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Can the mobile phone app Medly improve self-care and quality of life of patients who have been in hospital for heart failure?

Submission date	Recruitment status	[_] Prospectively registered
11/11/2018	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
21/01/2019	Ongoing	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
16/04/2025	Circulatory System	[X] Record updated in last year

Plain English summary of protocol

Background and study aims

Heart failure is a chronic illness that happens when the heart is unable to pump well enough to properly support the body's needs. Many people with heart failure run the risk of getting hospitalized frequently and are at high risk of death. This study aims to explore the impact of a mobile phone-based home monitoring system that allows participants to record their weight, blood pressure, heart rate, and symptoms. The home monitoring system provides patients with self-care instructions and their healthcare providers are alerted when it appears that the patient's health is getting worse. This study aims to determine the impact of the home monitoring system on self-care, quality of life, and other health outcomes.

Who can participate?

Participants must be 18 years of age or older. There are no gender restrictions. Participants must be able to read and understand English (or have a caregiver who can assist them) in order to complete the study questionnaires and be able to follow the instructions on Medly. Participants must have heart failure and have been hospitalized for 48 hours or more within 2 weeks of beginning the study.

What does the study involve?

Standard care for a person with heart failure who has recently been hospitalized is to receive self-care instructions from their healthcare provider regarding dietary restrictions, exercise, symptom management and an explanation of how to appropriately take their medications. Both groups in the study will receive this standard care. The intervention group will also receive a blood pressure cuff, scale and smartphone with the Medly app pre-loaded onto it. Participants in the intervention group will use the Medly app and equipment to record their weight, blood pressure, heart rate and symptoms every morning. Once complete, the app will provide a self-care message depending on their measurements, and their clinician will be alerted if necessary. Their heart failure clinicians will also be able to see these measurements to keep track of their health status in between clinic visits.

Participants in both groups will be asked to complete a baseline questionnaire within 24 hours of being enrolled in the study and then one at the end of the study (after 3 months of being enrolled). Participants may be asked to take part in an interview that can be done over the phone. When contacted, participants can always decline the interview. Questions will be similar to those asked in the questionnaire but with more detail.

What are the possible benefits and risks of participating?
Participants may or may not experience benefits from the study. The only known risk is that some participants may feel uncomfortable or have anxiety about taking their measurements every morning. Participants are welcome to discuss this with their healthcare team and are also able to withdraw from the study at any time. It is believed that this discomfort would not persist if they withdraw from the study.

Where is the study run from?
1. Sunnybrook Health Sciences Centre, Canada
2. Mt. Sinai Hospital, Canada
3. North York General Hospital, Canada

When is the study starting and how long is it expected to run for?
November 2018 to September 2025

Who is funding the study?
This study is funded by the Ted Rogers Centre for Heart Research and the Sunnybrook AFP Innovation Fund.

Who is the main contact?
The main contact for this study will be Dr. Emily Seto, the co-Principal Investigator along with Dr. Stephanie Poon. She can be reached at Emily.Seto@utoronto.ca.

Contact information

Type(s)
Public

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number
NCT03358303

Secondary identifying numbers
17-5887

Study information

Scientific Title
Medly-AID: Effect of a mobile phone-based telemonitoring program on the outcome of heart failure patients After an Incidence of acute Decompensation

Acronym
Medly-AID

Study objectives
If heart failure patients use the telemonitoring system after discharge from hospital, then they will perform better self-care and have improved health outcomes including quality of life.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. University Health Network Research Ethics Board (approval number 17-5887): 15/01/2018
2. Sunnybrook Health Sciences Centre Research Ethics Board (approval number 143-2017): 13/09/2017
3. Mt. Sinai Hospital Research Ethics Board (approval number 19-0231-E): 16/10/2019 (added 13/12/2019)
4. North York General Hospital Ethics Board (approval number 20-0046): 23/11/2020 (added 14/01/2022)

Study design
Randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised parallel trial

Study setting(s)
Hospital

Study type(s)

Diagnostic

Participant information sheet

Health condition(s) or problem(s) studied
Heart failure

Interventions
Every patient at each site will be randomized to either the intervention or control group. For each participating site, block randomization will be used with random block sizes of 2, 4, or 6. The study coordinator will be blinded to which group the patient will be assigned until he/she has consented to participate in the study. The control group will receive standard of care, while the patients in the intervention arm will receive standard of care plus the telemonitoring.

