

**The Effects of “Social Optimization Chat for Interactive Learning for Heart Failure”  
(SOCIAL\_HF) on improving social frailty: A Randomized Controlled Trial**

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## 1 Background

In the past decade, social frailty has gained attention due to the widespread recognition of its close association with social health and healthy aging [1, 2]. It is perceived as a vulnerable state resulting from the cumulative loss of social resources (including tangible resources as well as interpersonal networks and interactions) in various domains, types, and quantities, reflecting an individual's overall social health status [3]. Evidence indicates that social frailty is prevalent among older adults, with a systematic review revealing an overall prevalence of 21.1% (95% CI = 17.8–24.5%) in global communities, making it more common than physical and cognitive frailty [4]. Furthermore, social frailty has been linked to adverse health outcomes, including all-cause mortality (HR=1.96, 95% CI 1.20-3.19) and disability (OR=2.06, 95% CI 1.55-2.74) [5]. Longitudinal studies have shown that social frailty influences physical frailty [6], cognitive decline [7, 8], intrinsic capacity impairment [9], and depression [10] in older adults, suggesting it may serve as an early indicator of health decline. Thus, actively preventing and reversing social frailty could improve health outcomes and enhance healthy life expectancy.

Heart failure, a clinical syndrome characterized by abnormal cardiac output affecting approximately 64 million people worldwide, poses a significant healthcare burden [11]. Patients with heart failure not only experience debilitating symptoms such as breathlessness and fatigue but also face declining daily functioning and comorbidities [12], which severely limit their social activities and access to resources [13, 14], leading to social frailty. As opportunities for interaction decrease, heart failure patients struggle to obtain necessary social support and resources for effective self-care or [15, 16] to make informed health decisions [17]. This further exacerbates their symptoms and disease progression, creating a vicious cycle. In this context, the prevalence of social frailty in this population is particularly concerning. For instance, a multicenter longitudinal study in Japan found that social frailty affected up to 66% of hospitalized heart failure patients aged 65 and older, predicting all-cause mortality and heart failure readmission [18]. Similarly, another Chinese cohort study involving 297 heart failure patients reported that nearly 70% of hospitalized patients exhibited social frailty or pre-frailty. The risk of death within six months post-discharge for those with social frailty or pre-frailty was 3.52 times and 1.43 times higher, respectively, compared to patients without social frailty [19]. Given the high prevalence of social frailty among elderly patients with heart failure and its detrimental impact on health outcomes, there is an urgent need for effective interventions. By enhancing social resources and interactions, patients can be empowered to proactively manage their symptoms, thereby potentially breaking the cycle of social frailty.

Social interaction activities based on Information and Communication Technologies (ICTs) have the potential to enhance the social resources and participation of older adults with heart failure. A systematic review indicates that ICT technologies, represented by touchscreen devices and social networking services (SNS), positively impact social

participation among older adults in the community. They empower older individuals to initiate or engage in interactions by sharing photos or participating in video calls with family, friends, or peers [20]. Through these social interactions, older adults can access news, health information, and other valuable resources, becoming important sources of social support, especially when mobility is limited [21]. Furthermore, another systematic review suggested that ICT-based social interventions, such as training older adults to use the internet and computers for social purposes, video conferencing, robots care, and conversational agents, can alleviate social isolation through expanding social networks, increasing social connections, enhancing social support, and improving self-efficacy [22]. In fact, ICT has been widely applied among heart failure patients. SNS, e-health platforms, and Mobile APPs [23-25] serve as platforms for disseminating health management knowledge and enable remote disease monitoring through reminders for symptom measurement and documentation. This encourages patients to adopt healthier behaviors and fosters effective collaboration with healthcare providers [26]. However, previous studies have mainly concentrated on the effects of these technologies on medical activities and health outcomes, with little attention given to their influence on social outcomes. While these technologies have the potential to integrate social activities, there has been limited focus on strategies that actively promote social interaction.

