Translating and Testing the ENABLE: CHF-PC Concurrent Palliative Care Model for Older Adults with Heart Failure and Their Family Caregivers

J. Nicholas Dionne-Odom, PhD, RN,¹ Alan Kono, MD,² Jennifer Frost, MSN, RN,² Lisa Jackson, BSN,³
Daphne Ellis, AA,² Ali Ahmed, MD, MPH,⁴ Andres Azuero, PhD,¹ and Marie Bakitas, DNSc, CRNP¹

Abstract

Background: Heart failure (HF) and palliative care (PC) organizations recommend early PC to improve the quality of life of patients living with HF.

Objective: We conducted a two-phase formative evaluation study to translate a cancer-focused concurrent PC intervention into one that would be appropriate for rural-dwelling adults with New York Heart Association Class III-IV HF and their primary caregivers.

Methods: Phase I: We tailored the intervention for an HF population via literature review, expert consultation, and clinician ($N=15$) small group interviews. Phase II: We enrolled 11 patient/caregiver dyads to assess intervention feasibility and satisfaction. We assessed participants' experiences and satisfaction after session/week three and session/week six via digitally recorded interviews. Clinician and participant interviews were transcribed and content analyzed. Outcome measures were evaluated for completion rates and effect sizes.

Results: Phase I: Clinicians described barriers to initiating PC in HF, triggers for initiating PC, and suggestions for intervention improvement. Phase II: Participants were able to complete the majority of study sessions, measures, and interviews. Satisfaction interviews revealed the content to be relevant and comprehensive in addressing HF patient and caregiver primary concerns; however, participants unanimously suggested making the intervention available earlier in the illness trajectory. Efficacy measures demonstrated small to medium effect sizes.

Conclusions: We tailored and demonstrated feasibility of providing an early, concurrent palliative care intervention to patients with advanced HF and their caregivers. Based on this experience we are now conducting an efficacy trial in a racially diverse sample.

Introduction

OVER FIVE MILLION AMERICANS carry a diagnosis of heart failure (HF) and half die within five years.¹ Because available therapies slow but do not halt HF decline, chronicity and significant morbidity accompany the high prevalence and fatality of HF. Persons with HF will live months to years with advanced stages of HF while often enduring marked symptom burden.² This is particularly concerning when the population of individuals with HF is predicted to surge by 46%, an additional eight million people, by 2030.¹

The American Heart Association (AHA) and New York Heart Association (NYHA) functional classification systems organize the HF stages by the degree that symptoms limit functional activities of daily living.³ The functional limita-

tions of advanced stages of HF, including NYHA Classes III and IV and AHA Stages C and D, are caused by pernicious symptoms that occur even at rest, such as dyspnea, pain, coughing and wheezing, edema and weight gain or loss, fatigue, anorexia, and impaired thinking.⁴ Symptom burden, especially dyspnea, increases as HF progresses and equals or exceeds that reported by cancer patients.⁵⁻⁹ Moreover, the consequences of this symptom burden extends beyond the patient, taking an equal or greater toll on family caregivers.¹⁰

Timely palliative care (PC) has been found to reduce the physical and emotional stress of a variety of serious life-limiting illnesses for both patients and their family caregivers.¹¹ Although most evidence of PC benefits has been demonstrated in persons with cancer, a growing body of empirical literature suggests that early PC may also play a

¹School of Nursing, University of Alabama at Birmingham, Birmingham, Alabama.

²Department of Medicine, Dartmouth-Hitchcock Medical Center, Lebanon, New Hampshire.

³Dartmouth College, Lebanon, New Hampshire.

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beneficial role in HF.^{2,12–15} This seems logical, since persons with advanced HF and their families, like patients with cancer, bear the brunt of unaddressed physical pain and emotional suffering, face a number of complex and difficult medical decisions,² and weather multiple hospitalizations in their last year of life.^{7,9,16–21} Initiation of interdisciplinary palliative care services beginning early in the course of advanced HF has been strongly recommended as a critical strategy in addressing these challenges by professional groups^{6,15,19,25–29} including the AHA²⁵ and many others.^{5,15,22,23}

However, few PC models have undergone systematic development and testing to address the individualized needs of patients with advanced HF and their family caregivers, especially for those in community-based rural locations where geographic distances and access to care can present significant challenges.³⁰ Following our first demonstration project in cancer, we recognized the challenges of access in our rural environment. We converted the intervention to be delivered primarily by phone and focused our nurse coaching on helping patients to identify prospectively local community resources.

