

# BMJ Open Effectiveness of a family customised online FOCUS programme aimed on building resiliency in dyad relationship to support dyadic illness management in persons with heart failure and their informal caregiver: a randomised clinical trial protocol

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**To cite:** Yang W, Cao Y, Li Y, *et al.* Effectiveness of a family customised online FOCUS programme aimed on building resiliency in dyad relationship to support dyadic illness management in persons with heart failure and their informal caregiver: a randomised clinical trial protocol. *BMJ Open* 2022;**12**:e061405. doi:10.1136/bmjopen-2022-061405

► Prepublication history for this paper is available online. To view these files, please visit the journal online (<http://dx.doi.org/10.1136/bmjopen-2022-061405>).

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Received 26 January 2022  
Accepted 06 July 2022



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## ABSTRACT

**Introduction** Living with heart failure (HF), is a shared journey and arduous work for patients and their informal family caregivers. Given the key role and limited evidence of dyad illness management in improving dyad health in the context of HF, we developed a customisable, relationship focused, family online dynamic disease management programme—FOCUS programme—to improve dyad health for HF patients and their informal caregivers in China.

**Methods and analysis** Based on the Theory of Dyadic Illness Management and the Systemic Transactional Model of Stress and Coping, the family customised online FOCUS programme has five modules: (1) family participatory; (2) open communication; (3) coping effectiveness; (4) uncertainty reduction and 5) shared dyad life stories. HF family dyads will be recruited in the cardiology wards of four university-affiliated hospitals in China. The dyads (N=142) will be randomly allocated to the intervention group that will receive the family customised online FOCUS programme, and the attention control group that will not receive elements of the FOCUS programme. Dyadic coping, HF somatic perception, self-care, anxiety and depression for patients and family caregivers and all-cause mortality and hospital admission for patients will be measured at baseline, 4 weeks (after the discharge, T1), 12 weeks (after the discharge, T2) and 24 weeks (after the discharge, T3). Statistical analysis will be performed using SPSS V. 22.0 software.

**Ethics and dissemination** The study protocol was approved by the ethics committees of Tianjin Medical University (Reference number TMUHEC2019002) that covers all the centres enrolled in this study. The findings of this study will be published in scientific journals and will be presented at scientific conferences.

**Trial registration number** ChiCTR2100053168.

## STRENGTHS AND LIMITATIONS OF THIS STUDY

- ⇒ A family customised online dyadic disease management protocol was developed specifically for heart failure dyads to be used as intervention.
- ⇒ In this study, we will use online intervention and WeChat follow-up to collect data, which is conducive to the implementation of the study during the COVID-19 pandemic.
- ⇒ Subject recruitment can be challenging due to the inclusion of patient-caregiver dyad in the study.
- ⇒ The attrition rate may be high due to the progression of heart failure and long follow-up of up to 24 weeks.
- ⇒ Participants are not blinded for group allocation which could cause bias.

## INTRODUCTION

Heart failure (HF), a chronic impairment of cardiac function typically characterised by shortness of breath, oedema and/or fatigue, affects over 37.7 million patients worldwide, with prevalence increasing as populations age and cardiovascular risk factors rise.<sup>1–3</sup> HF patients, with a greater number of comorbidities, experience more subsequent all cause hospitalizations and outpatient and emergency visits as well as higher HF-related and all-cause care costs.<sup>1</sup> According to survey analysis, patients with worsening HF events have anxiety and depression more commonly.<sup>4</sup> In turn, anxiety and depression also contribute significantly to decreases in overall quality of life, neglect of self-care and increases in worsening HF events.<sup>5–7</sup>



Living with HF is a shared journey and arduous work for patients and their informal family caregivers who provided unpaid support.<sup>8</sup> Caregivers play an integral role in HF management, such as supporting activities of daily living, improving and maintaining self-care, psychosocial support and navigating the complex healthcare system.<sup>9</sup> The HF journey adversely impacts the caregiver's physical, mental and social well-being and can bring about fear, uncertainty, depression and anxiety.<sup>10 11</sup> Research has also demonstrated that anxiety and depression in caregivers are associated with higher levels of stress, lower quality of life and higher risk of mortality and also increase depression in patients.<sup>12–15</sup> In addition, living with HF could disrupt dyad relationships between patients and caregivers that would otherwise be highly protective in buffering the negative effects of both HF itself and the stresses of caregiving.<sup>16 17</sup>

A dyad is typically defined as two individuals maintaining a sociologically significant relationship.<sup>18</sup> Many HF patients live within a family system as part of a patient/informal caregiver dyad. HF management is known as a dyadic phenomenon. Recently, a dyadic disease management systematic review points out that findings across dyadic self-care interventions are inconclusive and the evidence from dyadic disease management to promote HF dyadic health, while growing, is still very limited.<sup>19</sup> Further innovative research into dyadic disease management is still needed.

A cross-sectional dyadic survey finds that the differences in how HF dyadic appraise symptoms (ie, dyspnoea, fatigue, pain and anxiety) must be taken into consideration when examining contributions to HF self-care.<sup>20</sup> Further findings suggest that patterns of dyadic HF appraise symptoms are associated with self-care behaviours over 6 months and contribute to dyadic mental health.<sup>21</sup> Based on the dyadic depression score, different patterns of mental health are identified, which associates with incongruent dyadic appraisal and social/familial support.<sup>22</sup> According to the Theory of Dyadic Illness Management proposed by Lyons and Lee, the way dyads appraised illness as a unit influences the ways in which they engaged in behaviours to manage the full course of illness together. Furthermore, dyadic appraisal and dyadic management behaviours have a recursive association over time, with both influencing dyad health.<sup>23</sup> However, all the above studies remain in a cross-sectional study design, and the relationship between dyadic symptom assessment, dyadic self-management and dyadic mental health need to be further verified in intervention experiments.