Indeed, a previous RCT that utilized robotic pets to improve social frailty among community residents did not report significant improvements. This suggests that ICTs may serve primarily as a tool for creating opportunities for interaction and safe social environments [27]. While they play an important role in providing basic social platforms, effectively enhancing older adults' willingness and engagement in social activities still requires the integration of effective social facilitation strategies. One promising approach is gamification, which involves using game mechanics or elements in non-game contexts to combine the desire for communication and achievement sharing with goal setting [28]. This strategy can effectively stimulate interaction and encourage proactive behavior. For example, Marcus et al. [29] developed a cooperative daily task challenge game for heart failure patients and their families, incorporating gamification concepts like badges, leaderboards, levels, and points. This design fostered interactions with both internal and external social networks through cooperation and competition. Moreover, a prospective cohort study indicated that group-based empathy discussions can help enhance the perception of social support [30]. The sense of belonging and acceptance of differences that emerges during these group interactions allows individuals to benefit from social activities, thereby contributing to sustained social participation [31, 32].

In summary, improving social frailty is a crucial strategy for promoting self-care and health outcomes among heart failure patients. Based on the conceptual model of social frailty, enhancing social resources and facilitating social activities are key targets for addressing this issue. By integrating ICT-based social activities with strategies such as gamification and group discussions, we have the opportunity to effectively improve social frailty. Given that the causes of social frailty in heart failure patients are often related to their disease symptoms, it is essential to provide knowledge and resources

related to disease management within social activities. To address these needs, the study aims to develop a program called “Social Optimization Chat for Interactive Learning for HF” (SOCIAL\_HF) and evaluate its effects on improving social frailty in older adults with heart failure. The intervention focuses on implementing group-based interactive learning through WeChat, incorporating strategies such as collaborative games, quizzes, point systems, and leaderboards. These components are designed to foster interaction and social network, thereby optimizing the social resources and activities of heart failure patients, ultimately leading to improved social frailty. This study will assess the feasibility, acceptability, and effects of SOCIAL\_HF intervention.

## **2 Objectives and hypothesis**

### **2.1 Objectives of the study**

This study will comprise two parts: a feasibility study and a full randomized controlled trial (RCT).

The feasibility study aims to:

- a. Develop the “Social Optimization Chat for Interactive Learning for HF” (SOCIAL\_HF) program to alleviate social frailty in older adults with heart failure.
- b. Evaluate the feasibility of the program, focusing on the practicality of the study design, methods, and interventions, as well as the capacity for participant recruitment.
- c. Assess the acceptability of the SOCIAL\_HF intervention by exploring participants' willingness, experiences, and perceptions regarding its practicality. This will help identify areas for improvement to optimize the intervention.
- d. Collect preliminary data on social frailty, perceived social support, social participation, and self-care. This data will provide a foundation for sample size calculations in future larger-scale studies.

The larger-scale RCT will aim to:

- a. Evaluate the immediate effects of the optimized SOCIAL\_HF program on the primary outcome of social frailty, as well as secondary outcomes of perceived social support, social participation, and self-care.
- b. Assess the longer-term effects of the intervention by determining whether improvements in social frailty, perceived social support, social participation, and self-care are maintained at three months post-intervention.

### **2.2 Hypothesis**

Participants in the intervention group receiving the SOCIAL\_HF intervention will demonstrate improvements in social frailty, perceived social support, social participation, and self-care compared to those in the control group, with the potential for sustained long-term effects.

### 3 Study design

The study comprises two phases: a feasibility study and a larger-scale, randomized controlled trial (RCT). This feasibility study employs a mixed-methods approach to evaluate the feasibility, acceptability, and preliminary effects of a WeChat-based social optimization chat for interactive learning for older patients with heart failure (SOCIAL\_HF). The SOCIAL\_HF program in two study phases is designed as a two-arm parallel randomized controlled trial with assessor blinding. Both phases will use the same recruitment and intervention procedures, with the main differences being the frequency of follow-ups and the measurement outcomes.

PI will recruit and screen participants face-to-face at hospitals in Shanghai, including Shanghai Jiao Tong University School of Medicine Affiliated Songjiang Hospital, Shanghai Baoshan District Integrated Traditional Chinese and Western Medicine Hospital, Shanghai Jiao Tong University School of Medicine Affiliated Sixth People's Hospital, and Fudan University Affiliated Huadong Hospital. Eligible participants will be randomly assigned to either the control group or the six-week online intervention group.

During the feasibility study phase, participants will receive baseline assessment by PI on-site and undergo outcome assessments immediately after the intervention by a investigator who was not involved in the initial allocation or intervention. Additionally, some participants will be invited to participate in qualitative interviews. In the large-scale randomized controlled trial phase, participants will also receive follow-up assessments three months after the intervention to evaluate the maintenance effects of the intervention.

