

Feasibility, Acceptability, and Preliminary Efficacy of the Taking Care of Us Intervention for Couples Living With Heart Failure

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Abstract

Background and Objectives: Despite the significant impact of heart failure on both members of the care dyad, few interventions focus on optimizing the health of the dyad. The current study examined the feasibility and acceptability of the novel Taking Care of Us (TCU) program with mid-late-life couples living with heart failure and explored preliminary efficacy.

Research Design and Methods: This NIH Stage I study used a 2-arm randomized controlled trial with pretest–post-test design and an additional 5-month follow-up to compare TCU with an educational counseling attention-control condition. 37 couples were randomized to TCU (18 couples) or an educational control group (19 couples). Both programs were delivered virtually over 2 months.

Results: Adults with heart failure were primarily male (mean age = 66.32, standard deviation [SD] = 13.72); partners were primarily female (mean age = 63.00, SD = 12.73). Feasibility findings were mixed with over half of the eligible couples randomized, but only 67% of TCU couples completed the post-test. Acceptability of the TCU program was strong for both adults with heart failure and their partners. Recommendations for change focused on shortening session length, offering fewer sessions, and providing alternative modes of delivery. Exploratory between-group analyses found medium effect sizes for physical and mental health and dyadic management for both members of the couple, with many effects remaining 3 months later.

Discussion and Implications: Findings suggest the TCU program is acceptable to couples with heart failure and shows promise for optimizing outcomes. Recommendations and strategies for improving retention and a more diverse sample are discussed.

Clinical Trial Registration: [NCT04737759](https://clinicaltrials.gov/ct2/show/study/NCT04737759)

Keywords: Dyadic benefits, Dyadic intervention, Dyadic relationship, Family care

Translational Significance: This study demonstrated the acceptability and promising preliminary efficacy of a novel, theoretically and empirically driven couple-based intervention for managing heart failure. The distance-friendly dyadic intervention was deemed highly acceptable across several domains by both adults with heart failure and their spouse/partner. Preliminary efficacy showed promising patterns of improvement in physical and mental health for both members of the care dyad, care strain, and symptoms of heart failure above those experienced in an attention-control group. Results indicate the potential benefits and feasibility of targeting both members of the care dyad to optimize health outcomes.

Background and Objectives

Over 80% of adults aged 65 and older in the United States have at least one chronic health condition (e.g., cardiovascular disease, diabetes, arthritis; [Ansah & Chiu, 2022](#)). Such health conditions commonly require a series of self-care behaviors

(e.g., monitoring glucose or swelling ankles, engaging in physical activity, special diets or mental relaxation, taking medications) to manage or prevent symptoms of the illness and optimize long-term physical and mental health ([Lorig et al., 1996](#); [Riegel et al., 2021](#)). Family members, particularly

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spouse/partners, play important roles in this illness management process, which can affect their own physical and mental health (AARP and National Alliance for Caregiving, 2020; Schulz et al., 2020). Despite strong evidence of the interdependent and interpersonal experience of health and illness within couples (Pauly et al., 2021; Streck et al., 2020; Varghese et al., 2023; Wilson et al., 2020) and the benefits of including both the older adult with the chronic condition and their care partner in interventions (Doyle et al., 2020; Hornbuckle et al., 2021; Martire et al., 2007; Orsulic-Jeras et al., 2019; Ouchi et al., 2024), there are still few interventions focused on optimizing health of both members of the dyad, particularly in heart failure (Kitko et al., 2020; Riegel et al., 2021).

Cardiovascular disease is the leading cause of death among older adults worldwide (Diseases & Injuries, 2020) and heart failure is the most common reason for hospitalization and rehospitalization among older adults in the United States (Bozkurt et al., 2023). Adults with heart failure (HF) can experience severe symptom burden that affects physical function and quality of life, with a continual need to monitor and manage symptoms to optimize health outcomes, placing significant strain on care partners (Buck et al., 2015) and resulting in poor physical and mental health in both members of the care dyad (Freedland et al., 2016; Timonet-Andreu et al., 2020). Yet, the majority of nonpharmacological heart failure interventions are education-focused or involve the care partner to optimize the outcomes of the adult with HF (i.e., partner-supported interventions) with small and mixed effects (Buck et al., 2018).

The guiding framework for the Taking Care of Us (TCU) program was the Theory of Dyadic Illness Management (Lyons & Lee, 2018), which highlights the importance of shared appraisal and collaboration within dyads to optimize the health of both members. Dyadic management involves couples communicating, collaborating, and feeling confident about management of the illness. The aims of the current NIH Model Stage I study (Onken et al., 2014) were to (1) determine the feasibility and acceptability of the TCU program and (2) explore preliminary change in physical and mental health and dyadic management (Lyons et al., 2023).