The systematic transactional model of Stress and Coping is prevalent in the fields of chronic disease. It points out that a partner's stressful experience (affecting the partner's mood, well-being and behaviour) could affect both partners in a commitment relationship, which can be regarded as 'we-stress'.<sup>24</sup> Based on the results of longitudinal and cross-sectional studies, when facing 'we-stress' event, the positive dyadic comprehension and dyadic coping relate to better dyadic adaptation and

relationship quality.<sup>25–27</sup> A better comprehension of the dyadic challenges couples coping with disease may face and more insight on how to expand the dyadic coping of these couples might facilitate improvements in the couples' relationship functioning. Future research is needed to examine whether or not HF family dyads might benefit from such interventions.

Given the key role and limited evidence of dyad illness management in improving dyad health in the context of HF, we developed the family FOCUS programme according to the characteristics of each family dyadic relationship and further explore the effect of it on dyad health for HF patients and their informal caregiver and reduce all-cause mortality and hospital admission for HF patients in China.

### Aims and hypotheses

The aim of this study is to evaluate the effectiveness of a customisable, relationship-focused, family online dynamic disease management programme.

We hypothesise that, compared with participants receiving routine care, participants receiving the family customised online FOCUS programme plus usual care will:

1. Have a greater improvement in dyadic self-care over time.
2. Have a greater improvement in consistency of symptom assessment and the level of dyadic coping, relationship, self-care, anxiety and depression at 4 weeks (after the discharge, T1), 12 weeks (after the discharge, T2) and 24 weeks (after the discharge, T3).
3. Have a significant reduction in all-cause mortality and readmission at the above follow-up time points.

