Patient Preference and Adherence

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STUDY PROTOCOL

Improving Medication Adherence in Heart Failure Through Pharmacist-Led Patient Education: Protocol for a Mechanism-Based Study of Information, Motivation, and Behavioral Skills

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Background: Heart failure (HF) remains a major global health challenge. Guideline-directed medical therapy can effectively reduce mortality and hospitalizations; however, persistent medication nonadherence hinders its real-world impact. Although recent guidelines emphasize the pivotal role of pharmacists in supporting medication adherence, the mechanisms through which pharmacist-led patient education influences medication adherence remain underexplored. Identifying these mechanisms could inform the development of evidence-based strategies to optimize medication adherence and ultimately improve long-term outcomes in HF management.

Objective: This study aims to establish an Information–Motivation–Behavioral Skills (IMB) model to elucidate the mechanisms influencing medication adherence among patients with HF and to compare pre- and postintervention models for identifying significant pathways affected by pharmacist-led patient education.

Methods: In this longitudinal pretest–posttest study, all IMB constructs—information, personal motivation, social motivation, behavioral skills, and behavior—will be assessed using validated patient-reported outcome measures (PROMs) at baseline and three and six months postintervention; additionally, verbal inquiries will be conducted to evaluate the information construct and prescription refill data will be incorporated to supplement the behavior construct. Multigroup structural equation modeling will examine relationships among these constructs and their impact on medication adherence. Latent class growth modeling will also be employed to identify distinct adherence trajectory subgroups after six-month follow-up.

Expected Outcomes: The recruitment phase commenced in early May 2025. By evaluating structural changes in IMB pathways pre- and postintervention using PROMs, followed by identifying short-term and sustained responders, the study is expected to facilitate the precise targeting of pharmacist-led interventions to maximize clinical impact. This approach emphasizes the importance of tailoring healthcare delivery to individual medication adherence profiles. It aims to ensure that pharmacist-led patient education achieves its fullest potential in populations expected to benefit the most, particularly patients with HF—a perspective that, to our knowledge, has not been previously explored.

Keywords: information–motivation–behavioral skills model, heart failure, pharmacist-led patient education, structural equation modeling, medication adherence, latent class growth modeling

Introduction

Heart failure (HF) is a pervasive and quintessential clinical syndrome that disproportionately affects geriatric populations, contributing to poor health-related quality of life (HRQoL)[1] and remaining a leading global health concern.[2] In 2019, an estimated 56 million individuals worldwide were battling HF; its prevalence is projected to increase from 2.4% in 2012 to 3.0% by 2030.[3] Significant progress has been made in improving outcomes, especially for patients with HF

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with reduced ejection fraction (HFrEF), a condition characterized by high hospitalization rates and mortality.[4,5] Recent advances are attributed primarily to guideline-directed medical therapy (GDMT), which has been shown to reduce hospitalizations, improve survival rates, and enhance HRQoL.[6–8] Given the promising benefits of GDMT, high utilization rates would be expected in real-world settings.

However, the persistent issue of medication nonadherence continues to limit the transformative potential of GDMT for patients with HF.[9] This issue is particularly pronounced in geriatric populations, who experience the greatest HF burden, thereby undermining the benefits of GDMT and resulting in poor prognoses.[10,11] Medication adherence, which mediates the association between HRQoL and survival,[5] is challenged by the compounded effects of polypharmacy, adverse side effects, inherent aging-related frailties, and comorbidities.[12,13] Current HF guidelines still mandate an essential compromise and advocate the use of multiple medications (often exceeding five) exclusively for HF management, implicitly framing polypharmacy as an unavoidable trade-off to achieve optimal patient outcomes.[7] This paradox reinforces polypharmacy as both a sanctioned standard and a persistent barrier to medication adherence in the populations,[14] which contributes to the deterioration of HRQoL.[15] Consequently, adherence rates are only 40%–60%, reflecting the difficulty in achieving and sustaining optimal medication use.[16] Clinical inertia among healthcare professionals and intolerance among patients with HF further complicate this landscape and hinder the full implementation of GDMT.[17] Therefore, nonadherence continues to impede optimal HF outcomes, and the promise of GDMT can be realized only if this issue is effectively addressed.[18]

HF clinical practice guidelines (the 2022 American Heart Association, American College of Cardiology, Heart Failure Society of America [AHA/ACC/HFSA]) recognize that nonadherence jeopardizes the potential of GDMT and underutilization compromises its outcomes.[19] However, patients with HF often face unique challenges, with worse outcomes among older patients compared with their younger counterparts.[13,20,21] This scenario demands dedicated efforts to refine care strategies that specifically target patients with HF, many of whom face ongoing risks related to health disparities.[20,21]

The ACC/AHA/HFSA emphasizes a collaborative, team-based approach that has become prominent in HF management.[7] Notably, pharmacists are indispensable in reinforcing medication adherence and facilitating the appropriate use of GDMT among patients with HF.[7,22] For example, pharmacists optimize GDMT by offering evidence-based recommendations, deprescribing potentially inappropriate medications, monitoring drug–drug interactions, and performing drug use evaluations to prevent medication-related issues.[23–25] Such pharmacist-led interventions have delivered wide-ranging favorable outcomes in both inpatient and outpatient settings,[23–26] and these positive outcomes support the integration of pharmacists into multidisciplinary HF management teams,[22,27] especially for improving medication adherence.[28–32]

Nevertheless, the benefits of pharmacist-led interventions could dissipate over time, particularly after active intervention ends.[30] Thus, critical concerns arise about gaps in the sustainability and long-term effectiveness of such initiatives. Additionally, mechanisms influencing medication adherence (e.g., motivational factors, behavioral tendencies, and patient–pharmacist interactions) remain insufficiently understood. Intensive exploration of such mechanisms could inform the development of sustainable and effective pharmacist-led interventions that can continually improve medication adherence and HRQoL, eventually optimizing HF outcomes.