#### 3.1 Study setting and participants

This study will recruit participants from heart failure outpatient clinics and cardiology wards. The feasibility study and the large-scale RCT will use the same inclusion and exclusion criteria.

Individuals meeting the following criteria can participate in the study: (1) 60 years old and above; (2) Live in the community; (3) a definitive diagnosis of heart failure based on the Framingham Heart Failure Diagnostic Criteria; (4) a diagnosis of heart failure for 6 months or longer; (5) evidence of social pre-frailty or frailty, determined by the SFS-8 scale score  $\geq 2$ ; (6) possession of a smartphone and experience using WeChat; (7) be able to read and write Chinese.

Individuals will be excluded if they have: (1) severe cognitive impairment or dementia, (2) known mental illnesses, (3) any communication barriers may hinder participation in SOCIAL\_HF, such as illiteracy, reading disabilities, speak local dialect only, and difficulties in language comprehension, (4) any sensory impairments that may affect

learning or interaction with others on WeChat, including untreated severe hearing loss and vision impairments or (5) are currently participating in other intervention studies.

PI will obtain informed consent and then collect demographic data and baseline outcome variables from participants in a quiet consultation room, using a baseline data questionnaire. The participants will then be randomly assigned to either the intervention group or the control group in a 1:1 ratio. The random sequence will be generated by a separate research assistant, not involved in recruitment, using a block randomization method (with block sizes of 4, 6, or 8) to ensure balance between groups. The research assistant will generate randomized group identifiers using computer-based randomization program and print them on standard 2cm × 2cm paper. These group identifiers will then be placed sequentially into opaque, sealed envelopes to maintain confidentiality and randomness in the allocation process.

During the allocation, PI will sequentially open the envelopes to assign each participant to either the intervention group or the control group. Participants in the intervention group will be added to a pre-established WeChat group to receive SOCIAL\_HF program. Furthermore, PI will provide a brief explanation of the intervention content and tasks, as well as guide participants in using WeChat. Participants' proficiency with WeChat will be assessed through several key tests, including sending voice messages, sending images, opening links, and answering video call invitations.

In contrast, participants in the control group will only connection with the research assistants on WeChat and will not participate in the group activities. Post-test outcome assessments will be conducted immediately after the completion of the assigned intervention (T1), at 3 months (T2, only for the large-scale RCT) thereafter through telephone, by the research assistants who is not involved in recruitment or the intervention and who is unaware of the random allocation status.

Participants will receive a reward of 100 RMB upon completing the follow-up, as a token of appreciation for their participation and support. The study will strictly follow the Declaration of Helsinki. Ethics approvals will be sought from the Institutional Review Board of the University of Hong Kong / Hospital Authority Hong Kong West Cluster and the Ethics Committees of Shanghai Jiao Tong University School of Medicine Affiliated Songjiang Hospital, Shanghai Baoshan District Traditional Chinese and Western Medicine Hospital, Shanghai Jiao Tong University School of Medicine Affiliated Sixth People's Hospital, and Fudan University Affiliated Huadong Hospital.

### **3.2 sample size**

For the two-arm feasibility study, the goal is to obtain an estimated effect size with small standardized difference, targeting a 80% powered and a two-sided 5% significance level for the main trial [33]. Accounting for a 20% dropout rate, each group is expected to require 24 participants, resulting in a total of 48 participants.

For the qualitative phase, sampling will be based on the variation range of social frailty. Participants will be purposefully recruited from three groups: those within the 0 to 34th percentile, the 35th to 68th percentile, and the 69th to 100th percentile of the social frailty changes. Sample collection will continue until data saturation is achieved.

Using G\*Power 3.1, we determined that a moderate effect size (Hedge's  $g = 0.54$ ) from previous meta-analyses justifies a conservative target effect size of 0.50 for primary and secondary outcomes [21, 34]. With a significance level ( $\alpha$ ) of 0.05 and 80% power, the required sample size for the large-scale RCT is 128. Factoring in a 20% dropout rate, we aim to recruit 160 participants. The sample size will be adjusted based on this result from the feasibility study. The expected total sample size for the entire program is currently planned to be 208 participants.