Method

Study Design

This feasibility and acceptability study used a two-arm randomized controlled trial with pretest–post-test design and an additional 5-month follow-up to compare TCU with an educational counseling attention-control condition, SUPPORT. Preliminary outcomes were also measured. The study protocol has been published (Lyons et al., 2023) and registered (ClinicalTrials.gov: NCT04737759) and the study received approval from the Boston College institutional review board.

Participants

Adults with HF were eligible to participate if they had received a diagnosis of heart failure as an adult, experienced heart failure symptoms (e.g., dyspnea, fatigue, pain), were at least 18 years of age, had a spouse or partner they lived with for at least 6 months willing and eligible to participate, and had access to a device to participate via Zoom or phone. Couples were not required to be married, and no couples were excluded due to sexuality or gender identity. Couples were excluded if either member had major uncorrected hearing

impairment, were enrolled in another trial that would interfere with participation, or if the adult with HF had received a heart transplantation or was in receipt of a mechanical circulatory support device.

Procedures

Recruitment began in February 2021 with participants enrolled between July 2021 and November 2022. Study investigators at Tufts Medical Center Heart Failure clinic, Boston, MA, provided their patients with recruitment materials in-person (when possible) and via mailings. Recruitment also involved community outreach locally (e.g., councils on aging, newsletters, media), and nationally via social media, websites (e.g., Family Caregiver Alliance), and clinical colleagues. Coronavirus disease 2019 (COVID-19) restrictions severely hampered in-person recruitment and community engagement (as originally planned). Interested participants contacted the study team by phone, email, or via the QR code provided on recruitment materials and were screened for eligibility and interest. Those couples deemed to be eligible and expressed interest in participating were emailed separate links to provide consent via Research Electronic Data Capture (REDCap; Harris et al., 2009). When both consent forms were received, separate links to the pretest surveys in REDCap were emailed. Once both surveys were complete, the couple was randomized with equal allocation to either TCU or SUPPORT using block randomization by gender of the adult with HF. Couples were also provided the option to complete consent and surveys via mail. Both programs were delivered over 2 months. Couples completed separate post-test surveys and final follow-up surveys 3 months later (approximately 5 months after randomization) via REDCap or by mail.

Measures

Acceptability and feasibility

Acceptability was measured at post-test with a series of Likert items adapted from other intervention work (Whitlatch et al., 2006) about the benefits and drawbacks of the program (e.g., overall satisfaction with the program, usefulness of information provided, relevance of topics, length, number and spacing of sessions, skills of the session leader, whether the program had improved their relationship and communication with their partner, and increased their confidence to manage heart failure). Participants were also asked several open-ended questions about what they liked about the program and suggestions for changes to the program or delivery of the program. Feasibility was measured by examining the rate of enrollment, percentage of couples who completed all sessions, and percentage of couples who completed the post-test surveys.

Physical and mental health

Physical and mental health were measured using the reliable and valid 10-item PROMIS Global Health short form (Hays et al., 2009). Items are used to create two summary scores representing physical and mental health, with higher scores indicating better health. Depressive symptoms were measured with the 20-item Center for Epidemiological Studies—Depression scale (Radloff, 1977) which has good internal consistency, sensitivity, specificity, and validity (Radloff, 1977; Radloff & Teri, 1986). Participants respond to items on a 0 (rarely or none) to 3 (most or all) scale, with higher scores

indicating greater depressive symptomatology. Anxiety was measured using the PROMIS anxiety four-item short form, with items rated on a 1 (never) to 5 (always) scale (Cella et al., 2019); higher scores indicate higher anxiety.

The 12-item psychometrically sound Kansas City Cardiomyopathy Questionnaire was used to measure adults with HF quality of life (Green et al., 2000). Scores range from 0 to 100 with higher scores indicating better heart-failure-specific quality of life. Additionally, given the importance of symptoms to the management of heart failure and quality of life of the adult with HF, three symptoms were assessed for adults with HF using reliable and valid measures (dyspnea, fatigue, and pain interference). Dyspnea was assessed with the six-item subscale of the Heart Failure Somatic Perception Scale (Jurgens, 2006). Items ask about how much the adult with HF was bothered by dyspnea during the last week on a 0 (not at all) to 5 (extremely bothersome) scale. Fatigue was assessed using the eight-item PROMIS fatigue scale and pain interference was assessed using the six-item PROMIS pain interference scale (Stone et al., 2016). Finally, the care strain of partners was measured using the reliable Multidimensional Caregiver Strain Index (Stull, 1996), with higher scores indicating higher levels of strain.

Health use

Health use was assessed using the established Stanford Patient Education Research Center Healthcare Utilization tool (Ritter et al., 2001). Five items were used to capture physician, mental health, emergency room visits, and hospitalizations (number of stays and total number of nights) for both the adult with HF and partner at pretest and 5-month assessments.