The Information–Motivation–Behavioral Skills (IMB) model, developed by Jeffrey D. Fisher and William A. Fisher in 1992, offers a promising theoretical framework for addressing the complexities of health behavior change.[33] Originally designed to promote acquired immunodeficiency syndrome-preventive behaviors,[34] the IMB model has since been applied to various health-related behaviors, including medication adherence.[35–37] The model comprises four core components—information, personal motivation, social motivation, and behavioral skills—which interact to influence the enactment of health-related behaviors, conceptualized as the fifth construct (Figure 1).[33]

Specifically, information refers to reliable and accurate knowledge about health behaviors and their implications, facilitating behavioral changes; conversely, misinformation can hinder this process. In the context of medication adherence, information entails understanding the importance of adhering to prescribed regimens, recognizing potential side effects, and comprehending the consequences of nonadherence. Healthcare practitioners, particularly pharmacists, are crucial in delivering information through effective communication and education.[38]

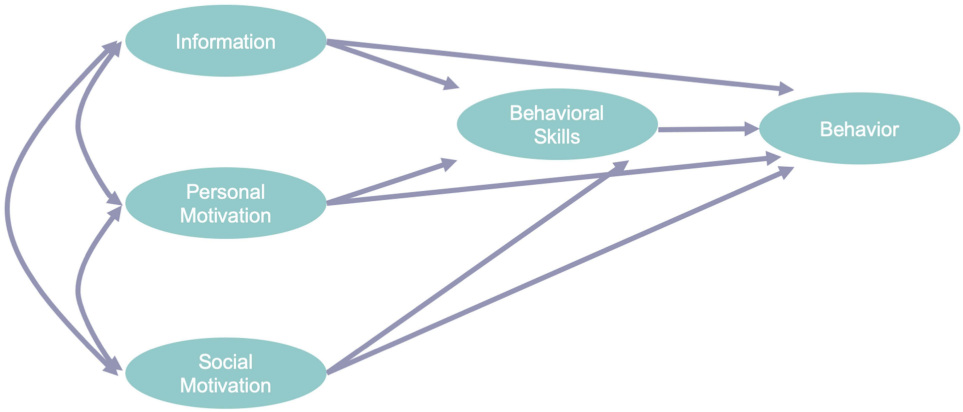

Figure 1 Structure of the Information–Motivation–Behavioral Skills (IMB) model. The IMB model illustrates the relationships between information, motivation (personal and social), behavioral skills, and behavior. The model demonstrates how these components influence behavior, with behavioral skills mediating the effects of information and motivation on behavior.

Motivation encompasses both personal and social dimensions.[39] Personal motivation reflects individual values, attitudes, and beliefs toward health behaviors, while social motivation stems from friends, peers, family, societal norms, and support systems.[40] Notably, support received from family members, peers, and particularly pharmacists enhances medication adherence.[38,41] The higher the satisfaction with pharmacist-provided services, the more likely are patients to adhere to their medication regimens.[38] Thus, pharmacist-led patient education reinforces positive social motivation, further promoting medication adherence.

Behavioral skills refer to the capabilities and self-efficacy individuals need to consistently engage in health-promoting behaviors, such as organizing medications, setting reminders, and maintaining medication adherence routines. These skills are essential for empowering individuals to overcome practical barriers to medication adherence.

These four fundamental constructs—information, personal motivation, social motivation, and behavioral skills—interact dynamically through direct, indirect, and reciprocal pathways to influence medication adherence (the behavior construct) (Figure 1).[33,38] A clear understanding of medication instructions (i.e., information) may independently encourage medication adherence, whereas motivation may drive efforts to acquire more health-related knowledge. Although knowledge alone may not guarantee medication adherence, it enables patients to interpret prescriptions and take appropriate actions, bridging the gap between intention and behavior. Therefore, behavioral skills are necessary to translate knowledge and intention into action, with enhanced motivation at both personal and social levels. While motivation for adherence and knowledge of medication usage and potential side effects mutually reinforce each other, patients develop greater self-efficacy, promoting medication adherence. These factors intertwine and highlight why targeted interventions—especially pharmacist-led ones—may improve long-term medication adherence, thus enhancing HRQoL and prognosis among patients with HF.

Taken together, the IMB model provides a valuable framework for understanding the multifaceted nature of medication adherence and insights into designing targeted interventions to achieve sustained, effective improvements in HF management. To the best of our knowledge, the IMB model has not yet been validated in patients with HF, nor has it been employed to specify how pharmacist-led patient education can enhance medication adherence in this population. Accordingly, this study aims to use the IMB model as a conceptual framework to examine the mechanisms through which pharmacist-led patient education influences medication adherence among patients with HF. A longitudinal pretest–posttest design will be employed to assess changes in medication adherence before and after the intervention. Patient-reported outcome measures (PROMs) will be integrated within the IMB framework, and structural equation modeling (SEM) along with latent class growth modeling (LCGM) will be applied to analyze the pathways affecting medication adherence and to identify distinct adherence trajectories.