### **3.3 Interventions**

#### **3.3.1 Theoretical framework of the intervention**

Randall Collins' Interaction Ritual Chains Theory (IRC) [35] provides significant guidance for constructing effective interventions in this study. This theory operates as a micro-interaction analytical framework within sociology, placing a strong emphasis on the fundamental roles of emotional energy and group solidarity in shaping social interactions. The emergence of interaction rituals requires the fulfillment of four key conditions: group gathering, bounded space, mutual focus of attention, and shared emotional mood. These conditions align the group's attention, behavior, and emotions, transforming individuals into ritual participants. Together, these elements evoke collective effervescence, a powerful and highly contagious group psychological state that further enhances emotional and social interaction processes among participants [36, 37].

The outcomes of these rituals manifest in several ways. Firstly, group solidarity emerges as a profound sense of belonging among members, helping to create a supportive social network. Secondly, the presence of group symbols serves as constant reminders of these relationships, enriching the group's identity. Additionally, individuals experience feelings of morality, which reinforce shared values and cooperations, further solidifying the group's cohesion. Finally, emotional energy develops as a lasting positive feeling that promotes social interactions, making individuals more likely to engage with each other in meaningful ways [38].

These outcomes collectively drive the dynamics of interaction within the group. Through repeated interaction rituals, the elements of emotional energy, group solidarity, feelings of morality, and group symbols continually reinforce one another, creating a robust interaction chain that promotes the stability and evolution of social behaviors over time.



**Figure 1 Conceptual framework of the interactive ritual chain and corresponding intervention components**

The WeChat platform provides an ideal environment for conducting interaction rituals. It creates a well-defined group for heart failure patients, their families, and nurses, effectively promoting the exchange and sharing of resources. Within this safe space, discussions and learning about heart failure self-care knowledge and symptom management strategies can quickly capture the interest and attention of group members. By sharing their feelings, achievements, and challenges related to heart failure self-care, members can foster emotional resonance, thereby strengthening their connections with one another. Thus, focusing on heart failure self-care as the theme for interactive learning in a WeChat group meets the four essential conditions for initiating interaction rituals. Figure 1 illustrates the conceptual framework of the interaction ritual chain and the corresponding intervention components.

Furthermore, integrating gamification strategies will enhance individual participation and initiative in interactive learning, activating the interactive ritual chain. For instance, gamified elements such as points, leaderboards, online check-ins, and tangible rewards, which are oriented towards achievement and progress, can significantly boost participants' interest in learning and their intrinsic motivation. Additionally, social-oriented gamified elements like turn-based games, problem-solving based team cooperations and competitions can promote participants' engagement and enhance their ability to overcome challenges, enabling them to maintain continuous interaction in group learning and discussion [39, 40].



### 3.3.2 Intervention group: SOCIAL\_HF

The main goal of this experimental intervention is to enhance social interaction among older adults with heart failure, thereby improving their social frailty. Participants will engage in a 6-week, WeChat-based group learning program called SOCIAL\_HF, focused on heart failure self-care. This program comprises two key components: structured real-time interactive learning and ongoing synchronous support. Real-time interactive learning will be conducted through WeChat video group meetings weekly, featuring peer sharing, problem-solving collaborative tasks, health goal setting, progress sharing, and the establishment of group contracts. Daily synchronous chat interactions will revolve around completing group contract tasks, weekly quizzes, and daily sharing. Additionally, participants will have access to an online self-care resource hub on the WeChat platform for reference and use.

The objectives of these components include: (1) promoting participant-driven interaction through shared focus and emotions; (2) enhancing and reshaping participants' perceptions of their social networks through cooperation and competition; and (3) providing social support to empower heart failure self-care. Furthermore, the program will implement gamification strategies, such as dynamic scoring, visual leaderboards, and periodic achievement rewards, to motivate participant engagement. Table 1 shows the weekly intervention structure.

Table1 Weekly intervention structure

Timing	Activity	Format
1 time/week	60-min video-based group meeting	Group sharing and discussion (Peer sharing + Cooperation + Goal attainment follow-up+ group contract)
1 time/week	Quiz	Online 5 MCQs
5 time/week	Group task relay	Fixed relay tasks (according to group contract) Random relay tasks (triggered by context, e.g. holidays, weather changes, and trending issues)
Ongoing	Resource hub	Online articles, videos, links and peer-shared strategies

#### Structured real-time interactive learning

Structured real-time interactive learning will be led by facilitators who will organize and guide participant interactions while providing knowledge and skills related to self-care. Participants will be divided into groups of six and will meet weekly via WeChat video conferences. There will be a total of seven sessions (see table 2), with the first six centered on the three key processes of heart failure self-care: self-care maintenance, symptom perception, and self-care management [41]. The goal of self-care maintenance

is to enhance participants' medication adherence and promote a healthy lifestyle. Symptom perception focuses on helping participants to consistently monitor their vital signs, identify early changes, and understand the causes and implications of common heart failure symptoms. In addition, self-care management aims to empower participants by providing strategies to address early changes and guidance for making informed decisions about the common symptoms.

