, primary care physician, addictions services in hospital and 1-year post-discharge) will be extracted from the electronic medical record for each patient. These outcomes will also be collected via self-report survey at 1, 3, 6, and 12 months
5. Perceived strengths, weaknesses, opportunities, and threats of the program and perceived acceptability will be explored via 1-on-1 semi-structured interviews with patients (at 3- and 12-

months post-discharge), peer support workers, addiction medicine physicians, systems navigator, primary care physician, peer support worker coordinator at 12 months. Clinicians who co-manage these patients during their in-patient stay (cardiovascular surgery, internal medicine, cardiology) and other community partners (primary care physicians, addictions care providers) will be asked to complete an open-ended survey to assess their perceived strengths, weaknesses, opportunities, and threats of the program, as well as acceptability of the program at study end

Completion date
11/03/2024

Eligibility

Key inclusion criteria
1. Age 18 or older
2. Able to provide informed consent in English
3. Admitted to either St Joseph's Hospital or Hamilton General Hospital located in Hamilton with the diagnosis of infective endocarditis at the time of recruitment
4. History of injection drug use within 3 months of recruitment

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. Does not live in the City of Hamilton

Date of first enrolment
01/12/2020

Date of final enrolment
15/03/2023

Locations

Countries of recruitment
Canada

Study participating centre
Hamilton General Hospital
237 Barton Street East
Hamilton
Canada
L8L 2X2

Study participating centre
St. Joseph's Healthcare Hamilton
50 Charlton Avenue East
Hamilton
Canada
L8N 4A6

Sponsor information

Organisation
McMaster University

ROR
https://ror.org/02fa3aq29

Funder(s)

Funder type
University/education

Funder Name
Hamilton Academic Health Sciences Organization

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated and/or analyzed during the current study during this study will be included in the subsequent results publication

IPD sharing plan summary
Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		28/10/2021	29/10/2021	Yes	No
Participant information sheet	Participant information sheet version v4	11/11/2025	11/11/2025	No	Yes
Protocol file		29/10/2020	04/02/2021	No	No