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Materials and Methods

Study Aims

This study's aims are threefold. Primarily, it aims to apply the IMB model using PROMs to investigate the impact of pharmacist-led patient education on medication adherence among individuals with HF. It hypothesizes that patients who acquire accurate medication-related knowledge, develop personal motivation, receive supportive social motivation from pharmacists and other sources, and possess adequate behavioral skills regarding medication use will exhibit significantly high levels of medication adherence. Furthermore, the study also seeks to compare the IMB models pre- and post-intervention to identify the pathways most influential in improving medication-taking behaviors. This comparison will inform refinements in existing pharmacist-led patient education programs. Multigroup SEM will be used to specify the pre- and postintervention models, testing whether specific relationships among IMB constructs are significantly strengthened or weakened following pharmacist-led patient education. This analysis will help identify the pathways that are the most responsive to intervention and inform targeted refinements in pharmacist counseling strategies. Finally, adherence trajectories will be classified using LCGM following pharmacist-led patient education in order to identify distinct patient subgroups based on their long-term adherence patterns. Subsequent multigroup SEM and comparisons of baseline characteristics will be conducted between subgroups to determine whether IMB pathways or demographic factors differ between responders, providing evidence to refine pharmacist-led interventions for sustained medication adherence.

Study Design

This prospective pre- and postintervention study will administer the same PROMs to eligible participants before and after pharmacist-led patient education. Baseline (preintervention) assessment will be performed immediately before the education session, and follow-up assessments will be administered approximately three and six months postintervention, aligning with routine HF follow-ups (i.e., 3-month intervals) in clinical practice.

Ethical Considerations

The study received approval from the Institutional Review Board and Ethics Committee of National Taiwan University Hospital (NTUH) (No. 202501197RINC). All eligible participants will be invited and fully informed of research objectives and procedures; voluntary informed consent will be obtained before study commencement. Participants will be assured of their entitlement to withdraw without negative repercussions at any time.

Study Setting

This study will be conducted in NTUH, a leading medical center in Taipei, Taiwan. Pharmacist-led sessions will be conducted in the HF education room near the pharmacist-led HF clinic, accessible by clinician referral.

Study Participants

Patients referred with HFrEF (defined as a left ventricular ejection fraction $\leq 40\%$)[7] as well as those referred at the clinicians' discretion, will be invited to participate via purposive sampling. Eligibility criteria include patients aged ≥ 20 years, referred by their clinicians, and willing to participate. Given the pragmatic nature of this pharmacist-led intervention, strict inclusion and exclusion criteria are intentionally not applied to better reflect real-world scenarios. Participants will be excluded only if they have previously received patient education at the pharmacist-led HF clinic in the NTUH, fail to complete baseline assessments, or are unwilling to participate. Consecutive eligible and willing participants will provide written informed consent before receiving pharmacist-led patient education. Recruitment will continue until the estimated sample size is reached.

Study Intervention

The Advanced Patient-centered Pharmacist-Led Education on Heart Failure (APPLE-HF) management program was developed to support patients with HF in the pharmacist-led HF clinic (Figure 2); this service at NTUH is accessible only

