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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	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 03/09/2024	**Overall study status** Ongoing	
Last Edited 30/10/2024	**Condition category** Circulatory System	

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

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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

Secondary study design
Randomised cross over trial

Study setting(s)
Hospital

Study type(s)
Other

Participant information sheet
Not available in web format, please use the contact details to request a participant information sheet

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 measure
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.

Secondary outcome measures
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.

Overall study start date
01/04/2024

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

Age group
Adult

Sex
Both

Target number of participants
70

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.
Zhongshan S. Rd.
Zhongzheng Dist.
Taipei
Taiwan
100

Sponsor information

Organisation
National Taiwan University Hospital

Sponsor details
No.7, Chung Shan S. Rd.
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111361@ntuh.gov.tw

Sponsor type
Hospital/treatment centre

Website
http://www.ntuh.gov.tw/en/default_P.aspx

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

Publication and dissemination plan
Upon completion, the study protocol and trial results will be submitted for publication in international peer-reviewed journals. These publications will ensure that the findings are well-communicated.

Intention to publish date
31/10/2026

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