Although the three self-care processes are intended to be mastered sequentially, the participants are more likely to have shared experiences related to heart failure symptoms, which can evoke common concerns and emotional connections. Therefore, the first session will focus specifically on symptom perception, allowing participants to discuss and recognize their shared experiences. The themes of sessions 2 to 4 will center on self-care maintenance. During these sessions, participants will learn to develop low-sodium dietary plans and safe exercise routines. They will also gain a deeper understanding of the medications they are taking, including their purpose, potential side effects and coping strategies. Sessions 5 and 6 will equip participants with essential skills to identify early physical changes and understand the underlying causes of their symptoms. They will master effective management strategies, such as assessing the urgency of different symptoms and learning how to adjust medications or implement fluid restrictions to alleviate symptoms. The final session will serve as a graduation ceremony.

**Table 2 Outline of Seven WeChat Group Interaction Learning**

Session No.	Self-care domain	Title	Core content
Session One	Symptom perception	Hello, my buddy	Heart failure experience
Session Two	Self-care maintenance	Wisdom on the tip of tongue	Dietary management of heart failure
Session Three	Self-care maintenance	Comrades in the pillbox	Understanding the purpose and side effect of medications and coping strategies
Session Four	Self-care maintenance	Energizing the Heart	Safe physical activities skills
Session Five	Symptom perception and self-care management	Symptom Scouts: These Symptoms Are Signals	Recognition early symptoms and severity
Session Six	Symptom perception and self-care management	Being Well-Aware	Strategies to management symptoms
Session Seven	All domains	Celebrating Progress: My Change List	Self-care improvements

Each session will incorporate four main activities: structured peer sharing, problem-solving collaborative tasks, goal setting or progress sharing, and group contracts. Each session will begin with a brief educational talk provided by the facilitator

to set the stage. The structured peer sharing will utilize a theme-guided approach, encouraging participants to engage in timed sharing and keyword fill-ins. This format aims to build emotional resonance and help reshape participants' understanding of health issues. The problem-solving collaborative tasks will integrate group experiences through interactive formats such as scenario simulations or graphical tools for co-creation, resulting in scalable solutions. Goal setting and progress sharing will focus on celebrating achievements and collaboratively addressing obstacles, utilizing group attention to foster positive social accountability. Finally, group contracts will establish daily health tasks, transforming external requirements into personal commitments while providing opportunities for daily interaction. Participants will be encouraged to use expression cards for real-time interaction.

Moreover, during the first session, participants will collaboratively create a group slogan and set a group name to form a group identity. The final session will celebrate participants' progress and reward achievements. The facilitator will also encourage caregivers or significant others to join the group discussions to further enhance the support system and increase engagement.

### **Daily synchronous interaction**

Daily synchronous interactions will take place in the WeChat group chat room, initiated by the facilitator. These interactions will include fixed group relays based on the group contract, random relays triggered by current events, and weekly quizzes. The aim of these activities is to repeat rituals of interaction that accumulates emotional energy among participants.

Each week, five group tasks closely aligned with the group contract will be conducted, such as weight monitoring check-ins and dietary sharing. The specific content and format will be decided during the group contract activity in the group discussion. On task days, the facilitator will reiterate the group slogan and remind members to start the relay tasks. Given the participants' age and health considerations, low-barrier forms of interaction, such as sending emojis, liking posts, and brief voice messages, will be encouraged.

To further enhance engagement, facilitators can introduce random relay tasks centered around focused topics. For example, approaching holidays, facilitators can inquire about holiday plans or dining arrangements while reminding participants to consider low-salt diets. Participants will also be encouraged to express themselves freely by posting photos and diaries to share daily stories, and other formats.

Additionally, weekly quizzes are designed to foster light competition while promoting the learning of self-care. Each online quiz will consist of five multiple-choice questions related to the self-care topics discussed. Participants will earn points by answering

questions, motivating them to actively engage in learning and discussions. Timely feedback will be provided, especially for incorrect answers.