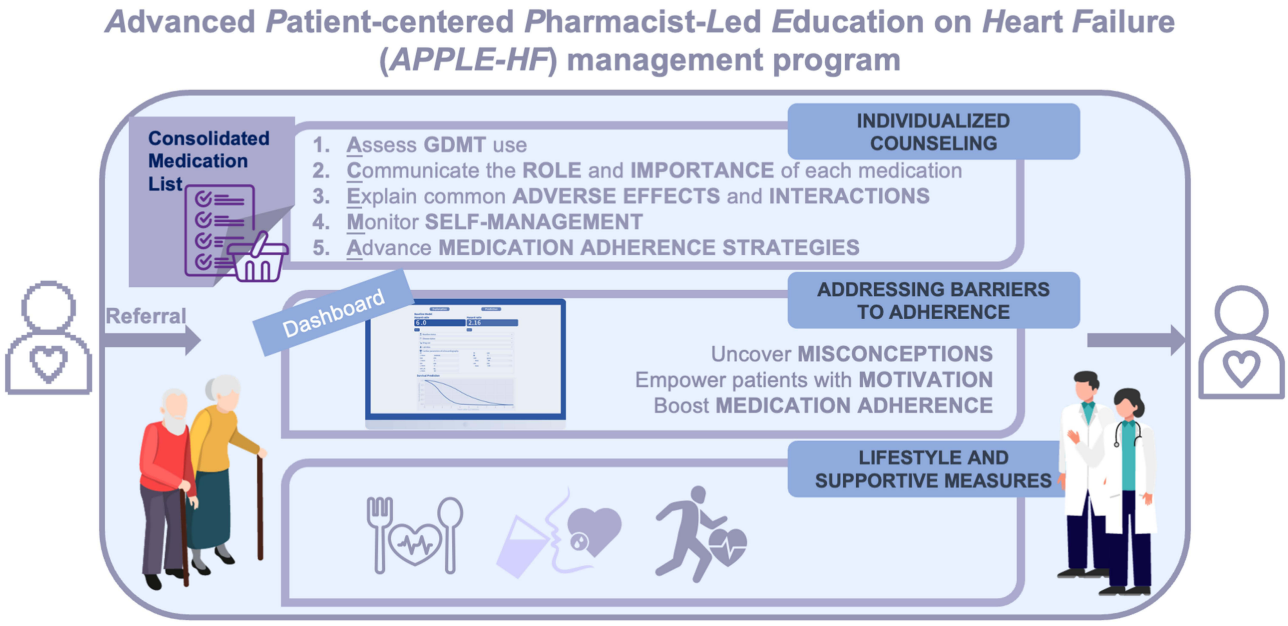

Figure 2 Illustration of the Advanced Patient-centered Pharmacist-Led Education on the Heart Failure (APPLE-HF) management program. The program integrates pharmacist-led individualized counseling, which addresses barriers to medication adherence and suggests lifestyle and supportive measures. Patients are referred by clinicians and co-managed with assigned pharmacists. They receive tailored education informed by the latest HF guidelines. Key components of the APPLE-HF management program include (1) using predefined consolidated medication lists to collaboratively review prescriptions and advance adherence strategies; (2) addressing barriers to adherence through proactive discussions and interactive dashboards with patient-specific visualizations of risks and projected survival curves to identify misconceptions and enhance medication adherence; and (3) guiding lifestyle modifications, including dietary control, fluid management, and exercise. This team-based, patient-centered model aims to improve HF outcomes.

Abbreviation: GDMT, guideline-directed medical therapy.

upon clinician referral. In this program, well-trained pharmacists with clinical pharmacy experience will deliver patient education sessions on a rotating schedule. Before this, all pharmacists will receive a standardized compendium containing evidence-based training materials to ensure consistency in education delivery.

Upon referral to the pharmacist-led HF clinic, patients will receive co-management by their primary clinicians and assigned consulting pharmacists, fostering a comprehensive, team-based model of care.[7] Prior to the patient's scheduled education visit, the clinical team will thoroughly review medical records, laboratory data, medication history (including data retrieved from the National Health Insurance [NHI] MediCloud System), and current prescriptions to document all current medications. Subsequently, a hard copy of the consolidated medication list will be provided during and after the education sessions for patients to monitor potential drug–drug or drug–food interactions and verify prescriptions following recognized HF guidelines.[7,42] Any identified concerns—particularly related to GDMT and its up-titration to target doses, such as potentially inappropriate prescriptions, notable adverse effects or interactions, or suboptimal use—will be recorded in the electronic health records (EHR), prepared for subsequent in-depth discussion with the patient, and communicated to the attending clinicians.

Face-to-face sessions will generally occur on the same day following the clinician visit, in lieu of patient preference, or as scheduled separate visits, with each session lasting approximately 1 h. The customized APPLE-HF program, enhanced by the interactive visualization dashboards developed by our research team,[43,44] is based on the most recent 2022 and 2024 AHA/ACC guidelines on HF management.[7,42] It begins with an introductory discussion and adopts the following three core objectives to improve clinical outcomes (Figure 2):

1. Individualized counseling: Pharmacists will adapt educational content to each patient's clinical profiles and health literacy. Counseling will follow the ACE Medication Adherence framework, which includes clarifying each medication's purpose (as detailed in the consolidated medication list), explaining common adverse effects and

interactions, assessing medication adherence, and demonstrating self-monitoring techniques (e.g., blood pressure and body weight monitoring), with an emphasis on reinforcing the appropriate use of GDMT.

2. Addressing barriers to adherence: Pharmacists will employ a think-aloud approach to uncover misconceptions about prescriptions, particularly GDMT, including concerns about side effects (e.g., hypotension), perceived benefits or risks, and doubts about efficacy. Through proactive discussions, incorporating nonverbal communication and empathetic responses, patients will be encouraged to articulate underlying factors affecting their medication adherence. This process will enable pharmacists to recommend practical, individualized reinforcement strategies. The interactive visualization dashboards will be pragmatically integrated into the intervention and leveraged at the pharmacist's discretion to address patient-specific needs.[43,44] The dashboards use patient-specific data to illustrate risk differences and projected survival curves based on selected patient-related variables and treatment options in real time. The dashboard-generated visualizations can facilitate a deeper understanding of different options and treatment plans, particularly among geriatric patients with HF, alleviating concerns that might otherwise impede medication adherence, and empowering patients with the motivation to change their behaviors.[43,44]
3. Lifestyle and supportive measures: Pharmacists will provide individualized guidance on lifestyle modifications, such as recommendations on protein- and potassium-rich dietary control, fluid management, and exercise, among others. Emphasis will be placed on how these nonpharmacologic interventions can complement and enhance the effectiveness of pharmacotherapy.

Following regulatory guidelines in Taiwan, pharmacists do not have the authority to prescribe independently. Consequently, any pharmacist recommendations will be formally documented in the EHR. Such proposed modifications to the patient's pharmacotherapeutic regimen or additional tests will be communicated to the attending clinicians. This interdisciplinary process will ensure the systematic integration of pharmacist-initiated suggestions into the APPLE-HF program.

Early introduction and stepwise up-titration of GDMT according to established HF treatment guidelines is essential.[7] Pharmacists will employ an evidence-based, stepwise strategy to achieve recommended or maximally tolerated doses, balancing efficacy with safety.[7,42] Given that complications such as hypotension, hyperkalemia, and renal dysfunction may arise during GDMT initiation or up-titration, careful monitoring will be implemented.[12] The approach will focus on proactive strategies such as advising patients to tolerate mild hypotension when clinically appropriate, promoting professional guidance before self-discontinuing medication, and recognizing early warning signs.[45]

By systematically integrating medication counseling, comprehensive patient education, and cohesive collaboration with prescribing clinicians, the APPLE-HF program addresses patient concerns about therapy, improves GDMT, medication adherence, and long-term clinical outcomes, and enables patient engagement in treatment. This structured pharmacist-led intervention strategy fosters an environment in which the patient is engaged and knowledgeable about the treatment plan, thereby encouraging medication adherence.