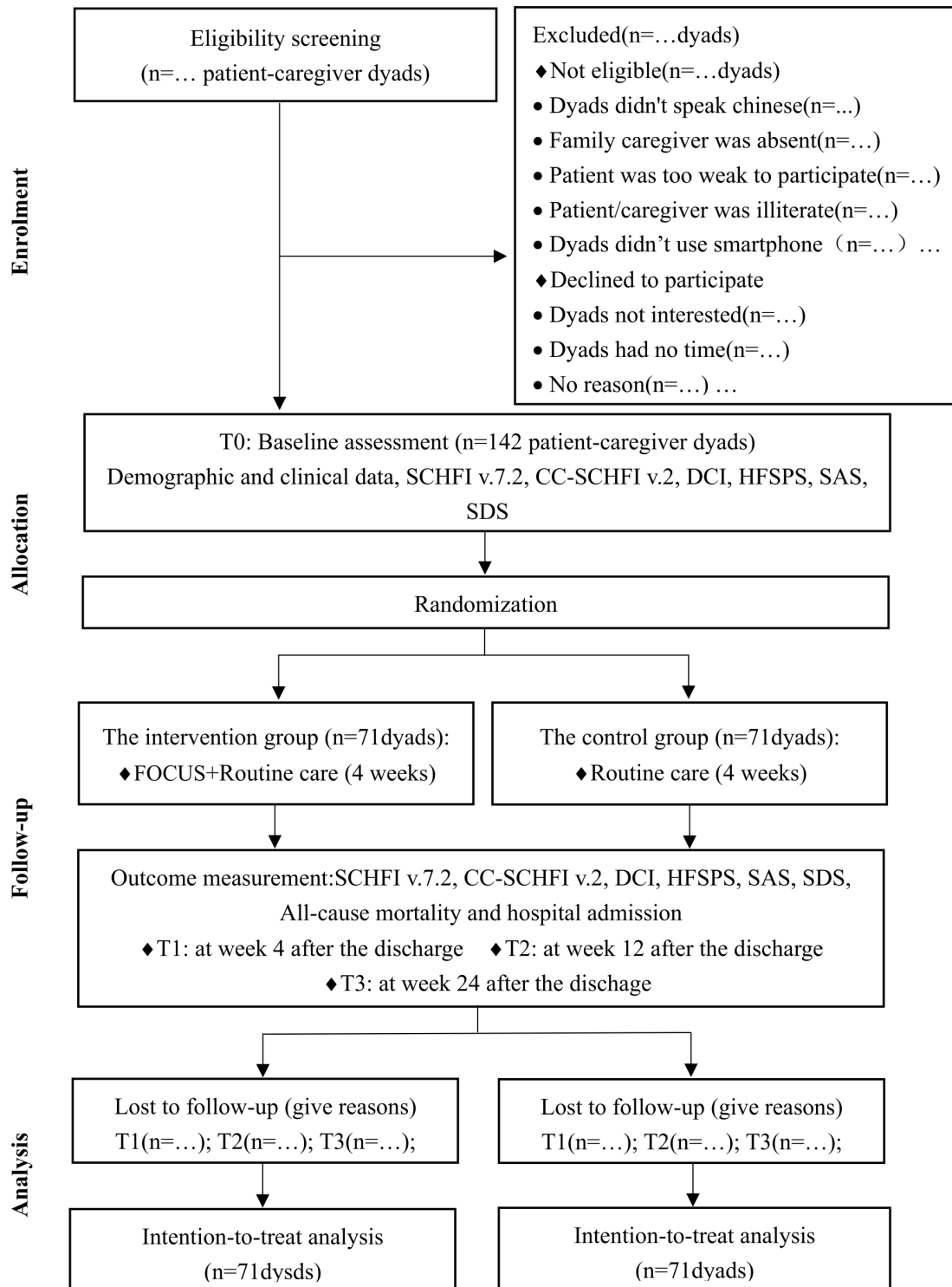
## METHODS AND ANALYSES

### Design

This study is a two-arm parallel group, randomised controlled trial with blinded outcome assessment and has been registered with the number 'ChiCTR2100053168'. The trial is expected to begin in May 2022 with the inclusion of the first patient and will end when 142 dyads are enrolled in the trial, expected to be September 2022. Data collection will end by March 2023. The intervention group will receive the family online FOCUS programme consisting of one face-to-face session and four online sessions. Assessments will be conducted at five time points: baseline (first week in the hospital, T0), 4 weeks (after the discharge, T1), 12 weeks (after the discharge, T2) and 24 weeks (after the discharge, T3). See [figure 1](#) for the flow chart of the study process, adapted from the Consolidated Standards of Reporting Trials 2010 flow chart.<sup>28</sup> This study protocol adheres to the Statement Standard Protocol Items: Recommendations for Interventional Trials 2013.<sup>29</sup>

### Study setting and recruitment

The participants (patient–family caregiver dyads) will be recruited from four grade III class A hospitals affiliated



**Figure 1** Flow chart of the study process—adapted from CONSORT flow chart (Moher *et al*<sup>28</sup>). CC-SCHFI V.2, Caregiver Contribution to Self-Care of Heart Failure Index Version 2; CONSORT, Consolidated Standards of Reporting Trials; DCI, Dyadic Coping Inventory; HFSPS, Heart Failure Somatic Perception Scale; SAS, Self-Rating Anxiety Scale; SDS, Self-Rating Depression Scale.

to Tianjin Medical University. The principal investigator (the first author), a registered nurse, needs to consult the patients' electronic medical records to get an understanding of the patients' basic social and disease characteristics. Then, the principal investigator will be responsible for screening participants and introducing

the purpose of the study to eligible patient–family caregiver dyads to obtain informed consent. A participation form will be filled out and the participants will contact the investigator through WeChat (a social software programme) or by telephone if they intend to participate in this study.

**Table 1** Inclusion and exclusion criteria of the study

	Inclusion criteria	Exclusion criteria
Patient	<ul style="list-style-type: none"> <li>▶ Had a diagnosis of HF<sup>44</sup> classified as New York Heart Association class I–III.</li> <li>▶ Aged 18 years or older.</li> <li>▶ Having been informed of the stage of the disease and the treatment.</li> <li>▶ Able to express themselves.</li> <li>▶ Able to read and write using their smartphone.</li> </ul>	<ul style="list-style-type: none"> <li>▶ Having cognitive impairment (comprehension or expression problems).</li> <li>▶ Taking psychotropic drugs.</li> <li>▶ Participating in other studies within the last 3 months.</li> </ul>
Caregiver	<ul style="list-style-type: none"> <li>▶ Patient's family members or close relatives.</li> <li>▶ Providing care free of charge and spending at least 24 hours per week caring for patients with HF.<sup>45</sup></li> <li>▶ Able to express themselves.</li> <li>▶ Able to read and write using their smartphone.</li> </ul>	<ul style="list-style-type: none"> <li>▶ Having cognitive impairment (comprehension or expression problems).</li> <li>▶ Taking psychotropic drugs.</li> <li>▶ Participating in other studies within the last 3 months.</li> </ul>

HF, heart failure.

### Participants

The inclusion and exclusion criteria of the HF patients and caregivers are presented in [table 1](#).

### Sample size calculation

The sample size calculation was based on the results for the self-care management level of Self-Care of Heart Failure Index version 7.2 (SCHFI V.7.2) from a previously study.<sup>30</sup> Assuming a power of 0.8 with alpha of 0.05, and before and after the intervention HF population self-management mean of 56.66 and 24.55, respectively, each study arm required at least 57 participants. Assuming an attrition rate of approximately 20% based on an attrition rate of 18%–22% in previous family interventions,<sup>31</sup> 71 family dyads will be required in each group. This study will recruit 142 family dyads.

### Randomisation, allocation and blinding

After confirming eligibility criteria and obtaining valid informed consent, baseline data collection will be carried out. Randomisation will be performed only after all baseline data collection has been completed. Participants will be randomly allocated in a 1:1 ratio using a random sequence set generated from the Research Randomiser Website (<https://www.randomizer.org/>). The sequence of numbers will contain 142 non-repeating numbers ranging from 1 to 142. Then, they will be packaged in sequentially numbered, sealed and opaque envelopes by a third party to ensure allocation concealment. In this study, as the investigator (the first author) will be unblind to the group allocation, the data collection and analysis will be performed by a research assistant and a statistician who will be blind to group allocation.