### **Gamification strategies**

The points system and leaderboard are designed to spark participants' interest through friendly competition, fostering a sustained engagement and attention to external social network. Participation in group online discussions, relay tasks and weekly quizzes will be awarded points. Points will be counted by the facilitator and updated in the group at a fixed time every day. By tracking points and leaderboard, participants will be motivated to actively participate and interact with one another, creating a dynamic environment that encourages ongoing interaction.

### **Resource hub**

The resource hub aims to provide ongoing support and optimize the accessibility of information. Participants will access the self-care resource hub via WeChat, which includes articles, videos, guidelines, peer experiences, and other useful information. Participants can freely and repeatedly access and view these resources for in-depth learning and practice. The resource hub will be regularly updated based on participants' needs to help them manage their health more effectively.

### **3.3.3 Control group: usual care**

The control group will establish a WeChat connection with the research assistants and receive standard care, which includes a health education manual. However, they will not participate in group learning or discussions. They can consult with the research assistants via WeChat for any questions they may have, but the research assistants will only provide explanations related to the health education manual and will not offer additional educational resources or group interactions.

## **3.4 Measures**

Both the feasibility study and the larger-scale RCT will collect the same primary and secondary outcomes, as well as demographic and clinical profiles. Additionally, the feasibility study will gather extra feasibility indicators, such as recruitment status, attendance, and retention rates. One-on-one semi-structured interviews will also be conducted to evaluate the appropriateness, practicality, and acceptability of the intervention measures.

### **3.4.1 Primary Outcomes**

Social frailty will be assessed by using SFS-8 scale was developed by Pek [42] in Singapore, comprising the items from Makizako's social frailty 5-item, Tsutsumimoto's 5-item, Teo's social frailty index, and Tanaka's social frailty assessment. It consists of eight questions covering whether they visit friends sometimes, seek advice from family

and friends, have people they can trust, go out less frequently, eat alone, have financial difficulties, live alone, talk to someone every day. It uses a dichotomous scoring method with a total score ranging from 0 to 8 points. A score of 0-1 indicates social non-frailty (SNF), 2-3 indicates social pre-frailty (SPF), and  $\geq 4$  indicates social frailty (SF). It was translated by Montayre in 2024 and validated in Hong Kong's elderly population with Cronbach's  $\alpha$  coefficient of 0.67[43].

### 3.4.2 Secondary Outcomes

Perceived social support as an indicator of social resources will be assessed by the Chinese Mandarin version of the Medical Outcomes Study Social Support Survey (MOS-SSS-CM), which consists of 19 items across four dimensions: tangible support (4 items), informational and emotional support (8 items), positive social interaction (4 items), and affectionate support (3 items). Each item is rated on a 5-point Likert scale, with higher scores indicating better support. Introduced by Yu in 2004, this scale was validated in Hong Kong heart failure patients and showed a Cronbach's  $\alpha$  of 0.98 and a 2-week retest reliability of 0.84 [44]. It was culturally adapted for coronary heart disease patients by Wang in 2013, demonstrating acceptable internal consistency (Cronbach's  $\alpha$  = 0.91, intraclass coefficient = 0.89) [45].

Social participation serves as an indicator of engagement in social activities. The Impact on Participation and Autonomy Questionnaire (IPA) [46], which is a self-report instrument that measures people's perceptions of participation and autonomy, will be used to evaluate the social participation in older adults with heart failure. The original scale has a Cronbach's  $\alpha$  ranging from 0.81 to 0.91[47]. The Chinese version of the questionnaire was translated by Li et al [48]. Comprising 25 items, the scale is organized into four distinct dimensions: autonomy indoors (7 items), family role (7 items), autonomy outdoors (5 items), and social life (6 items). A 5-point Likert scale is utilized, with "a lot" receiving 0 points and "a little" receiving 4 points. Scores can range from 0 to 100, where a higher score reflects a lower level of social participation. The scale has been validated for reliability and validity in stroke patients, with Cronbach's  $\alpha$  coefficients for each dimension ranging from 0.782 to 0.965, and the content validity index (CVI) for individual items ranging from 0.87 to 1.00 [48]. The Chinese version has also demonstrated good internal consistency in studies involving other elderly populations[49].