Guided by the Medical Research Council's (MRC)³¹ model of systematic intervention development (see Fig. 1), we embarked on translating our successful early, concurrent PC model, ENABLE (Educate, Nurture, Advise, Before Life Ends)^{32–34} for the HF population. ENABLE is a phone- and manual-based intervention conducted by advance practice PC nurse coaches with patients and their primary family caregivers. Using a guidebook called *Charting Your Course*, coaches facilitate six sessions with patients and three sessions

with caregivers. All patient sessions begin with a general assessment using the Distress Thermometer, which was adapted for HF,³⁵ and then each session addresses specific content areas: problem solving, symptom management, self-care, communication, care coordination and use of local community resources, decision making, advance care planning, and life review and creating legacy (see Fig. 2). The formal sessions are followed by monthly follow-up calls for the purpose of reinforcing prior sessions and providing additional coaching as determined by individual patient/caregiver needs. Because the study length is six months, on average, three monthly calls are made. In addition, patients receive an in-person PC team assessment based on National Consensus Project PC guidelines.²² ENABLE^{21–23} is the first successful PC intervention in the rural advanced cancer population to apply Wagner's Chronic Illness Care (CIC) model,^{24–30} which shifted the cancer care paradigm by introducing concurrent PC earlier in the disease trajectory (see Fig. 3). Because ENABLE is based on the CIC, which is also the basis of some of the most successful HF disease self management programs demonstrating improved disease-focused HF self-management and survival outcomes,^{30,33–42} we were confident that it would be adaptable to this very different illness trajectory.

We conducted a two-phase formative evaluation intervention development study to (1) translate and determine acceptability of ENABLE: CHF-PC intervention content, including patient and caregiver guidebooks and treatment manuals; and (2) determine feasibility of recruiting and retaining HF patient/caregiver dyads for 24 weeks,

FIG. 1. The Medical Research Council formative and summative evaluation processes used to systematically develop and pilot test the *original* ENABLE I palliative care intervention (ENABLE I 1999–2001) and 2 large RCTs (ENABLE II 2003–2008 & ENABLE III 2009–2013). **Box A. Development:** The *ENABLE I* demonstration project (N=380) conceptual foundation was developed via systematic literature review and clinician and patient/family focus groups. **Box B. Feasibility/piloting:** ENABLE I provided important feasibility data about recruiting, enrolling, and retaining seriously ill patients across the disease trajectory, measurement methods and challenges, and caregiver research. We implemented a fundamental design change to convert the intervention to a primarily phone-based coaching model to increase access to a rural population. **Box C. Evaluation:** This positive preliminary data supported the development of *ENABLE II* RCT in which we assessed intervention effectiveness and cost-effectiveness. **Box D. Implementation:** The multi-site *ENABLE III* RCT allowed us to evaluate intervention timing and dissemination to community centers. The adaptation of ENABLE for HF is shown in the box between Box A and B, and a second pilot study to further assess feasibility which is currently active. Adapted from Medical Research Council, 2008.³¹

FIG. 2. Study schema.

representing the minimum amount of follow-up time that would be anticipated in a larger concurrent care trial. An exploratory aim was to seek a signal of potential efficacy and intervention effect based on participant reported outcome measures.

Methods

Subsequent to Dartmouth College institutional review board approval, we conducted a two-phase formative evaluation study from August 1, 2012 through August 1, 2013.

FIG. 3. Conceptual model of early concurrent palliative care in advanced HF. The figure from left to right depicts The ENABLE: CHF-PC model of advanced HF delivered over time as the illness progresses. The outermost box, A. Primary Care, represents that an individual's care over time is consistently directed by community-based providers. Moving inwards, B. Heart Failure Care emphasizes that specialized cardiac care complements the primary care focus. The innermost space, C. Palliative Care is present early in the advanced HF course and is concurrent with both A. Primary Care and B. Heart Failure Care. The principle elements of C. Palliative Care delivered in the ENABLE: CHF-PC framework include a comprehensive PC assessment and telephone coaching by the PC nurse using the *Charting Your Course* work book. The Chronic Illness Care model principles underlying the nurse coaching are listed within the Palliative Care space. D. Hospice & Bereavement Care are available and offered when appropriate when HF is in the terminal stage and for family support after the patients' death. Dotted lines separating HF and PC indicate increasing/decreasing emphasis of HF and PC at different points along the HF trajectory to account for the waxing and waning periods of HF decompensation. Dotted lines between HF care and Primary Care indicate "porous" boundaries allowing for information flow among the disciplines.

Phase I

From August to November 2012, members of the study team (AK, JF, JNDO, LJ, MB) translated the *Charting Your Course* (CYC) guidebooks by replacing cancer-specific topics with HF topics, sought input from external advisors, and then edited and further tailored the materials to HF patients and caregivers. We then assembled a clinician expert advisory group by recruiting clinicians who were part of the Dartmouth Primary Care Cooperative Research Network (CO-OP), one of the oldest primary care research networks in the United States.⁴³ Fifteen community-based clinicians representing primary care and cardiology agreed to participate in either an in-person or a web-based small group interview moderated by the study project coordinator (LJ). The semistructured interview guide explored clinicians' personal definition of "palliative care;" characteristics of HF patients appropriate for PC; clinicians' approach to advanced stage (versus early stage) HF patients; PC referral triggers; and feedback regarding the proposed intervention design, materials, and outcome measures. Clinicians were paid a \$50 consulting fee for participation.