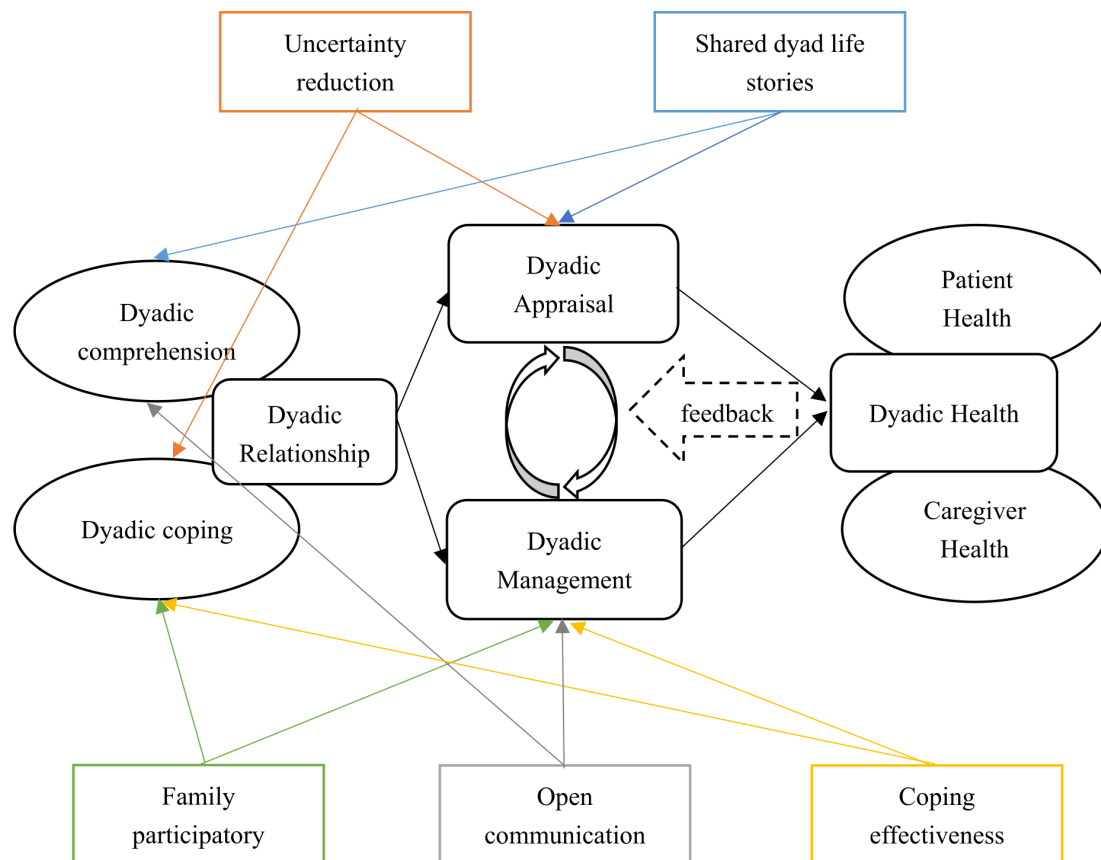
### Development and description of the family FOCUS programme

A family FOCUS programme protocol was developed by members of the research team consisting of cardiologists experienced in treating patients with HF, psychologists with experience in family intimate relationship and clinical nurses who communicate regularly with HF dyad. We first conducted short interviews with 10 HF dyads

and found that the quality of the relationship between patients and their caregivers was poor in cocoping with the self-management of the disease, leading to often inconsistent perceptions of the assessment of HF symptoms. Based on findings from these interviews and literature review,<sup>19</sup> we decided to apply the dyadic illness management theory<sup>23</sup> and the systemic transactional model<sup>24</sup> to guide the development of the family FOCUS programme, aiming to improve dyadic assessment of HF symptoms, strengthen dyadic self-management and optimise dyadic relationship.

We then conducted two focus group discussions. In the first discussion, we preliminarily identified the modules of intervention (see [figure 2](#)), which include family participatory, open communication, coping effectiveness, uncertainty reduction and shared dyad life stories. In the second discussion, the specific content, intervention time and frequency of each module were further determined (see [figure 3](#)). Finally, we selected six HF dyads to conduct pilot experiments and found patients exclusively interested in face-to-face sessions (either in-person or using a video conference). Considering the special hospital management requirements during the COVID-19 pandemic and the feasibility of the experiment, we finally chose to deliver the intervention through online face-to-face video via Voon Meeting mobile app (an online video conferencing software).

Participants in the intervention arm will receive the family FOCUS programme led by a masters' level clinical nurse who has been trained on it. The family FOCUS programme consists of one family participatory discharge health education and four online sessions over 4 weeks after discharge, with each session focusing on new topics and skills for the patient and their caregiver. Taking into account the specific circumstances of the dyads and in order to reduce the lost follow-up rate, our online sessions time will be flexible and reconcilable according to the situation of the dyad, with a view to completing four online meetings within 4 weeks. In addition, at the end of each session, the family will create a 'Hand in Hand Plan'



**Figure 2** Theoretical framework of family customised online focus programme.

in which nurses who take into account the characteristics of each family dyads will note what skills they will focus on practicing throughout the week. In each session, family dyads will spend about 10 min reviewing homework and ‘Hand in Hand Plan’, 40 min learning new content and skills, and 10 min creating a new ‘Hand in Hand Plan’ for the week. Before and after the session, the researchers will contact patients and caregivers by telephone or WeChat to ensure that the family dyads will stay engaged in each intervention as much as possible.

### Control

The control group will receive usual care provided by a clinical nurse that includes: general discharge health education and routine follow-up. To reduce the potential of patient contact acting as a confounding variable, the control group will also receive matched video interviews, although the content of these video interviews will differ to that of the intervention group by being of a generic nature. They will discuss in general terms how the patient and caregiver are feeling and will not contain information based on the family FOCUS programme. In addition, we will send related health information through WeChat to keep in touch with patients and reduce the rate of lost to follow-up. In consideration of the principle of fairness, after the 24 weeks follow-up period, participants in the control group will be offered the option of receiving the family FOCUS programme.

### Study variables

#### Demographic data and clinical characteristics for patients and family caregivers

The participants’ demographic data and clinical characteristics will be collected through a self-designed questionnaire. For patients with HF, sociodemographic variables: age, sex, level of education, living alone or with someone, received social support, religion and race. Clinical variables: date of HF diagnosis, severity of HF via the New York Heart Association functional class, previous HF hospitalisation and comorbid conditions measured via the Charlson Comorbidity Index.<sup>32</sup> For informal caregivers, sociodemographic variables: age, gender, marital status, level of education, religious belief, relationship to the patient and hours of caregiving per day.