Dyadic management

Five measures were used to capture the three aspects of dyadic illness management focused on in the TCU program—communication, collaboration, and confidence. Communication within the couple was assessed using both scales from the Dyadic Coping measure (Buunk et al., 1996; Hagedoorn et al., 2000). Active engagement has five items that ask about how much one's partner engages in open communication and support. Protective buffering has six items that ask about how much one's partner engages in hiding concerns and denying worries. Heart failure collaborative management was assessed using the four-item management scale of the Self-Care of Heart Failure Index v6.2 (SCHFI; Riegel et al., 2009). Items ask about four management behaviors (i.e., reducing fluid, reducing salt, taking a diuretic, calling a provider) and were reworded to ask how much the couple worked together to do each behavior when needed on a 1 (not likely) to 4 (very likely) scale. Collaborative symptom management was assessed using the six-item Stanford Chronic Disease Self-Management measure (Lorig et al., 1996) with items reworded to ask how much couples worked together to prevent symptoms (e.g., fatigue, pain, emotional distress) from interfering with what the adult with HF wanted to do or to reduce the need to see a provider on a 1 (never) to 10 (always) scale. The five-item dyadic coping subscale of the Dyadic Coping Inventory (Bodenmann, 2008) was used to assess how much couples engaged in joint coping behaviors (e.g., shared decision-making) on a 1 (very rarely) to 5 (very often) scale. Finally, we used the Stanford Chronic Disease Self-Management measure (Lorig et al., 1996) to assess confidence to manage six aspects of the illness (e.g., fatigue,

emotional distress) on a 1 (no confidence) to 10 (a great deal of confidence) scale.

Taking Care of Us

The TCU program is a theoretically and empirically informed intervention that is communication-based and relationship-focused, building on the strengths of the couple while fostering new skills. There were seven weekly sessions (approximately 45–60 min long) delivered by Zoom (or phone) over a 2-month period by trained and supervised social work students, who followed a standardized protocol. Fidelity assessment checklists were completed after every session. Couples were mailed a TCU binder with materials for each session that included information and activity sheets and local and national resources (e.g., heart failure, mental health, disability, caregiving, housing). The primary goals of the program and sessions were to improve shared symptom appraisal, communication, collaboration, and confidence within the couple. Session 1 focused on an overview of the program, the benefits of a dyadic approach to heart failure, practicing supportive communication (i.e., speaker-listener), and essential elements of heart failure management. Session 2 focused on the positive roles of communication, collaboration, and confidence with activity sheets to guide the session. Session 3 focused on specific communication about symptoms and symptom recognition within the couple. Session 4 focused on collaboration and supportive behaviors and developing shared goals. Session 5 focused on the health of the care partner and meeting their needs. Session 6 focused on strengthening the relationship and covered fun activities, closeness, and physical intimacy. The final session focused on reviewing the program and strategies and goals the couple wanted to carry forward, the importance of revisiting goals and strategies over time, and involving healthcare providers and other family support to help reach those goals. All sessions were designed to support couples reflecting on their strengths and areas of challenge and were tailored to the area couples agreed to work on together, reflecting respect for each couple's readiness to change. Couples practiced skills during sessions and were asked to try out simple strategies between sessions and reflect on how things went in follow-up sessions.

SUPPORT Comparison Condition

The attention-control condition had three sessions (approximately 45–60 min long) at 1, 4, and 8 weeks via Zoom (or phone) to match the 2-month period of TCU. Sessions were delivered by trained and supervised social work students, who followed a standardized protocol. Fidelity assessment checklists were completed after every session. Couples were mailed a binder with materials for each session that included information and activity sheets and local and national resources. The program was similar to heart failure educational interventions currently available and considered a more realistic comparison condition than usual care. Session 1 focused on the same information as TCU regarding heart failure management and an overview of the SUPPORT program. Session 2 focused on healthy eating. Session 3 focused on physical activity. All sessions focused primarily on adults with HF (though the partner was required to be present in all sessions).

Analysis Plan

Descriptive statistics were used to examine feasibility and acceptability with a priori goals (Lyons et al., 2023) to recruit

Table 1. Demographics of Adults With Heart Failure and Their Partners ($N = 37$)