Study Measures

Seven PROMs will be administered face-to-face to eligible patients before and three and six months after the intervention (i.e., all questions except sociodemographic items will have to be answered three times) to assess the IMB model's five corresponding components. The first instrument is a sheet containing 13 sociodemographic questions (age, sex, education, employment status, marital status, living status, monthly income, number of medications taken, self-reported HF status, self-reported health status, exercise status, experience of using digital health tools, and attitude toward using digital health tools), followed by a PROM involving oral inquiries and six PROMs presented as a 48-item sheet, as outlined below.

Medication Understanding Questionnaire (MUQ)

The MUQ assesses knowledge of medication purpose, dosage, and frequency.[46] Each current GDMT (and diuretics) in the consolidated medication list will be evaluated on a 3-point scale: 1 point for the indication, 0.5 points for the dosage strength, 0.5 points for the dosage unit, and 1 point for the frequency. Oral inquiries will be incorporated into the patient

education process. All medication scores will be averaged to assess patients' overall understanding of the medication regimen and to measure the information construct.

Patient-Perceived Medication Knowledge and Confidence in Medication Use (Okere–Renier Survey)

The Okere–Renier Survey assesses patients' medication knowledge and confidence in medication use. It has demonstrated good reliability and an acceptable model fit through prior exploratory and confirmatory factor analyses.[47] The original survey comprises ten items divided into three dimensions: six items measure medication knowledge (of which one was finally removed due to low inter-item correlation), three assess confidence, and one evaluates satisfaction. Each item is rated on a five-point Likert scale, ranging from 1 (strongly disagree) to 5 (strongly agree), with higher scores indicating greater knowledge and confidence. Given that the information construct in the IMB model emphasizes patients' medication knowledge over confidence, only the five items examining medication knowledge were retained from the original questionnaire to measure this construct.

Beliefs About Medicines Questionnaire–Specific (BMQ-Specific)

The BMQ-Specific assesses patients' beliefs about their prescribed medications and evaluates their personal motivation through two subscales: Necessity and Concerns.[48,49] Each subscale comprises four items. The Necessity subscale captures patients' perceptions of medication importance, while the Concerns subscale reflects potential fears or anxieties regarding medication use. Items are rated on a five-point Likert scale, ranging from 1 (strongly disagree) to 5 (strongly agree), with higher scores indicating stronger beliefs. A previous study reported the Cronbach's alpha values of 0.77 for the Necessity subscale and 0.76 for the Concerns subscale, demonstrating good reliability.[49]

Patient Satisfaction with Pharmacist Services Questionnaire 2.0 (PSPSQ 2.0)

Sakharkar et al developed and validated the PSPSQ 2.0 to measure patient satisfaction with pharmacist-provided services.[50] The questionnaire has been translated into and validated in multiple languages; it comprises 16 items divided into two domains: 10 items assess patient satisfaction with the quality of care (QOC) and six evaluate satisfaction with the patient–pharmacist relationship (PPR). Each item was rated on a four-point Likert scale, ranging from 1 (strongly disagree) to 4 (strongly agree), with higher scores indicating greater satisfaction with pharmacist-provided services. The Traditional Chinese version of the modified PSPSQ 2.0 (C-mPSPSQ 2.0), translated and validated by our research team, will be used to assess the social motivation construct.[51] The C-mPSPSQ 2.0 comprises six items retained from the original PSPSQ 2.0, demonstrating acceptable model fit and strong validity, with a Cronbach's alpha of 0.919 and McDonald's ω of 0.922; it includes three items assessing the QOC domain and three evaluating the PPR domain.

Medication-Specific Social Support Questionnaire (MSSS)

The MSSS evaluates the frequency with which patients received support for their medication-related behaviors over the preceding 3 months,[52] capturing their social motivation component. The questionnaire comprises eight items, each rated on a scale from 0 (never) to 4 (very often), demonstrating good reliability and Cronbach's alpha values of 0.878–0.920.[37,52] The final score averages all item scores, with higher average scores indicating greater social support for medication-related behaviors. Along with the C-mPSPSQ 2.0, the MSSS was employed to collectively measure the social motivation construct.

Self-Efficacy for Appropriate Medication Use Scale (SEAMS)

The SEAMS assesses patients' self-efficacy in medication management, indicating their behavioral skills. It demonstrated excellent reliability, with Cronbach's alpha values of 0.89–0.93.[53,54] The scale measures patients' confidence in maintaining proper medication adherence under various environmental challenges. Responses are scored on a three-point scale from 1 (not confident) to 3 (confident), with higher scores indicating greater self-efficacy and stronger behavioral capabilities regarding medication use.

Eight-Item Morisky Medication Adherence Scale (MMAS-8)

The MMAS-8 is widely applied to assess patients' medication adherence and actual medication-taking behavior.[55] It comprises seven yes/no items and one item rated on a five-point frequency scale, with higher overall scores indicating better adherence to prescribed medications.

In addition to the MMAS-8, the proportion of days covered (PDC) will be calculated to assess medication adherence (the behavior construct). The PDC is a commonly used and preferred indicator for measuring medication adherence,[56] calculated as the ratio of the number of days in a specified period during which patients have access to their medication (based on prescription refills) to the total number of days in the specified period. A threshold of 80% indicates adequate medication adherence.[57] The PDC will be calculated 3 and 6 months postintervention using data from the NHI MediCloud System.