### Primary outcome

#### SCHFI V.7.2 for patients

The SCHFI V.7.2 will be used to measure the patient’s self-care<sup>33</sup> and the Chinese version can be available from <http://self-care-measures.com/>. It is a 29-item 5-point Likert-type scale consisting of three dimensions: self-care maintenance, symptom perception and self-care management, with higher scores indicating better self-care. Recent psychometric testing supports the factorial structure, high construct validity, and reliability (Cronbach’s  $\alpha$  between 0.73 and 0.88) of the SCHFI v.7.2.<sup>33</sup>

	Topic	Location	Focus
Module 1	Family participatory	Cardiology ward	<ul style="list-style-type: none"> <li>◆ Discharge self-management education: sleep, diet, movement, pleasant activities, engaging support;</li> <li>◆ Exploring the heart failure self-management experience for both patient and caregiver;</li> <li>◆ Strategies to adhere to self-management;</li> <li>◆ Setting specific, measurable, attainable, realistic, and time-bound (SMART) goals to achieve them;</li> <li>◆ Assisting each other in making these goals;</li> <li>◆ Skill practice planning; individually, together, or both using vooon meeting mobile app (an online video conferencing software)</li> </ul>
Module 2	Open communication	online	<ul style="list-style-type: none"> <li>◆ Self disclosure and Share self-management concerns; Review changes in the relationship;</li> <li>◆ Diaphragmatic breathing — immediate relief from intense emotions;</li> <li>◆ Dialectics, ie, how to let more than 1 thought or feeling be true at the same time;</li> <li>◆ Using dialectics and developing positive attitude towards heart failure self-management;</li> <li>◆ Educating them about relational uncertainty and interdependence;</li> <li>◆ Communication strategies and interpersonal effectiveness skills;</li> </ul>
Module 3	Coping effectiveness	online	<ul style="list-style-type: none"> <li>◆ Coping with self-management concerns, ie, deciding between change and acceptance;</li> <li>◆ Identifying things that changed and things that are the same post-heart failure for both patient and caregiver;</li> <li>◆ Understanding active vs emotional coping;</li> <li>◆ Acceptance and self-appreciation; positive psychology skills, ie, humor, optimism</li> </ul>
Module 4	Uncertainty reduction	online	<ul style="list-style-type: none"> <li>◆ Education on heart failure symptom recognition tailored to dyad answers on HFSPS; Provide video animation understanding;</li> <li>◆ Analyze reasons for dyad symptom assessment inconsistencies;</li> <li>◆ Decision coping tree to differentiate symptoms that you can control from those you cannot;</li> <li>◆ Using mindfulness and dialectics to cope with fear of symptoms worsen;</li> <li>◆ learning if it is time for acceptance or change;</li> </ul>
Module 5	Shared dyad life stories	online	<ul style="list-style-type: none"> <li>◆ Review progress on SMART goals dyad have set;</li> <li>◆ Review and identify changes in self-image and personal identity;</li> <li>◆ Review again changes in the relationship;</li> <li>◆ Share the most memorable experience in dyad life;</li> <li>◆ Progressive muscle relaxation and guided imagery;</li> <li>◆ Interpersonal effectiveness skills;</li> </ul>

**Figure 3** The family customised online focus programme session content.

### Caregiver Contribution to Self-Care of Heart Failure Index Version 2 for caregivers

The Caregiver Contribution to Self-Care of Heart Failure Index Version 2 (CC-SCHF V.2) will be used to measure the caregiver's contribution to the patient's self-care<sup>34</sup> and the Chinese version can be available from <http://self-care-measures.com/>. The CC-SCHF mirrors the

SCHF with the same number of scales and items but measures the caregiver how often they recommend self-care activities versus the patient-oriented SCHFI, which measures how often the patient performs the activities. Recent psychometric testing supports the factorial structure, high construct validity and reliability (Cronbach's  $\alpha$  between 0.81 and 0.83) of the CC-SCHF V.2.<sup>34</sup>

## Secondary outcomes

### Dyadic coping inventory for patients and family caregivers

The Chinese versions of Dyadic Coping Inventory (DCI) will be used to assess patients' and the family caregivers' coping strategies.<sup>35</sup> The scale is based on System Interaction Model to assess the quality of perceived stress communication and dyadic support coping of one-party intimate relationships in stress. It is a 37-item 5-point Likert-type scale with a Cronbach's  $\alpha$  coefficient of 0.51–0.80.<sup>35</sup> Higher scores indicate more supportive behaviour.

### Heart Failure Somatic Perception Scale for patients and family caregivers

The Heart Failure Somatic Perception Scale will be used to assess patients' and the family caregivers' awareness and perceived distress of HF symptoms<sup>36</sup> and has been translated into Chinese version with a Cronbach's alpha of 0.87.<sup>37</sup> It measures how much the participant was bothered by symptoms during the last week. It is an 18-item 6-point Likert scale with a total score ranging from 0 to 90. Higher scores indicate higher perceived distress.

### Self-Rating Anxiety Scale and Self-Rating Depression Scale for patients and family caregivers

The Chinese versions of the Self-Rating Anxiety Scale (SAS) will be used to assess the severity of anxiety in patients and caregivers.<sup>38</sup> It is a 20-item 4-point Likert scale with a total score ranging from 20 to 80, with a higher score indicating higher anxiety severity. The internal consistency of the Chinese version of SAS is 0.81, indicating high homogeneity reliability.<sup>39</sup> Similarly, the Chinese versions of the Self-Rating Depression Scale (SDS) will be used to assess the severity of depression in patients.<sup>40</sup> It is also a 20-item 4-point Likert scale scored in the same way as the SAS scale. The internal consistency of the Chinese version of SDS is 0.79, indicating high reliability in the investigation of psychological and mental impairment of the Chinese population.<sup>41</sup>

### All-cause mortality and hospital admission for patients

Information on all-cause mortality and hospital admission will be obtained from the patients or caregivers and confirmed by reviewing the medical charts at the cardiology or emergency department.