Self-care will be assessed by the Chinese version of the Self-care Heart Failure Index version 7.2 (SCHFI v7.2-C), which comprises 29 items across three dimensions. This scale assesses the ability of heart failure patients to manage their care and make informed decisions. The maintenance dimension measures compliance and symptom detection, the management dimension evaluates symptom recognition and care assessment, and the confidence dimension reflects patients' beliefs in their abilities. Scores range from 0 to 100, with 70 or above indicating adequate self-care. Introduced in 2010 by Yu, the SCHFI was validated for reliability and validity in the Chinese heart failure population [50]. The updated version 7.2 showed Cronbach's  $\alpha$  coefficients

between 0.77 and 0.89, with test-retest reliability of 0.75-0.78 [51].

**3.4.3 Demographic and clinical profiles**

Demographic variables will be collected through self-reporting, including gender, age, education, monthly income, marital status, and living area. The etiology of heart failure, time since diagnosis of heart failure, NYHA classification, and the most recent medical test results such as B-type natriuretic peptide (BNP), pro-BNP, and left ventricular ejection fraction will be retrieved from the medical record. Furthermore, the number of hospitalizations in the past year, co-morbidity assessed by the age-adjusted Charlson Comorbidity Index (a-CCI), and heart failure symptom burden evaluated by the Chinese version of the Memorial Symptom Assessment Scale for Heart Failure (MSAS-HF) will be recorded through the self-report.

**3.4.4 Feasibility indicators**

For the feasibility study, we will comprehensively assess the feasibility through recruitment status, attendance, and retention rates. First, the recruitment status will be divided into screening eligibility rates and final recruitment rates to evaluate the ability to successfully recruit target participants within the designated time and environment. Specifically, the screening eligibility rate is calculated as the ratio of eligible participants to the total number of screened individuals, while the recruitment rate is defined as the ratio of successfully recruited participants to the total number of potential participants contacted, with both expressed as percentages.

Next, attendance will be measured using two specific indicators: (1) the attendance rate for online group meetings, which is calculated based on the total number of meetings attended divided by the expected number of intervention meetings; (2) the number of weekly group interactions, including text, voice, or image contributions, as well as active days, which will help indicate effective dosage. Retention rate will be calculated as the ratio of the number of participants who completed the intervention to the total number of participants.

We will conduct one-on-one semi-structured interviews to evaluate the appropriateness, practicality, and acceptability of the intervention measures. The interviews will focus on three areas: (1) Appropriateness: Assessing whether the intervention meets participants' needs and expectations; (2) Practicality: Evaluating the feasibility of the intervention in real-world settings, including participants' experiences; (3) Acceptability: Understanding participants' overall perceptions, including satisfaction, engagement factors, and potential barriers. Additionally, we will collect participants' suggestions for improving the intervention, providing a basis for future optimization. Interview outline is listed in table 3.

**Table 3** Semi-structured interview guide for acceptability

Topic	Questions
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Appropriateness	Does the content provided by this intervention program meet your needs? Please be specific. Do you feel that the goals and content of the intervention meet your expectations? Are there any aspects that you feel are particularly appropriate or inappropriate for your situation? Please be specific.
Practicality	What difficulties have you encountered in your participation? Please provide examples. How would you describe the experience of participating in online group sessions and daily in-group interactions? Are there any parts of the program that are difficult to implement? What do you think are the biggest challenges to complete the intervention program? How do you think the intervention program could have been made easier to implement? More easily replicated or accepted by heart failure patients?
Acceptability	How satisfied are you with the intervention overall? On a scale of 1-10, how many points would you give? Why? Which parts or activities appealed to you the most? Or which parts may have caused hesitation or loss of interest? Would you like to continue to participate? Why? What reasons do you anticipate might prevent others from participating in the program?
Improvements	If you were asked to suggest 1-2 changes, what would you change or add? Are there any other comments that were not mentioned but are important?

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### 3.5 Data analysis

Data analysis will be conducted using SPSS version 25. Descriptive statistics will be calculated for all variables, including means, standard deviations, frequencies, and percentages. The baseline characteristics of the two groups of participants will be compared using t-tests, chi-square tests, Fisher's exact tests or Mann-Whitney *U*-test, as appropriate. The significance level for all tests will be set at  $p < .05$ .