Control Group: Standard of care of HF patients being discharged from hospital include receiving discharge instructions for self-care at home (ie. dietary restrictions, symptoms), prescription for home medications and a follow-up appointment with a primary care provider or specialized hospital clinic (internal medicine, heart function).

Intervention Group: In addition to the standard of care mentioned above, on discharge from hospital, each patient in the intervention group will receive a Medly kit that includes a smart phone with a limited data plan, a Bluetooth-enabled weight scale, and a blood pressure cuff.

Each participant will be in the study for a total of 3 months. They will be asked to complete their questionnaires at baseline (within 24h of joining the study) and again at the 3-month end point. Patients in the Medly group will return their equipment at this point as well. Bloodwork and any heart failure-related hospitalizations during this 3-month period will also be recorded for data analysis.

Intervention Type
Device

Pharmaceutical study type(s)
Not Applicable

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Medly kit

Primary outcome measure
1. Self-care of heart failure, as measured with the Self-Care of Heart Failure Index (SCHFI) will be measured at baseline and 3 months.
2. Quality of life, as measured with the Kansas City Cardiomyopathy Questionnaire (KCCQ-12) and EuroQol (EQ5D) at baseline and 3 months.
3. Heart failure classification (NYHA class) will be measured using clinical notes at baseline and 3 months.
4. Brain natriuretic peptide (BNP) levels will be measured at baseline and 3 months.
5. Compliance with Medly utilization will be measured using the Medly database at 3 months.

Secondary outcome measures
1. 30-day HF re-admission rate will be measured using clinical notes at 3 months.
2. Length of hospital stay will be measured using clinical notes at 3 months.
3. Number of visits to the emergency department (ED) will be measured using the discharge summary at baseline and 3 months.
4. Creatinine levels will be measured at baseline and 3 months.
5. Sodium levels will be measured at baseline and 3 months.
6. Potassium levels will be measured at baseline and 3 months.

Overall study start date
01/01/2017

Completion date
01/09/2025

Eligibility

Key inclusion criteria
1. Aged 18 years or older
2. Hospitalization for decompensated heart failure (HF) for >48 h
3. Speaks and reads English adequately to provide informed consent and understand the text prompts in the application
4. Ability to comply with using Medly (for example, able to stand on the weight scale, able to answer symptom questions, etc.)

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
150

Total final enrolment
90

Key exclusion criteria
Current exclusion criteria as of 13/12/2019:
1. Dementia
2. Resident of long-term care facility
3. Will require inpatient rehabilitation after discharge
4. Participating in another clinical trial that could conflict/confound results

_____
Previous exclusion criteria:
1. Dementia
2. Resident of long-term care facility
3. Will require inpatient rehabilitation after discharge
4. Participating in another clinical trial

Date of first enrolment
16/11/2018

Date of final enrolment
01/03/2023

Locations

Countries of recruitment
Canada

Study participating centre
Sunnybrook Health Sciences Centre
2075 Bayview Ave
Toronto
Canada
M4N 3M5

Study participating centre
The Mount Sinai Hospital
600 University Ave
Toronto
Canada
M5G 1X5

Study participating centre
North York General Hospital
4001 Leslie St
Toronto
Canada
M2K 1E1

Sponsor information

Organisation
University Health Network

Sponsor details
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M5G 2C4
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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/042xt5161

Funder(s)

Funder type
Government

Funder Name
AHSC AFP Innovation Fund

Funder Name
Ted Rogers Centre for Heart Research

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal.

Intention to publish date
01/09/2025

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are not expected to be made available because data contains personal health information that would require consent from patients to be used for other research, as well as appropriate research ethics board approval.

IPD sharing plan summary

Not expected to be made available