Feasibility Study Protocol for the Effects of "Social Optimization Chat for Interactive Learning for HF" (SOCIAL_HF) on improving social frailty: A Feasibillity Study of a Randomized Controlled Trial

Informed consent form for study participants

Principal investigator: Miao Miao
Department: School of Nursing, The University of Hong Kong
Phone: +86 13391385030
Email: marymiao@connect.hku.hk

Dear participant:

We plan to conduct a randomized controlled study aimed at optimizing social functioning and self-care among heart failure patients, and we sincerely invite your participation. Before you decide whether to join, please read the following information carefully to understand the content, purpose, and process of the study, the possible benefits, risks, discomforts of participating, and the rights you have. You can also discuss it with friends and family before making a decision.

Objectives

This study has developed a program called "Social Optimization Chat for Interactive Learning for Heart Failure" (SOCIAL_HF), aimed at helping older adults with heart failure alleviate social frailty. The research will evaluate the feasibility and practicality of the program. Additionally, we will gather insights into participants' willingness, experiences, and perceptions regarding the project to improve the program.

Study Procedures

Participants will be randomly assigned to different groups in a 1:1 ratio, with one group joining a WeChat group to participate in a 6-week interactive learning course. The course will be conducted via video meeting in the WeChat group, allowing participants to join from home. Sessions will occur once a week, lasting one hour each. An online graduation ceremony will be held in the final week, totaling seven sessions. Participants will also engage in daily activities within the WeChat group, discussing, learning, and completing various challenges with other heart failure peers. They will receive a self-care booklet to learn more. The other group will also receive a self-care booklet and can consult via WeChat for any questions during their self-study, but they will not participate in group learning.

Participants can inquire about the study details at the recruitment site, undergo an assessment by researchers, and receive a participation gift pack. Those participating in the online course will have a follow-up phone call after the course concludes, lasting

approximately 15 minutes. The other group will receive a follow-up phone call about 15 minutes after six weeks. Some participants will also be invited to participate in interviews to share their feelings and feedback regarding the intervention.

If you agree to participate in the study, the following information will be collected during recruitment (about 30 min):

(1) Demographic profile, such as age, education, marital status, and living situation
(2) Clinical profile, such as height, weight, and heart failure history
(3) Heart failure symptoms
(4) Social frailty level
(5) Social support situation
(6) Social participation situation
(7) Self-care level

We will also obtain your biomarker levels and imaging data (if available) through the medical records.

During the follow-up phone call, we will inquire about and assess the following information:

(1) Social frailty level
(2) Social support situation
(3) Social participation situation
(4) Self-care level

Potential risks and discomfort

This study does not involve any invasive procedures and poses no risks to your health, nor will it cause harm or discomfort. If you feel unwell or fatigued during the study, you can take breaks or seek assistance from healthcare personnel at any time.

Potential benefits

This study aims to develop an effective program that optimizes social resources and interactions for heart failure patients, supporting them in better managing their condition. Through this study, you will gain necessary self-care knowledge and skills to minimize the impact of heart failure symptoms on your life and maintain a good quality of life. Upon completing two questionnaire surveys, you will receive a reward of 100 RMB as a token of appreciation for your participation and support.

Confidentiality

Your participation in this study will be treated in strictest confidence. This study has been reviewed and approved by the Institutional Review Board of the University of Hong Kong / Hospital Authority Hong Kong West Cluster (Ethics Code:), as well as the Ethics Committees of Shanghai Jiao Tong University School of Medicine Affiliated Songjiang Hospital (Ethics Number:), Shanghai Baoshan District Traditional Chinese and Western Medicine Hospital (Ethics Number:),Shanghai Jiao Tong University School of Medicine

Affiliated Sixth People's Hospital (Ethics Number:), and Fudan University Affiliated Huadong Hospital (Ethics Number:).

All data collected during the study will be securely stored and will be processed and verified only by the researchers, 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. Any information that could identify you will be removed from the data prior to analysis and reporting. The results of the research may be published or presented at conferences, but your personal data will not be revealed. At the completion of the study, personal and study data will be encrypted and stored for 10 years for the sole use of the research team.

Right of withdrawal

Whether or not to participate in this study depends entirely on your wishes. You may choose not to participate or withdraw your consent at any time without penalty or loss of benefits to which you would otherwise be entitled. If you decide to withdraw from the study, your data will be destroyed and will not be included in the analysis.