Data Collection

After completing baseline assessments, participants will be invited for the intervention session. During the session, a hard copy of the individualized consolidated medication list prepared by the assigned pharmacist will be provided to facilitate in-depth patient–pharmacist interaction; this list will also help assess patients' understanding of current medications through oral inquiries (the MUQ). Participants will complete the same assessments and PROMs at 3 and 6 months postintervention. Baseline characteristics will be collected from a questionnaire comprising 13 sociodemographic items and a consolidated medication list, as well as from the EHR at NTUH, which includes medical history and comorbidities. All collected data will be de-identified and stored on a secure, access-restricted server. Access will be limited to authorized study personnel, and regular backups will be conducted to maintain data integrity.

Conceptual Framework

This study adopts the IMB model as its theoretical framework, comprising four core constructs—information, personal motivation, social motivation, and behavioral skills—which collectively influence patients' medication adherence behaviors. The information construct was assessed using the Okere–Renier Survey and oral MUQ inquiries to evaluate patients' depth of understanding regarding medication knowledge. Motivation is divided into two components: personal and social motivation. Personal motivation is measured using the BMQ-Specific, which evaluates patients' beliefs about the necessity of medications and their concerns about potential adverse effects. Social motivation is assessed using two instruments: (1) the C-mPSPSQ 2.0, which evaluates patients' satisfaction with pharmacist-provided services and (2) the MSSS, which evaluates the level of social support available to patients. Behavioral skills are evaluated using the SEAMS, focusing on patients' self-efficacy in managing their medications correctly. Finally, medication-taking behaviors are assessed using the MMAS-8, which reflects patients' adherence to prescribed regimens, combined with the PDC. The IMB model's conceptual framework, as applied in this study, is illustrated in Figure 3.

Sample Size

The required sample size was estimated based on the SEM framework, considering the model's configuration. The model includes nine observed variables and 26 parameters for estimation, resulting in 19 degrees of freedom. Sample size determination was performed using root mean square error of approximation (RMSEA)-based calculations to achieve a statistical power of 0.80 and the significance level of $\alpha = 0.05$ following the method proposed by MacCallum et al.[58] RMSEA values were set to 0.05 for the null hypothesis (H_0) and 0.10 for the alternative hypothesis (H_1) to detect a meaningful difference in model fit. This analysis indicated the need for a minimum of 191 samples. A 10% adjustment was applied to account for potential attrition or incomplete responses,[59] resulting in a final target sample size of 200 participants. This sample size meets the minimum requirement for modeling two trajectories (short-term and sustained responders) in LCGM.[60]