### Data collection

The data will be collected by a research assistant blinded to the assignment of groups. Due to the flexibility of the patients' discharge date, the data at the baseline (T0) and four follow-ups will be collected using Questionnaire Star (a tool for questionnaire surveys) via WeChat at 4 weeks (T1), 12 weeks (T2) and 24 weeks (T3) after the discharge (see table 2). If the participant has not completed the online questionnaire, two reminder messages will be sent out for each measurement time point. Trial patients are free to withdraw their informed consent at any time and be followed up according to the department's standard procedures.

### Data management

Study data will be collected and managed using ResMan (www.medresman.org) hosted at Chinese Clinical Trial Registry. ResMan is a secure, web-based software platform designed to support data capture and share. All of the collected data will be kept pseudonymised and confidentially and will be entered into the computerised ResMan database and transferred for analysis portal in encrypted mode. All data could only be accessed by the research team members who are fully responsible for ensuring the safety of the research data. All completed baseline questionnaires and informed consent forms signed by participants will be stored in locked filing cabinets in areas with limited access at the sites.

### Data monitoring

We have not included a data monitoring committee in this project. The family FOCUS programme is a safe,

**Table 2** Schedule of assessments

Outcomes (measures)	Completed by		Baseline	After discharge		
	Patient	Caregiver	T0	T1:4 weeks	T2:12 weeks	T3:24 weeks
Inclusion criteria	Demographic and clinical data	x	x	x		
Primary outcome	SCHF V.7.2	x	x	x	x	x
	CC-SCHF V.2		x	x	x	x
Exploratory outcomes	DCI	x	x	x	x	x
	HFSPS	x	x	x	x	x
	SAS	x	x	x	x	x
	SDS	x	x	x	x	x
	All-cause mortality	x			x	x
	All-cause readmission	x			x	x

CC-SCHF V.2, Caregiver Contribution to Self-Care of Heart Failure Index Version 2; DCI, Dyadic Coping Inventory; HFSPS, Heart Failure Somatic Perception Scale; SAS, Self-rating anxiety scale; SCHF V.7.2, Self-Care of Heart Failure Index version 7.2; SDS, Self-rating depression scale.

non-invasive, non-pharmacological intervention. There is a potential beneficial effect of participation in the FOCUS programme as self-care levels may increase. As we believe harm is unlikely, the interim analysis will not be done only for the sake of checking how the intervention is working. We will continuously monitor the 24-week period after the patient's hospitalisation to avoid clinical adverse events.

### Data analysis

Descriptive statistics will be used to describe sociodemographic and outcome variables with measures as appropriate of frequency or central tendency (mean, SD or median, IQR if not normally distributed), ordinal (median, IQR) and nominal variables (mode, percentages) as appropriate. The incongruence scores of dyadic symptoms appraisal will be calculated by subtracting the caregiver's score (caregiver appraisal of patient's symptoms) from the patient's score (patient appraisal of own symptoms). A two-way repeated-measures analysis of variance will be used to explore between-group (group: intervention vs control), within-group (time: baseline and three follow-ups), and interaction (group  $\times$  time) effects. Data of all randomised participants will be included in the analyses (ie, intention-to-treat analysis). Missing data at follow-up will be handled under the assumption of missing at random<sup>41</sup> and be imputed by a respective method (eg, predictive mean matching). Data will be analysed using IBM SPSS Statistics for Windows, V.22.0 (IBM SPSS Data Collection). The criterion for statistical significance will be set at  $p < 0.05$  in a two-tailed test. P values of secondary outcomes will be adjusted for multiplicity.

### Ethics and dissemination

#### Ethics

The study protocol was approved by the ethics committees of the Tianjin Medical University (Reference number TMUHEC2019002) that covers all the centres participating in this study. This study will comply with the ethical principles of the Declaration of Helsinki. The study aims, intervention content, voluntary participation, right to refuse the participation and free to withdraw at any time will be explained verbally and outlined in detail on an information sheet. If the intervention proves to be effective, participants enrolled in the control group will be invited to receive it as well.

#### Dissemination and availability of data

The findings of this study will be published in scientific journals and will be presented at scientific conferences. The authors that contributed to the results of this study will be granted authorship. The original dataset produced by this study will be available from the corresponding author on reasonable request.

#### Patient and public involvement

Patients with HF and their family caregivers were involved during the development stage of the family FOCUS programme and were asked to give us feedback

to improvise and finalise it. The public was not directly involved in developing research questions, intervention designs and writing this protocol. The patients will receive their test results from the baseline and follow-up postintervention/standard care.

### DISCUSSION

To our knowledge, this is the first study to explore the effectiveness of family customised online dyadic disease management programme for family dyads with HF using a rigorous study design. The strengths of this study include that it combines online technology considered as low cost, sustainable and highly scalable with customised health interventions according to the relationship characteristics of each family dyad. Furthermore, research will obtain a large amount of data to analyse the association of dyadic relationships and dyadic health outcomes over a longitudinal period of time.