This study will employ an intention-to-treat (ITT) approach, ensuring that all participants will be included in the final analysis regardless of whether they complete the study. Missing data will be addressed using direct maximum likelihood estimation to minimize bias. The effect sizes for changes in social frailty, perceived social support, social participation, and self-care will be investigated using means (M) and standard deviations (SD). A mixed repeated measures ANOVA and post-hoc comparisons will be used to

examine the effects of the intervention group compared to the control group on the outcomes. To explore which outcome indicators may be most important for the primary trial, Pearson correlation analysis will be conducted between the change scores of social frailty, perceived social support, social participation, and self-care, and the weekly average number of active days and group interactions, and group meeting participation rate.

In the qualitative data analysis, investigators will independently employ a phenomenological inductive approach to conduct thematic analysis of the interview data. They will carefully read the transcriptions to identify recurring important themes and sub-themes, aiming to gain a deeper understanding of participants' experiences and perspectives. Following the initial analysis, investigators will discuss and compare their results to validate the accuracy of the themes and ensure the comprehensiveness of the analysis.

For the full RCT analysis, A generalized estimating equation (GEE) model will be used to compare the changes in outcomes between the two groups at time points T0 (baseline), T1 (post-test), and T2 (3 months post-test), adjusting for potential confounding variables. Interaction terms for time points and groups will be included in the GEE model to assess the differences in outcomes between groups from baseline to each post-test endpoint while controlling for significant baseline confounding variables ( $p < .25$ ) [52, 53]. When significant interactions are found, post hoc analyses will be conducted to compare changes at each time point relative to baseline, providing a deeper understanding of the intervention effects. The significance level for all tests will be set at  $p < .05$ . Results will be presented as means with 95% confidence intervals (CIs) to clearly illustrate group differences, ensuring the reliability and validity of the study conclusions.

### **3.6 Data management**

Paper copies of raw data will be stored securely in locked cabinets with keys held by the Principal Investigator. Electronic versions of the data will be stored on a hard disk. All data collected will be processed and verified only by the investigators, research assistants involved in the project, the investigator's designated inspectors, and the ethics committees. Individuals who leave their current position will forfeit the right to access or use the data. Measures will be in place to ensure that individual participants cannot be identified directly from the datasets used for analysis. All collected personal information, research data, and related documents will be retained for 10 years following the completion of the study. Upon the expiration of the designated storage period, all data will be securely destroyed. All digital files containing personal and study data will be permanently deleted using secure deletion methods to ensure that they cannot be recovered. A record of the destruction process will be maintained, detailing the date, method of destruction, and individuals involved, ensuring accountability and compliance with ethical guidelines.



#### **4 Timetable**

Proposed study start date: 1<sup>st</sup> September 2025

Proposed study end date: 30<sup>st</sup> September 2027

Tentative final report submission date to CIRB/CREC/IRB: 31<sup>st</sup> December 2027

#### **5 Consent**

The procedure for obtaining patient informed consent involves face-to-face communication. Following a detailed discussion to ensure patients have a comprehensive understanding of the study's purpose, risks, and benefits, a printed version of the informed consent form will be provided to the patients. Emphasis will be placed on the voluntary nature of participation, with patients informed of their right to refuse or withdraw from the study at any time without repercussions. Patients will be given a minimum of 30 minutes to consider their decision and ask questions without feeling rushed or pressured. Only participants who meet the inclusion criteria and demonstrate understanding of the informed consent form will be asked to sign it.

#### **6 Major ethics issue**

This study will adhere to the ethical principles outlined in the Declaration of Helsinki. Participation in the study is voluntary. Participants will provide written informed consent and have the right to discontinue or withdraw from the study at any time without facing any repercussions. If a participant decides to withdraw, the data will be destroyed and will not be included in the analysis.

For the quantitative analysis, the dataset will be free of personally identifiable information to ensure participant anonymity. Furthermore, this dataset will not be made publicly available for secondary analysis. Any sensitive information that could potentially identify participants will be omitted from the research report. The results of the research may be published or presented at conferences, but personal data will not be revealed.

#### **7 Describe any unusual or discomforting procedures to be used:**

No.

#### **8 Are there any hazards associated with the investigation?**

No.

#### **9 Financing and insurance**

There was no financial support from any source for this study. Insurance is not required for this study.

#### **10 Dissemination of study result**

The results will be shared at local and international conferences and published in peer-reviewed journals. The progress and final reports will be gathered and sent to the Institutional Review Board of the University of Hong Kong/ Hospital Authority Hong Kong West Cluster (HKU/HA HKW IRB).

## 11 Conflict and interest

No.

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