Variable	Overall sample ($N = 37$)		SUPPORT ($n = 19$)		TCU ($n = 18$)	
	Adults with HF	Partners	Adults with HF	Partners	Adults with HF	Partners
	M (SD) or n (%)	M (SD) or n (%)	M (SD) or n (%)	M (SD) or n (%)	M (SD) or n (%)	M (SD) or n (%)
Age (years)	66.32 (13.72)	63.00 (12.73)	68.03 (12.33)	64.26 (10.35)	64.61 (15.15)	61.67 (15.03)
Length marriage (years)	33.35 (16.94)	–	36.01 (17.68)	–	30.56 (16.15)	–
Sex (female)	8 (22%)	29 (78%)	4 (21%)	15 (79%)	4 (22%)	14 (78%)
Race (non-White)	2 (5%)	0 (0%)	1 (5%)	0 (0%)	1 (6%)	0 (0%)
Hispanic	1 (3%)	1 (3%)	1 (5%)	0 (0%)	0 (0%)	1 (6%)
HF stage ^a	2.24 (0.86)	–	2.21 (0.86)	–	2.28 (0.90)	–
Education (<some college)	27 (73%)	30 (81%)	16 (84%)	16 (84%)	11 (61%)	14 (88%)
Financial security (don't have enough to make ends meet)	7 (19%)	–	3 (16%)	–	4 (22%)	–
Arthritis	19 (51%)	12 (32%)	12 (63%)	6 (32%)	7 (39%)	6 (33%)
Asthma/emphysema	8 (22%)	2 (5%)	5 (26%)	2 (11%)	3 (18%)	0 (0%)
Cancer	4 (11%)	0 (0%)	2 (11%)	0 (0%)	2 (11%)	0 (0%)
Diabetes	13 (35%)	6 (16%)	7 (37%)	2 (11%)	6 (33%)	4 (22%)
Digestive problems	9 (24%)	5 (14%)	4 (21%)	3 (16%)	5 (28%)	2 (11%)
Heart disease/failure	37 (100%)	1 (3%)	19 (100%)	0 (0%)	18 (100%)	1 (6%)
Kidney problems	5 (14%)	1 (3%)	3 (16%)	1 (5%)	2 (11%)	0 (0%)
Liver problems	2 (5%)	1 (3%)	0 (0%)	0 (0%)	2 (11%)	1 (6%)
Stroke	3 (8%)	1 (3%)	3 (17%)	1 (5%)	0 (0%)	0 (0%)

Notes: HF = heart failure; SD = standard deviation; SUPPORT = educational counseling attention-control condition; TCU = Taking Care of Us.

^aSelf-reported 1 (can do ordinary physical activities without symptoms); 2 (ordinary physical activities causes symptoms); 3 (less than ordinary physical activity causes symptoms); 4 (experience symptoms at rest).

≥30% of eligible couples, have ≥70% of assigned couples complete the TCU program, and ≥80% complete the post-test follow-up. A priori goals for acceptability were to have ≥80% of couples report satisfaction with the program.

Our original analytic plan for a proposed 60-couple sample (Lyons et al., 2023) was to explore changes in health and dyadic management between groups using multilevel modeling with no correction for multiple tests given the primary focus on feasibility and acceptability. Due to the current small sample, between-group effect sizes were deemed the most appropriate to explore preliminary efficacy and have been used in other small-sample, early-phase interventions (Gremore et al., 2021; Lyons et al., 2021) rather than reporting statistical tests (Eldridge et al., 2016). Between-group effect sizes were calculated for pretest–post-test change and pretest–5-month change for adults with HF and partners separately in each condition using intent-to-treat analysis (i.e., last data point carried forward). We coded effect sizes using Cohen's d : small effect (0.20–0.30), medium effect (0.30–0.79), and large effect (≥0.80). The sample was deemed too small to examine the effects of healthcare use in any meaningful way.

Results

Participant Characteristics

Thirty-seven couples agreed to participate and were randomized. Adults with HF were primarily male (78%; mean age = 66.32, standard deviation [SD] = 13.72) and on average experienced heart failure symptoms during ordinary physical activities. Partners were primarily female (78%; mean age = 63.00, SD = 12.73). Couples who had been married/partnered for an average of 33.35 years (SD = 16.94) were

primarily White and non-Hispanic. Almost one-fifth reported not having enough money to make ends meet. Over half of adults with HF (51%) and a third of partners (32%) reported a diagnosis of arthritis; 35% of adults with HF; and 16% of partners had a diagnosis of diabetes (Table 1).

Feasibility

Of the 261 contacts from across the United States we received through outreach and advertisement via Tufts Medical Center, social media, clinical colleagues, Family Caregiver Alliance, community outreach, and ResearchMatch, 71 were deemed eligible and valid, and 37 (52%) were randomized (19 to SUPPORT and 18 to TCU). Ten (56%) of the TCU couples completed all seven sessions (68% of SUPPORT couples completed all three sessions). Twelve TCU couples (67%) completed the post-test follow-up (compared to 63% of SUPPORT couples) and 44% (compared to 58% of SUPPORT couples) completed the 5-month follow-up (see Supplementary Figure 1, CONSORT flowchart).