Dyadic illness management is emerging as a novel behavioural paradigm that focuses on partnerships between patients and family caregivers to manage health and illness for both members of the dyad.<sup>23</sup> Dyadic relationships shape how they responded to and interpreted the changes of HF symptoms and demands of self-management, and over time contributed to dyad emotional distress. There is emerging qualitative and quantitative research providing evidence that dyad relationship quality is related to reduced risk of patient mortality, improved patient self-management, and health status and reduced caregiver strain.<sup>22 42 43</sup> This study will provide practical information to promote the further development of dyadic disease management.

Moreover, the global health emergency generated by the COVID-19 pandemic is posing an unprecedented challenge to family health management of chronic diseases. If family customised online FOCUS programme is effective in Chinese HF family dyads to improve dyadic health outcomes, this trial will provide valuable evidence to support HF groups worldwide and family dyads with multiple chronic diseases.

#### Limitations

Although we have carefully crafted this protocol, a few main limitations still remain. First, subject recruitment can be challenging due to the inclusion of patient-caregiver dyad in the study. We will work with cardiology nurses at the four affiliated hospitals to inform us immediately of any dyad that meets the inclusion criteria. Second, the attrition rate may be high due to the progression of HF and the long follow-up of 24 weeks. Therefore, a 20% loss rate will be taken into account in the sample size calculation and we will make an appointment before each assessment and give some financial subsidies to the participants after each assessment. Finally, our research will be conducted in Tianjin, China, which may limit the generalisation of this study research due to cultural differences.



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**Contributors** XiaZ and XinZ conceived the presented idea. YL, YC and YL planned and conducted the study design. XiaZ and MC developed the plan for the statistical analyses. XL, SJ and QL looked up research tools. All authors contributed to the reporting of the study protocol.

**Funding** The study was funded by the National Natural Science Foundation of China (71904143 and 71974142).

**Competing interests** None declared.

**Patient and public involvement** Patients and/or the public were involved in the design, or conduct, or reporting, or dissemination plans of this research. Refer to the Methods section for further details.