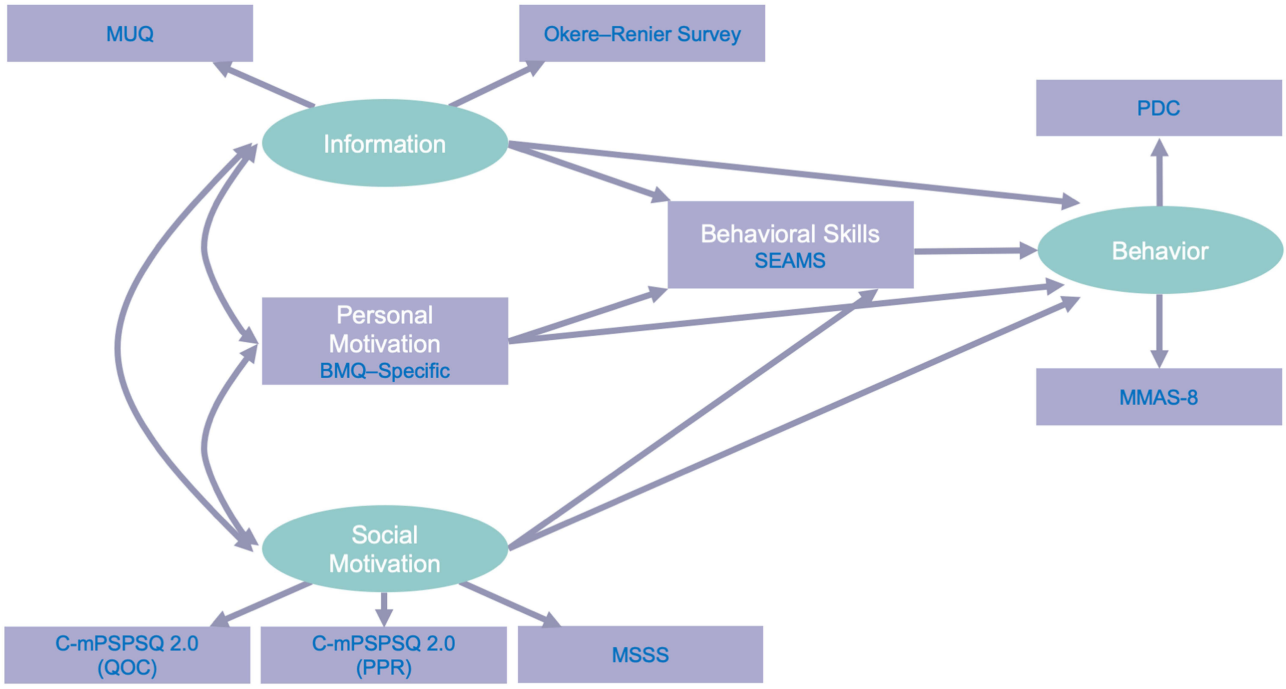

Figure 3 Proposed conceptual framework of the Information–Motivation–Behavioral Skills (IMB) model integrated with selected instruments. Ellipses represent latent variables conceptualized and measured through observed variables, while rectangles represent observed variables directly associated with a single instrument. The latent construct of information is measured using two tools: the Medication Understanding Questionnaire (MUQ) and the Okere–Renier Survey. Personal motivation and behavioral skills are represented as rectangles because each construct is measured using a single instrument—personal motivation via the Beliefs about Medicines Questionnaire–Specific (BMQ-Specific) and behavioral skills via the Self-Efficacy for Appropriate Medication Use Scale (SEAMS). Social motivation is measured using two instruments, the Traditional Chinese version of the modified Patient Satisfaction with Pharmacist Services 2.0 (C-mPSPSQ 2.0) (subscales for quality of care [QOC] and patient–pharmacist relationship [PPR]) and the Medication-Specific Social Support Questionnaire (MSSS). Finally, behavior is represented as an ellipse and assessed using the proportion of days covered (PDC) and the Eight-Item Morisky Medication Adherence Scale (MMAS-8).

Statistical Analysis

Descriptive statistics will be conducted using Statistical Package for the Social Sciences version 30.0 and R version 4.3.2 to summarize baseline characteristics. Depending on data distribution, categorical variables will be presented as frequencies and percentages, while continuous variables will be presented as means and standard deviations or medians and interquartile ranges, as appropriate. Group comparisons will be performed for adherence trajectory subgroups identified through LCGM. Chi-square (χ^2) tests will be employed for categorical variables, with Fisher's exact test applied when expected cell counts are < 5. For continuous variables, independent *t*-tests or Mann–Whitney *U*-tests will be used, as appropriate. A two-sided *p*-value < 0.05 will be considered statistically significant.

SEM and LCGM will be conducted using Mplus 8.0 to analyze the IMB models, evaluate hypothesized structural relationships, assess overall model fit, and classify prespecified two-class adherence trajectories. To assess the robustness of this assumption, a sensitivity analysis will be conducted by fitting models with alternative class structures (e.g., one to four classes) and comparing their fit using the Akaike information criterion (AIC) and Bayesian information criterion (BIC). The results will be reported to inform future research involving larger sample sizes.

Two separate SEMs will be developed for pre- (Model 1) and post- (Model 2) intervention assessments to determine the structural relationships among latent variables. Following LCGM, additional SEMs will be conducted separately for short-term responders and sustained responders. Goodness-of-fit will be evaluated using multiple fit indices: the χ^2 to degrees-of-freedom ratio (χ^2/df), comparative fit index (CFI), Tucker–Lewis index (TLI), RMSEA with a 90% confidence interval, and standardized root mean square residual (SRMR).[61] The maximum likelihood estimation method will be employed to estimate model parameters. Acceptable thresholds for model fit are defined as χ^2/df < 5, CFI and TLI > 0.95, and RMSEA and SRMR < 0.08.[62,63]

After fitting each model, a multigroup SEM approach will be employed to compare structural changes between pre- and postintervention models and between short-term responders and sustained responders. Given the use of identical

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questionnaires, measurement invariance will be assumed. Path coefficients will first be constrained and then freely estimated to identify statistically significant differences. This approach enables an examination of how the intervention influences key pathways within the IMB model, particularly with regard to changes in path strength and direction. Additionally, path analysis will be conducted to assess direct, indirect, and total effects among latent variables. Missing data, if any, will be handled using the full information maximum likelihood approach, which is well-suited for SEM and LCGM analyses.

Dissemination

Once the study is completed, the results will be submitted for publication in an international peer-reviewed journal to dissemination the findings to the broader scientific community.

Study Status

As of May 19, 2025, the study protocol is at Version 1.1. Recruitment commenced in early May 2025 and is projected to conclude by September 2026.

Discussion

Nearly half of all patients with HF do not receive GDMT prescriptions or do not adhere to prescribed regimens,[64,65] thus exacerbating their prognoses. Particularly in Taiwan, time-constrained clinical settings and the absence of robust support systems pose additional barriers.[66] Pharmacists are therefore uniquely positioned to bridge this gap by providing essential education, supporting patients, and following up with them to improve medication adherence after clinician visits.[7,22]

Extensive evidence underscores that pharmacist-led interventions effectively enhance medication adherence for various diseases,[67–69] including HF.[22,27,32] However, the precise mechanisms underlying such improvements remain underexplored, limiting the ability to optimize current pharmacist-led models. Further investigation into these mechanisms and the optimization of pharmacist-led interventions is essential for refining current practices and enhancing the quality of pharmacist-provided care for patients with HF. Thus, our study aims to evaluate the impact and mechanisms of pharmacist-led patient education on medication adherence among patients with HF by employing the IMB model with PROMs in a longitudinal pretest–posttest framework. We seek to compare IMB model structures before and after the intervention to identify pathways with significant potential for enhancing medication adherence. A multigroup SEM approach will be employed to address this gap and enable a robust comparison of pre- and postintervention models, highlighting how pharmacist-led interventions affect medication adherence and provide insights into the pathways of influence. We hypothesize that patients with HF can significantly enhance medication adherence after pharmacist-led interventions. Additionally, this study incorporates LCGM to classify distinct adherence trajectory subgroups, identifying patients who may require more intensive interventions. Multigroup SEM and baseline characteristic analysis will be used to examine differences between short-term responders and sustained responders, determining key factors influencing long-term adherence to inform tailored strategies.