Questions & Contact Information

If you have any questions or concerns about the study, or if you would like to know the results of the study, please contact Principal Investigator Miao Miao, using the contact information listed above. If you have any questions regarding your rights as a participant in the study, you may contact the following ethics committees:

- Institutional Review Board of the University of Hong Kong / Hospital Authority Hong Kong West Cluster (Tel: +852 2255 4086)
- Shanghai Jiao Tong University School of Medicine Affiliated Songjiang Hospital Ethics Committee (Phone: +021 6772 0001)
- Shanghai Baoshan District Integrated Traditional Chinese and Western Medicine Hospital Ethics Committee (Phone: +021 5617 7192)
- Shanghai Jiao Tong University School of Medicine Affiliated Sixth People's Hospital Ethics Committee (Phone: +021 2405 6678)
- Fudan University Affiliated Huadong Hospital Ethics Committee (Phone: +021 6248 3180)

Informed consent

I have read the above presentation of this study and have had the opportunity to discuss and ask questions about this study with the researchers. All the questions I asked were answered satisfactorily.

I am aware of the risks and benefits that may arise from participating in this study. I understand that participation in the study is voluntary, I confirm that I have had sufficient time to consider this, and I understand that:

1. I can always ask the researchers for more information.
2. I can withdraw from this study at any time without discrimination or retaliation,

and my rights and interests will not be affected.

3. I am aware that my privacy will be protected in the research and that the data will be kept in encrypted form for 10 years after the study is completed. Any public reporting of the results of this study will not reveal my personal identity. I also agree that my records may be accessed by researchers, research-appointed monitors, college and ethics committees.

4. I agree that researchers and institutions will contact me in the future for follow-up investigation.

5. If I request to withdraw from the research in the middle of the study, I agree that the researcher can continue to use the research data provided before my withdrawal.

6. I will be provided with a signed and dated copy of the informed consent form.

In the end, I decided to agree to participate in the study and promised to follow the study protocol as much as possible and complete follow-up.

Subject Name	Signature	Contact Number	Date

Investigator's Name	Signature	Contact Number	Date

香 港 大 學
THE UNIVERSITY OF HONG KONG

HKU Med LKS Faculty of Medicine
School of Nursing
香港大學護理學院

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Objectives

This study will evaluate the immediate effects of the "Social Optimization Chat for Interactive Learning for Heart Failure" (SOCIAL_HF) intervention on the primary outcome of social frailty, as well as its effects on secondary outcomes such as perceived social support, social participation, and self-care. Additionally, we will assess whether these improvements can be maintained three months after the intervention to understand the long-term effects of the intervention.

Study Procedures

Participants will be randomly assigned to different groups in a 1:1 ratio, with one group joining a WeChat group to participate in a 6-week interactive learning course. The course will be conducted via video meeting in the WeChat group, allowing participants to join from home. Sessions will occur once a week, lasting one hour each. An online graduation ceremony will be held in the final week, totaling seven sessions. Participants will also engage in daily activities within the WeChat group, discussing, learning, and completing various challenges with other heart failure peers. They will receive a self-care booklet to learn more. The other group will also receive a self-care booklet and can consult via WeChat for any questions during their self-study, but they will not participate in group learning.

Participants can inquire about the study details at the recruitment site, undergo an assessment by researchers, and receive a participation gift pack. Those participating in

the online course will have a follow-up phone call after the course concludes and 3 months thereafter, with each call lasting about 15 minutes. Another group of participants will receive follow-up phone calls approximately 15 minutes each at six weeks and three months after the intervention.

If you agree to participate in the study, the following information will be collected during recruitment (about 30 min):

(1) Demographic profile, such as age, education, marital status, and living situation
(2) Clinical profile, such as height, weight, and heart failure history
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This study aims to develop an effective program that optimizes social resources and interactions for heart failure patients, supporting them in better managing their condition. Through this study, you will gain necessary self-care knowledge and skills to minimize the impact of heart failure symptoms on your life and maintain a good quality of life. Upon completing two questionnaire follow-ups, you will receive a reward of 100 RMB as a token of appreciation for your participation and support.

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Medicine Affiliated Sixth People's Hospital (Ethics Number:), and Fudan University Affiliated Huadong Hospital (Ethics Number:).

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Right of withdrawal

Whether or not to participate in this study depends entirely on your wishes. You may choose not to participate or withdraw your consent at any time without penalty or loss of benefits to which you would otherwise be entitled. If you decide to withdraw from the study, your data will be destroyed and will not be included in the analysis.

Questions & Contact Information

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3. I am aware that my privacy will be protected in the research and that the data will be kept in encrypted form for 10 years after the study is completed. Any public reporting of the results of this study will not reveal my personal identity. I also agree that my records may be accessed by researchers, research-appointed monitors, college and ethics committees.

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6. I will be provided with a signed and dated copy of the informed consent form.

In the end, I decided to agree to participate in the study and promised to follow the study protocol as much as possible and complete follow-up twice.

Subject Name	Signature	Contact Number	Date

Investigator's Name	Signature	Contact Number	Date