**Patient consent for publication** Not applicable.

**Provenance and peer review** Not commissioned; externally peer reviewed.

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## REFERENCES

- Butler J, Djatche LM, Sawhney B, *et al*. Clinical and economic burden of chronic heart failure and reduced ejection fraction following a worsening heart failure event. *Adv Ther* 2020;37:4015–32.
- Rogers C, Bush N. Pathophysiology heart failure: diagnosis, medical treatment guidelines, and nursing management. *Nurs Clin North Am* 2015;50:787–99.
- Savarese G, Lund LH. Global public health burden of heart failure. *Card Fail Rev* 2017;3:7–11.
- Dunbar SB, Tan X, Lautsch D, *et al*. Patient-Centered outcomes in HFREF following a worsening heart failure event: a survey analysis. *J Card Fail* 2021;27:877–87.
- AbuRuz ME. Anxiety and depression predicted quality of life among patients with heart failure. *J Multidiscip Healthc* 2018;11:367–73.
- Müller-Tasch T, Löwe B, Lossnitzer N, *et al*. Anxiety and self-care behaviour in patients with chronic systolic heart failure: a multivariate model. *Eur J Cardiovasc Nurs* 2018;17:170–7.
- Sokoreli I, de Vries JGG, Pauws SC, *et al*. Depression and anxiety as predictors of mortality among heart failure patients: systematic review and meta-analysis. *Heart Fail Rev* 2016;21:49–63.
- Kitko LA, Hupcey JE. The work of spousal caregiving of older adults with end-stage heart failure. *J Gerontol Nurs* 2013;39:40–7.
- Kitko L, McIlvennan CK, Bidwell JT, *et al*. Family caregiving for individuals with heart failure: a scientific statement from the American heart association. *Circulation* 2020;141:e864–78.
- Lacerda MS, Prado PRdo, Barros ALBLde, *et al*. Depressive symptoms in the family caregivers of patients with heart failure: an integrative review. *Rev Gaucha Enferm* 2019;40:e20180057.
- McHale S, Astin F, Neubeck L, *et al*. A systematic review and thematic synthesis exploring how a previous experience of physical activity influences engagement with cardiac rehabilitation. *Eur J Cardiovasc Nurs* 2020;19:31–43.
- Chung ML, Lennie TA, Mudd-Martin G, *et al*. Depressive symptoms in patients with heart failure negatively affect family caregiver outcomes and quality of life. *Eur J Cardiovasc Nurs* 2016;15:30–8.
- Evangelista LS, Strömberg A, Dionne-Odom JN. An integrated review of interventions to improve psychological outcomes in caregivers of patients with heart failure. *Curr Opin Support Palliat Care* 2016;10:24–31.
- Hu X, Huang W, Su Y, *et al*. Depressive symptoms in Chinese family caregivers of patients with heart failure: a cross-sectional study. *Medicine* 2017;96:e6480.
- Schulz R, Beach SR. Caregiving as a risk factor for mortality: the caregiver health effects study. *JAMA* 1999;282:2215–9.
- Hooker SA, Grigsby ME, Riegel B, *et al*. The impact of relationship quality on health-related outcomes in heart failure patients and informal family caregivers: an integrative review. *J Cardiovasc Nurs* 2015;30:S52–63.
- Noonan MC, Wingham J, Taylor RS. 'Who cares?' the experiences of caregivers of adults living with heart failure, chronic obstructive pulmonary disease and coronary artery disease: a mixed methods systematic review. *BMJ Open* 2018;8:e020927.
- Merriam-Webster. Merriam-Webster, n.d. Available: [https://www.merriamwebster.com/dictionary/dyad?utm\\_campaign=sd&utm\\_medium=serp&utm\\_source=jsonld](https://www.merriamwebster.com/dictionary/dyad?utm_campaign=sd&utm_medium=serp&utm_source=jsonld) [Accessed 05 Mar 17].
- Buck HG, Stromberg A, Chung ML, *et al*. A systematic review of heart failure dyadic self-care interventions focusing on intervention components, contexts, and outcomes. *Int J Nurs Stud* 2018;77:232–42.
- Lee CS, Mudd JO, Auld J, *et al*. Patterns, relevance and predictors of heart failure dyadic symptom appraisal. *Eur J Cardiovasc Nurs* 2017;16:595–604.
- Lyons KS, Johnson SH, Lee CS. The role of symptom appraisal, concealment and social support in optimizing dyadic mental health in heart failure. *Aging Ment Health* 2021;25:734–41.
- Lyons KS, Sadowski T, Lee CS. The role of concealment and relationship quality on patient hospitalizations, care strain and depressive symptoms in heart failure dyads. *Eur J Cardiovasc Nurs* 2020;19:118–24.
- Lyons KS, Lee CS. The theory of Dyadic illness management. *J Fam Nurs* 2018;24:8–28.
- Bodenmann G, Falconier M, Randall AK. *Systemic-Transactional model of Dyadic coping*. In: Encyclopedia of Couple and Family Therapy, 2017: 1–7.
- Falconier MK, Jackson JB, Hilpert P, *et al*. Dyadic coping and relationship satisfaction: a meta-analysis. *Clin Psychol Rev* 2015;42:28–46.
- Mittinty MM, Kindt S, Mittinty MN, *et al*. A Dyadic perspective on coping and its effects on relationship quality and psychological distress in couples living with chronic pain: a longitudinal study. *Pain Med* 2020;21:e102–13.
- Rusu PP, Nussbeck FW, Leuchtman L, *et al*. Stress, dyadic coping, and relationship satisfaction: a longitudinal study disentangling timely stable from yearly fluctuations. *PLoS One* 2020;15:e0231133.
- Moher D, Hopewell S, Schulz KF, *et al*. CONSORT 2010 explanation and elaboration: updated guidelines for reporting parallel group randomised trials. *Int J Surg* 2012;10:28–55.
- Chan A-W, Tetzlaff JM, Gøtzsche PC, *et al*. SPIRIT 2013 explanation and elaboration: guidance for protocols of clinical trials. *BMJ* 2013;346:e7586.
- Sezgin D, Mert H, Özpelit E, *et al*. The effect on patient outcomes of a nursing care and follow-up program for patients with heart failure: a randomized controlled trial. *Int J Nurs Stud* 2017;70:17–26.
- Wang C, Chen J, Wang Y, *et al*. Effects of family participatory dignity therapy on the psychological well-being and family function of patients with haematologic malignancies and their family caregivers: a randomised controlled trial. *Int J Nurs Stud* 2021;118:103922.
- Charlson ME, Pompei P, Ales KL, *et al*. A new method of classifying prognostic comorbidity in longitudinal studies: development and validation. *J Chronic Dis* 1987;40:373–83.
- Vellone E, De Maria M, Iovino P, *et al*. The self-care of heart failure index version 7.2: further psychometric testing. *Res Nurs Health* 2020;43:640–50.
- Vellone E, Barbaranelli C, Pucciarelli G, *et al*. Validity and reliability of the caregiver contribution to self-care of heart failure index version 2. *J Cardiovasc Nurs* 2020;35:280–90.
- Xu F, Hilpert P, Randall AK, *et al*. Validation of the Dyadic coping inventory with Chinese couples: factorial structure, measurement invariance, and construct validity. *Psychol Assess* 2016;28:e127–40.
- Jurgens CY, Fain JA, Riegel B. Psychometric testing of the heart failure somatic awareness scale. *J Cardiovasc Nurs* 2006;21:95–102.
- Chen C, Fang W, An Y, *et al*. The multiple mediating effects of illness perceptions and coping strategies on the relationship between



- physical symptoms and depressive symptoms in patients with heart failure. *Eur J Cardiovasc Nurs* 2020;19:125–33.
- 38 Zung WW. A rating instrument for anxiety disorders. *Psychosomatics* 1971;12:371–9.
- 39 Gao J, Zhang X, Su P, *et al.* The impact of intravaginal ejaculatory latency time and erectile function on anxiety and depression in the four types of premature ejaculation: a large cross-sectional study in a Chinese population. *J Sex Med* 2014;11:521–8.
- 40 Zung WW, Gianturco JA. Personality dimension and the self-rating depression scale. *J Clin Psychol* 1971;27:247–8.
- 41 White IR, Horton NJ, Carpenter J, *et al.* Strategy for intention to treat analysis in randomised trials with missing outcome data. *BMJ* 2011;342:d40.
- 42 Gould KA. Family and caregiver relationships influence patient self-management of heart failure. *Evid Based Nurs* 2020. doi:10.1136/ebnurs-2019-103247. [Epub ahead of print: 17 Jun 2020].
- 43 Hooker SA, Schmiede SJ, Trivedi RB, *et al.* Mutuality and heart failure self-care in patients and their informal caregivers. *Eur J Cardiovasc Nurs* 2018;17:102–13.
- 44 McDonagh TA, Metra M, Adamo M. ESC guidelines for the diagnosis and treatment of acute and chronic heart failure: developed by the task force for the diagnosis and treatment of acute and chronic heart failure of the European Society of cardiology (ESC). with the special contribution of the heart failure association (HFA) of the ESC. *Eur J Heart Fail* 2021;24:4–131.
- 45 Jackson JD, Cotton SE, Bruce Wirta S, *et al.* Burden of heart failure on caregivers in China: results from a cross-sectional survey. *Drug Des Devel Ther* 2018;12:1669–78.