While the study is designed to be feasible and well-integrated into clinical practice, several anticipated challenges may arise. These have been proactively addressed through the proposed solutions. First, given the longitudinal nature of the study, which involves data collection across multiple time points, participant loss to follow-up represents a potential concern. Attrition could lead to a reduced sample size and diminished statistical power, thus affecting the stability and interpretability of the SEM and LCGM analyses. To mitigate this risk, an attrition buffer of at least 10% has been incorporated into the sample size estimation. Moreover, follow-up assessments will be scheduled to coincide with routine clinical visits to reduce participant burden. Reminder notifications will also be sent via a designated LINE communication group one week and one day before each scheduled follow-up; phone calls will be made if needed. As an incentive to improve retention, participants will receive a gift card valued at NT$100 upon completing each follow-up phase.

Another anticipated challenge involves the stability of the latent classes identified through LCGM, particularly in light of the projected sample size of approximately 200 participants. To address this, the study will prespecify a two-class solution based on theoretical assumptions, distinguishing short-term responders from sustained responders. Sensitivity analyses using AIC and BIC will be conducted to assess the robustness of the latent class solution. Any limitations

regarding class stability due to sample size constraints will be transparently reported, and findings will be positioned as preliminary and exploratory, underscoring the need for future validation with larger cohorts.

Finally, recruiting a sufficient number of eligible participants solely through the pharmacist-led HF clinic alone may be difficult. To enhance recruitment, the study will also include patients enrolled in the NTUH Heart Failure Post-Acute Care (HF-PAC) program, which routinely refers patients to pharmacist-led education sessions. The HF-PAC program offers holistic, team-based care for hospitalized patients with HF in Taiwan,[70] incorporating pharmacists to provide predischarge counseling, reinforce patients' understanding of home-based care, strengthen self-care capabilities, and promote medication adherence. In addition, collaboration is ongoing with clinicians participating in NTUH's pharmacist-led clinic referral program, which includes twelve cardiology outpatient clinics, therefore broadening the recruitment base. These proactive strategies are intended to ensure recruitment feasibility, uphold methodological rigor, and enhance the validity, robustness, and generalizability of the study's findings through the inclusion of a more diverse participant population.

To our knowledge, no prior study has utilized the IMB model in conjunction with SEM and LCGM to evaluate pharmacist-led patient education among patients with HF, a predominantly geriatric population often challenged by polypharmacy and poor HRQoL. This research will serve as a foundation for advancing the APPLE-HF management program, expanding holistic care for patients with HF, and reshaping future adherence strategies to optimize pharmacist-led interventions.

Conclusion

This study will employ a longitudinal pretest–posttest design to evaluate the impact and underlying mechanisms of pharmacist-led patient education on medication adherence in individuals with HF. By integrating the IMB model with PROMs through SEM, the study will identify the pathways through which pharmacist-led interventions improve medication adherence. In addition, it seeks to refine pharmacist-led patient education by examining the interactions among information, motivation, behavioral skills, and adherence behavior. Tailored interventions will also be developed to support long-term medication adherence by classifying distinct adherence trajectories using LCGM. Consequently, this study is expected to empower pharmacists with evidence-based strategies to optimize their practice, enhance medication adherence among vulnerable patients with HF, enable more precise identification of individuals requiring targeted interventions, and reinforce pharmacists' role as essential members of healthcare teams.

Abbreviations

ACC, American College of Cardiology; AHA, American Heart Association; AIC, Akaike information criterion; APPLE-HF, Advanced Patient-centered Pharmacist-Led Education on Heart Failure; BIC, Bayesian information criterion; BMQ-Specific, Beliefs About Medicines Questionnaire–Specific; C-mPSPSQ 2.0, Traditional Chinese version of the modified Patient Satisfaction with Pharmacist Services Questionnaire 2.0; CFI, comparative fit index; EHR, electronic health records; GDMT, guideline-directed medical therapy; HF, Heart failure; HF-PAC, Heart Failure Post-Acute Care; HFSA, Heart Failure Society of America; HFrEF, Heart failure with reduced ejection fraction; HRQoL, health-related quality of life; IMB, Information–Motivation–Behavioral Skills; LCGM, latent class growth modeling; MMAS-8, Eight-Item Morisky Medication Adherence Scale; MSSS, Medication-Specific Social Support Questionnaire; MUQ, Medication Understanding Questionnaire; NHI, National Health Insurance; NTUH, National Taiwan University Hospital; PDC, proportion of days covered; PPR, patient–pharmacist relationship; PROMs, patient-reported outcome measures; PSPSQ 2.0, Patient Satisfaction with Pharmacist Services Questionnaire 2.0; QOC, quality of care; RMSEA, root mean square error of approximation; SEAMS, Self-Efficacy for Appropriate Medication Use Scale; SEM, structural equation modeling; SRMR, standardized root mean square residual; TLI, Tucker–Lewis index.

Data Sharing Statement

Data supporting the findings of this study will be available from the corresponding author upon reasonable request.

Ethics Approval and Consent to Participate

The Research Ethics Committee of the National Taiwan University Hospital (No. 202501197RINC) granted approval for this study.

Consent for Publication

Patients will provide informed consent for their data to be published, and anonymity will be ensured by excluding any identifying information.

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Author Contributions

All authors made a significant contribution to the work reported, whether in study conception or design; took part in drafting, revising, or critically reviewing the article; approved the version to be published; have agreed on the journal to which the article has been submitted; and agree to be accountable for all aspects of the work.

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Disclosure

The authors report there are no competing interests to declare for this work.

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