TCU drop-out

Of the 18 couples allocated to TCU, 2 couples dropped after randomization (before session 1)—couple A felt they had too much going on and decided to withdraw and couple B never responded to our scheduling calls. Another two TCU couples (C and D) dropped after the first session. Couple C was rated as very engaged in the session by the interventionist and the couple reported really enjoying the session and how interactive it was. But after several reschedules due to work and life events, couple C stopped responding to the team. Similarly, couple D was also rated as very engaged in the session, but could not continue due to health limitations.

Four couples (E, F, G, and H) dropped after the second session. Couple E was rated as very engaged in both sessions, completed homework, and liked the sessions, but had a significant life event that prevented them from continuing in the study. Couple F was also rated as very engaged in both sessions and completed activities, but could not continue due to the poor health of the adult with HF. Couple G was rated as very engaged, and said they really enjoyed the activities, but experienced several family deaths and significant life events and could no longer continue. Finally, couple H was rated as engaged and completed activities and liked being in the study, but the adult with HF was hospitalized and was too sick to continue the study.

Phone versus Zoom

We allowed both programs to be completed via phone (as an alternative to Zoom) to maximize access to the intervention for couples who might not have a smartphone or device to use Zoom. We strongly encouraged, when appropriate, that couples participate via Zoom and offered a presession phone call with a team member to support setting up Zoom and practice connecting (a handout with steps was also emailed to couples). Couples who still had trouble navigating Zoom during the first session were provided with support from the interventionist and in some cases participated by phone for that first session and received further support after the session so they felt comfortable using Zoom by the second session.

Out of 30 couples who completed at least one session of TCU or SUPPORT, only four (13%) couples exclusively participated via phone. All four of these couples had been assigned to the SUPPORT program and all four couples completed the SUPPORT program and were rated as highly engaged in sessions and completed activities together. Seven couples (23%) did one session by phone due to technical or internet issues and the remaining sessions via Zoom; two couples (7%) did half their sessions by phone and the other half by Zoom due to technical or internet issues. Of those couples who used phone at least once, all couples except one completed their respective programs and were rated as highly engaged in the sessions by the interventionist. The remaining 17 couples (57%) participated exclusively via Zoom.

Within the TCU program specifically, no couple participated via phone exclusively. Ten (63%) participated exclusively via Zoom and six (37%) used the phone at least once. Of the 85 TCU sessions delivered, 74 (87%) were delivered via Zoom. Couples participating in phone sessions were rated as very engaged and completed activities. Reasons for using the phone for at least one session included power outage, internet connectivity issues, unsure how to use Zoom, and the decision to view the worksheets electronically while on the phone. We found no evidence that TCU couples who used the phone at least once differed significantly from those who never used the phone in adults with HF age (Zoom only $M = 61.90 \pm 18.72$; Some phone $M = 66.83 \pm 8.61$), education (Zoom only: 70% had at least some college; Some phone: 60% had at least some college), financial security (Zoom only: 30% reported not having enough to make ends meet; Some phone: 17% reported not having enough to make ends meet), or their overall satisfaction with the program (Zoom only $M = 3.33 \pm 1.21$; Some phone $M = 3.50 \pm 1.23$), though there was a tendency for those who had at least one phone session to be older and less educated. Four (67%) of these couples went on to complete the six remaining TCU sessions via Zoom after

receiving additional Zoom support; one couple completed four of the seven TCU sessions via Zoom, and one couple completed three of the seven TCU sessions via Zoom. Our interventionists were carefully trained to ensure the engagement of both members of the couple during TCU, regardless of the mode of delivery. Session activities and worksheets (included in the program binder couples received) ensured their active participation and collaboration throughout the session and the vast majority of couples were rated as highly engaged and interested throughout the sessions.

Acceptability

Adults with HF in TCU reported mean satisfaction ratings of 3.42 ($SD = 1.17$) and partners reported 3.58 ($SD = 0.50$) on a 4-point scale with 83% and 100% of adults with HF and partners, respectively, reporting satisfaction with the program. Over 80% of TCU couples found information provided useful (82% adults with HF; 92% partners), looked forward to sessions (83% adults with HF; 92% partners), felt the program helped them communicate better (91% adults with HF; 100% partners), provided opportunity to express feelings/thoughts to partner (100% adults with HF; 92% partners), topics were relevant to them (100% adults with HF; 92% partners), helped them understand their partner's needs better (100% adults with HF; 92% partners), felt their relationship had improved (91% adults with HF; 92% partners), and felt more confident to manage heart failure (92% adults with HF; 92% partners). Seventy-five percent of TCU adults with HF and 100% of partners would recommend the program to other couples. Session leaders were rated highly positively, and questions about the number, spacing, and length of sessions were equally positively rated.

