

Improving medication adherence and satisfaction with pharmacist-provided services for heart failure patients using a risk management dashboard

Submission date 02/09/2024	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 03/09/2024	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 30/10/2024	Condition category Circulatory System	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

Heart failure with reduced ejection fraction (HFrEF) is a severe health issue, leading to frequent hospital visits and high death rates. Although there are effective treatments available, many patients do not take their medications as prescribed, which worsens their condition. This study aims to see if using an interactive patient-centered dashboard during pharmacist consultations can help patients better understand their condition, stick to their medication schedule, and be more satisfied with the services provided by pharmacists.

Who can participate?

Adults aged 20 years or older diagnosed with HFrEF can participate and receive care at the National Taiwan University Hospital (NTUH), including its pharmacist-led heart failure clinic, cardiology department, or cardiology ward. Participants need to be able to give consent and complete some simple questionnaires.

What does the study involve?

Participants will be randomly assigned to receive either standard care from a pharmacist or standard care with the addition of an interactive dashboard. The dashboard will show personalized risk and survival information to help patients understand their health better. Participants will complete short questionnaires at the start and after 3 and 6 months to measure how well they follow their medication plan and how satisfied they are with the pharmacist's help.

What are the possible benefits and risks of participating?

Participants may become more actively involved in their treatment process. By better understanding their current health status and medications, they are more likely to improve their medication adherence. This increased engagement and understanding can lead to better health outcomes and greater satisfaction with the pharmacy care they receive. The study may also help

develop better tools for managing heart failure.

The risks are very low, but some participants might feel anxious or uncomfortable seeing their health information on the dashboard.

Where is the study run from?

National Taiwan University Hospital (Taiwan)

When is the study starting and how long is it expected to run for?

April 2024 to October 2025

Who is funding the study?

National Taiwan University (Taiwan)

Who is the main contact?

Dr Wan-Tseng Hsu, wantsenghsu@ntu.edu.tw and wantsenghsu@gmail.com

Contact information

Type(s)

Public, Scientific, Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

Protocol serial number

Nil known

Study information

Scientific Title

A pragmatic improvement for medication adherence and patient satisfaction with pharmacist services with an interactive dashboard for heart failure with reduced ejection fraction

Acronym

PRIME PharmD-HFrEF

Study objectives

Integrating a dashboard within pharmacist-led interventions can improve medication adherence among patients with heart failure with reduced ejection fraction (HFrEF).

Ethics approval required

Ethics approval required

Ethics approval(s)

approved 22/08/2024, National Taiwan University Hospital Research Ethics Committee B (No.7, Chung Shan S. Rd. Zhongshan S. Rd., Zhongzheng Dist., Taipei, 100, Taiwan; +886 (0)2 2312 3456 ext. 263417; ntuhrec@ntuh.gov.tw), ref: 202001049RINB

Study design

Single-center pragmatic two-arm crossover randomized controlled trial

Primary study design

Interventional

Study type(s)

Other

Health condition(s) or problem(s) studied

Heart failure

Interventions

Before conducting the education sessions, the pharmacists will review the patients' medical records, including medications and laboratory data, using the portal system. This review is part of their standard routine before patient education into which dashboard interventions will be pragmatically integrated. After the screening, potential participants will first be invited by their attending pharmacist. The researchers will allocate participants to treatment groups using permuted block randomization to ensure a balanced distribution across the groups, with permuted blocks of size 4. Eligible and consenting participants randomly assigned to Group A will receive standard pharmacist-led education (e.g., regular follow-ups and medication education) along with the dashboard intervention, while those in Group B will receive only standard pharmacist-led education, with a crossover occurring after 3 months. The dashboard intervention is pragmatically incorporated into patient education.

Intervention Type

Other

Primary outcome(s)

Medication adherence will be assessed using the Morisky 8-item Medication Adherence Scale (MMAS-8) at baseline (T0), 3 months (T1), and 6 months (T2) after randomization.

Key secondary outcome(s)

1. Patient satisfaction with pharmacist services will be evaluated using the adapted Chinese version of the Patient Satisfaction with Pharmacist Services Questionnaire 2.0 (C-PSPSQ 2.0) at baseline (T0), 3 months (T1), and 6 months (T2) after randomization.

2. Facilitators and barriers to the implementation: To explore potential facilitators and barriers to the implementation of the dashboard, a subgroup of pharmacists and patients will complete the Acceptability of Intervention Measure, Intervention Appropriateness Measure, and Feasibility of Intervention Measure (AIM-IAM-FIM) questionnaire at 6 months (T2) after randomization.

Completion date

31/10/2025

Eligibility

Key inclusion criteria

Patients with heart failure and a documented left ventricular ejection fraction (LVEF) <40%

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Key exclusion criteria

1. Patients unable to provide full informed consent
2. Patients unable to comply with study procedures
3. Patients unable to complete the required questionnaires in person on three occasions or return for follow-up visits
4. Patients who cannot understand or respond to the required questionnaires

Date of first enrolment

01/02/2025

Date of final enrolment

31/03/2025

Locations

Countries of recruitment

Taiwan

Study participating centre

National Taiwan University Hospital

No.7, Chung Shan S. Rd.

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Zhongzheng Dist.
Taipei
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Sponsor information

Organisation

National Taiwan University Hospital

ROR

<https://ror.org/03nteze27>

Funder(s)

Funder type

University/education

Funder Name

National Taiwan University

Alternative Name(s)

, NTU

Funding Body Type

Government organisation

Funding Body Subtype

Local government

Location

Taiwan

Results and Publications

Individual participant data (IPD) sharing plan

All de-identified data and dashboard code supporting this study may be provided upon reasonable written request from the corresponding author of the original article. The full protocol, final de-identified dataset, and statistical code will be made available exclusively for scientific purposes after the publication of the study outcomes.

IPD sharing plan summary

Available on request