Open-ended feedback regarding TCU included both benefits and room for improvement. The majority of adults with HF felt the program had helped them to better communicate and share with their partner in ways they had not before and liked learning communication skills, skills to deal with stress, and working together with their partner. Partners also expressed that the benefits of the program were in improving communication and collaborating more with the adult with HF; several partners said they really liked that the program helped their male partner with heart failure to share his thoughts and feelings. Although several adults with HF and partners said they would not recommend any changes, the majority of recommendations involved reducing the length of sessions to 30 min and having fewer sessions (range: 4–5); two participants wanted more sessions. The majority liked the sessions being delivered via Zoom, but others suggested in-person delivery, an app, or group format with other couples living with heart failure. Finally, several suggested that some content was repeated, something also noted by the interventionists in their exit surveys.

Preliminary Efficacy

Supplementary Table 1 provides means and SDs for health and dyadic management variables. No significant differences were found between TCU and SUPPORT adults with HF at pretest. However, partners in TCU had significantly worse physical health $t(34) = 2.42, p < .05$ and reported significantly higher dyadic coping $t(35) = -2.16, p < .05$ at pretest than SUPPORT partners. Table 2 provides the between-group effect sizes for health and dyadic management variables for both pre-to-post and pre-to-5-month follow-up.

Table 2. Between-Group Effect Sizes Using Intent-to-Treat ($N = 37$)

Variable	Adults with HF		Partners	
	Pre-post (d)	Pre-5 months (d)	Pre-post (d)	Pre-5 months (d)
Health variables				
Global physical health	0.68 ^b	0.80 ^c	0.74 ^b	0.73 ^b
Global mental health	-0.04	0.03	0.22 ^a	0.42 ^b
Depressive symptoms	-0.79 ^b	-0.73 ^b	-0.15	-0.01
Anxiety	-0.40 ^b	-0.69 ^b	-0.10	-0.07
Heart-failure-specific quality of life	0.43 ^b	0.46 ^b	-	-
Care strain	-	-	0.12	-0.53 ^b
Dyspnea	-0.54 ^b	-0.44 ^b	-	-
Pain interference	-0.94 ^c	-1.21 ^c	-	-
Fatigue	-0.42 ^b	-0.34 ^b	-	-
Dyadic management variables				
Active engagement	0.51 ^b	0.57 ^b	-0.12	0.50 ^b
Protective buffering	0.17	-0.57 ^b	0.08	-0.12
Heart failure collaborative management	-0.28 ^a	-0.46 ^b	-0.10	0.31 ^b
Collaborative symptom management	0.19	0.32 ^b	0.33 ^b	0.53 ^b
Dyadic coping	0.55 ^b	0.57 ^b	0.40 ^b	0.29 ^b
Confidence to manage heart failure	-0.11	0.23 ^a	-0.03	0.38 ^b

Notes: HF = heart failure. Results in italics indicate effects that were in the opposite direction to what was hypothesized.

^aSmall effect size (0.20–0.30).

^bMedium effect size (0.30–0.80).

^cLarge effect size (>0.80).

Physical and mental health

A medium effect size was found for physical health ($d = 0.68$) at post-test and large effect ($d = 0.80$) at 5 months for adults with HF; medium effect sizes were found for partners at both post-test ($d = 0.74$) and 5 months ($d = 0.73$). For adults with HF, medium effect sizes were also found for depressive symptoms ($d = -0.79$ at post-test and $d = -0.73$ at 5 months), anxiety ($d = -0.40$ at post-test and $d = -0.69$ at 5 months), and HF-specific quality of life ($d = 0.43$ at post-test and $d = 0.46$ at 5 months); no significant effects were found for mental health for adults with HF. For partners, a small effect was found for overall mental health at post-test ($d = 0.22$) and a medium effect ($d = 0.42$) at 5 months. There was also a medium effect for care strain at 5 months ($d = -0.53$). There were no significant effects for depressive symptoms ($d = -0.15$) or anxiety ($d = -0.10$) for partners.

Heart failure symptoms

Medium effect sizes were found for dyspnea ($d = -0.54$ at post-test and $d = -0.44$ at 5 months) and fatigue ($d = -0.42$ at post-test and $d = -0.34$ at 5 months), and large effects for pain interference ($d = -0.94$ at post-test and $d = -1.21$ at 5 months) for adults with HF.

Dyadic management behaviors and confidence

For adults with HF, medium effect sizes were found for active engagement ($d = 0.51$ at post-test and $d = 0.57$ at 5 months), protective buffering notably only at 5 months ($d = -0.57$), dyadic coping ($d = 0.55$ at post-test and $d = 0.57$ at 5 months), collaborative symptom management ($d = 0.32$) at 5 months only and a small effect for confidence to manage HF ($d = 0.23$) at 5 months only. Unexpected small and medium effects were found for HF collaborative management, with

TCU adults with HF remaining fairly stable over time compared to an increase among SUPPORT adults with HF.

For partners, medium effects were found for collaborative symptom management ($d = 0.33$ at post-test and $d = 0.53$ at 5 months). Both active engagement ($d = 0.50$) and HF collaborative management ($d = 0.31$) only showed medium effects at 5 months. Medium effects were also found for dyadic coping at post-test ($d = 0.40$) and small effect ($d = 0.29$) remained at 5 months. There were no significant effects for protective buffering for partners.

Discussion and Implications

The primary aim of this NIH Stage I study (Onken et al., 2014) was to determine the feasibility and acceptability of a new program, TCU, and explore the preliminary efficacy of the program on health and dyadic management. Findings regarding feasibility were mixed. Although recruitment was severely affected by COVID-19, our enrollment rate of eligible participants was 52%; far higher than our target of 30% and that reported in other early-phase couple-based interventions (Gremore et al., 2021; Porter et al., 2018). Our retention rate, however, was lower than anticipated, with only 56% of couples completing all seven sessions (goal was 70%) and only 67% of couples completing the post-test (goal was 80%). The majority of couples who did not complete all sessions and follow-up surveys did so primarily due to the health of the adult with HF and in some cases the death of the adult with HF or death in the family/major life event, reflecting the volatility being experienced by these couples and recruitment time period. Attrition also occurred in the comparison condition at similar rates at the post-test follow-up. Couples in TCU were most likely to drop after Session 1 or 2; 100% of couples who remained after Session 2, completed all sessions.

We found no evidence that any of the couples who dropped after the first or second TCU session were less satisfied with the sessions than those who continued in the program. It is also noteworthy that the drop-outs were primarily during the tumultuous summer and winter of 2021 (three dropped in Spring 2022). This first year of the pandemic saw many clinics close for in-person appointments and placed many of our participants in socially isolated contexts feeling under-supported. Several couples during that early recruitment phase expressed interest in participation as a way to gain support.

Our acceptability findings were highly positive and met our a priori targets, with the majority of couples reporting high levels of satisfaction with the TCU© program overall and felt it improved their relationship, communication, and confidence to manage heart failure. Most couples said they would recommend the program to other couples. Recommendations for improving or changing the program centered on reducing the number of sessions and length of sessions, eliminating some redundancies in content across sessions, and providing different modes of delivery. We are currently working on integrating these revisions for future trials.

Although our small sample does not permit us to draw strong conclusions about the effects of the TCU program on the health of the couple living with heart failure and their dyadic management, this early-phase study shows promising patterns of change for both adults with HF and partners at both post-test follow-up and 3 months later. TCU adults with HF and partners saw improvements in physical and mental health, and most aspects of dyadic management compared to the couples in the comparison condition. In some cases, notable effects were not present until 5 months (i.e., care strain, protective buffering, confidence) suggesting potential delayed benefits. Although effects suggest some communication benefits for couples, there also appeared to be potential benefits to how the couple coped together (particularly for adults with HF) and managed symptoms together (particularly for partners). Both communication and collaboration are key components of the TCU program. One unexpected effect was found for perceptions of collaboration regarding heart-failure-specific management behaviors (i.e., reducing fluid, reducing salt, taking a diuretic, calling a provider), which appeared to increase in the comparison group for adults with HF; partners in TCU saw improvements at 5 months. Although difficult to conclude in a small sample, it may be that these behaviors were more specifically addressed in the education-counseling comparison program, SUPPORT. In contrast, perceptions of collaborative symptom management (degree the couple worked together to manage a series of physical and emotional symptoms in the adult with HF) saw improvements in both adults with HF and partners underscoring the importance of capturing different aspects of illness management, and were more reflected in the TCU activities. Clearly, further work is needed in larger samples to more adequately test the efficacy of the program.

Limitations

The three biggest limitations of the study were small sample, lack of diversity, and less than favorable retention, which limits generalizability and must be taken into consideration when interpreting results. Despite our best efforts to achieve a sample of 60 couples and a diverse sample, we fell far short of our goals. Our original proposal included recruitment through a community-based cardiology clinic with a diverse population.

But funding began in September 2020 and the site had ceased all research activities and in-person care. Like so many, our team regrouped and launched a multiprong recruitment approach locally and nationally via social media (including targeted campaigns to cities with large, diverse populations), outreach to clinical colleagues, repeated community outreach through print media, newsletters, flyers, and Councils on Aging (all severely hampered by limited in-person activities and access). Our multiple attempts at in-person community engagement were also discouraged or not considered the right time. Our investigators at Tufts promoted the study to their patients. These efforts were all important, but not originally planned or budgeted for, and were further hampered by a fully remote team for the first half of the study.

We also experienced a significant increase in fraudulent contacts during the second half of the study. At least 42% of study contacts (this may be higher given the number of lost-to-follow-up contacts we could not screen) were deemed fraudulent after thorough screening that included verification of IP addresses, validating phone numbers, and identifying anomalies as has become the norm. This process took considerable staff time that was also not planned for and took away from recruitment and retention efforts. Our lack of diversity in the sample was very disappointing, particularly as we had several women of color who were eager to participate in the study, but whose partner was not interested. We also fell short of our goal for enrolling women with heart failure for similar reasons. We are conducting a supplemental qualitative study with several of these women to explore this challenge and their needs.

Although we found that both adults with HF (primarily men) and partners (primarily women) benefitted from TCU and reported high satisfaction with the program overall and across dimensions, including communication, collaboration, and support with their partner, we were unable to tease apart gender differences from role given the small sample. It is possible that the program may involve approaches and behaviors (e.g., open communication, shared problem-solving) that are more comfortable to those who identify as women versus men (Acquati & Kayser, 2019; Mahalik & Dagirmanjian, 2019). It will be important going forward to attain more gender-balanced samples in future studies to untangle this and to examine if those conforming to more masculine-gendered norms of self-reliance and emotional control (Mahalik et al., 2003), regardless of role or gender, are more or less likely to benefit from such communication-based, psychosocial dyadic interventions.

Implications and Lessons Learned

Acknowledging these limitations, we believe this early-phase study has several important strengths. First, it is a novel couple-based, theoretically informed intervention that targets the health of both members of the couple living with heart failure and the way they communicate and collaborate. Second, in contrast to many early-phase studies that are single arm or compare to usual care, we used a randomized controlled trial to compare TCU to an education-counseling attention-control condition as we felt this was a more realistic comparison, but also a higher bar to demonstrate effects. Third, our need to switch from an in-person delivery to Zoom also allowed us to move beyond local recruitment with a final sample of 37 couples from 16 different states in the United States in both rural and urban areas

and variability in educational status and financial security. Finally, we demonstrated strong acceptability of the program, strong feasibility to recruit, and promising patterns of change in both adults with HF and care partners at both immediate post-test and 3 months later.

We have learned several important lessons to inform the next phase of development and testing of the TCU program. First, the importance of budgeting time, personnel, and money to forming community partnerships and sustaining those partnerships. Second, the importance of building successful strategies such as warm hand-offs and more active follow-up, particularly for people of color (Epps et al., 2021, 2024). Our experience, late in the study, and confirmed by colleagues, supports multiple outreach and contacts to interested participants. Third, we believe our conscious decision to offer Zoom support throughout the study, maximized participation via Zoom, including among those who were older and less educated. Fourth, building in screening specifically to deter and identify fraudulent contacts also requires budgeted time and money. Fifth, although TCU was rated highly by couples, there were clear areas of recommendation to condense the number of sessions by removing redundancies and shortening sessions to approximately 30 min. Although there was no consistent recommendation for mode of delivery, exploring potential modes as we move this work forward (e.g., in-person, group, Zoom, app) will be important to optimize access and success.

Sixth, it is unclear how much the attrition in both programs was due to the time period in which the study took place (primarily during the first year of the pandemic), recruitment of adults with HF, who may have been too sick to engage in a 2-month program, or a late decision that the program was not of interest. However, moving forward, we are mindful of these possibilities and the need to strengthen our screening criteria (e.g., adults with HF in earlier stages of illness) and description of what the program entails, but also the need to shorten the program and explore alternative formats. We also learned the value of dedicating staff time to retention beyond what is happening in the intervention sessions. Seventh, the funding mechanism only allowed for the examination of sustained effects three months post-test. It is unclear if the sustained effects observed at follow-up remained at 6 months. Future work will need to examine the longer-term outcomes of the program. Finally, we conducted a Stage I study. The NIH Stage Model (Onken et al., 2014) describes Stage I studies as involving all aspects of development and preliminary evaluation of behavioral interventions, including modifications, in an iterative process to obtain feasibility, acceptability, and preliminary testing before moving to Stage II (pure efficacy). Clearly, it is important that we revise the program in the recommended ways, improve our recruitment and retention strategies, and then conduct another Stage I study to further test the feasibility, acceptability, and preliminary efficacy of TCU in larger samples with diverse populations and couples where women have heart failure, before confidently moving to a Stage II study. It is our hope to also explore the potential for the program to be adapted to other chronic conditions (e.g., diabetes), particularly as the TCU program only includes heart-failure-specific content in Session 1 and whether the program can be adapted for noncouple care dyads, which would further increase access.

Supplementary Material

Supplementary data are available at *Innovation in Aging* online.

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Conflict of Interest

None.

Data Availability

Data are available upon request from the first author. The study protocol has been published (Lyons et al., 2023) and registered (ClinicalTrials.gov: NCT04737759).

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