Phase II

From November 2012 to May 2013 we recruited 11 patient/caregiver dyads to serve as participant "advisors" to intervention development. Patients were referred by HF program clinicians within the Dartmouth-Hitchcock Medical Center's, Section of Cardiology, and were contacted and screened by the study project coordinator (LJ). Eligibility criteria were (1) able to read and understand English; (2) age ≥ 65 ; (3) NYHA III/IV HF and one of the following: (a) one unscheduled inpatient admission in past year for worsening HF or (b) at a decision point for interventional HF therapy (e.g., home inotropes, pacemaker, mechanical assist devices, transplantation, etc.); and (4) have a willing caregiver/partner to participate in the study. Following referral and eligibility screening, willing patient/caregiver participants each signed an informed consent and completed baseline data collection. We indicated as part of the consent process that our main goal was to "test out" a new intervention for persons with advanced HF and we encouraged participants to be extremely "critical" of all the study procedures. In order that HF participants and their caregivers could feel comfortable expressing their true thoughts and feelings, which often concerned one another, each was assigned a different advance practice PC nurse coach. Nurse coaches contacted the patient or caregiver by phone to schedule both an in-person PC assessment and the first *Charting Your Course* (CYC) session. Satisfaction interviews were conducted following the third and sixth CYC session for HF participants and following the third session for caregivers. Consistent with IRB policies for subject remuneration, to recognize their important role and compensate for their time, study participants were provided \$25 for each CYC session and \$10 for their participation in the satisfaction interviews and outcome measures (baseline, 12, and 24 weeks). All nurse coaches had or were in school for masters' degrees in nursing as were experienced interventionists from the previous ENABLE RCT, and had received at least 24 hours of initial training followed by fidelity checks as detailed elsewhere.³³

Instruments

Clinician interview guide. The clinician interview guide was developed by our study team and was based on our pre-

vious work interviewing oncologists who referred their patients to our prior PC trial.⁴⁴ Clinicians were asked to discuss three main topics: (1) their experience with HF patients in their clinical practice; (2) their experiences with PC and when they considered involving PC in HF patient care; and (3) their impressions of the intervention and suggestions for improvement.

Patient/caregiver satisfaction interview guide. The patient/caregiver satisfaction interview guide was adapted from an evaluation measure created for our previous PC trial.⁴⁵ Individuals with HF and caregivers were asked to discuss their experience and satisfaction with three main domains of the intervention including (1) the content, activities, and layout of each of the CYC chapters and the chapter's relevance to their day-to-day HF management; (2) the logistical convenience of the intervention (e.g., scheduling and length of phone calls); and (3) their overall impression of the intervention and suggestions for improvement.

Patient/caregiver self-report efficacy measures. Patient and caregiver efficacy outcome domains and measures were selected based on our prior cancer clinical trials;^{46,47} however the quality of life and symptom burden tools were replaced by ones that were HF specific. Participants completed outcome measures by telephone at enrollment (baseline) and again at approximately 12 and 24 weeks after enrollment. (See Table 1 for detailed description of outcome measures.)

Data analysis

All clinician small group interviews and participant satisfaction interviews were digitally recorded, transcribed by a professional transcriptionist, reviewed for accuracy, and analyzed using a content analysis procedure similar to previous studies.^{44,45} Assisted by HyperRESEARCH software version 3.0.2 (Researchware, Inc., Randolph, MA), members of the research team (MB, LJ, JNDO, JF) performed *in vivo* coding of the transcripts. *In vivo* excerpts resembling one another across multiple participants were clustered into categories and further refined into themes that informed the aims of the study.

For all efficacy measures we used generalized estimating equations using time point (baseline, 12, and 24 weeks) as the predictor variable to compute means, standard deviations, and effect size changes from baseline.

Results

Phase I: Clinician small group interviews

Table 2 shows the demographic characteristics of the 15 clinicians who participated in small group interviews. The mean age of clinicians was 54 years, 53% ($n=8$) were female, 87% ($n=13$) were white, 74% ($n=11$) were MDs/DOs, 26% ($n=4$) were APRNs, 33% ($n=5$) were in primary care, 27% ($n=4$) were in cardiology, and 27% ($n=4$) were in internal medicine.

The findings emerging from the clinician interviews centered on three main themes: barriers to initiating PC in HF, triggers for initiating PC, and positive and negative elements of the proposed intervention. Barriers to initiating PC in HF included the uncertainty and difficulty of predicting prognosis combined with the belief that individuals with HF rarely

TABLE 1. DESCRIPTION OF OUTCOME MEASURES

<i>Instrument</i>	<i>Description</i>	<i>Reliability</i>
Individuals with HF		
Kansas City Cardiomyopathy Questionnaire (KCCQ) ⁵⁴	Quality of life measure with 5 domains: physical limitations, symptoms, self-efficacy, social interference, and QOL; 23 items	Subscales $\alpha=0.62-0.90$
Hospital Anxiety and Depression Scale (HADS) ⁵⁵	Two domains measuring depression and anxiety; 14 items	Subscales $\alpha=0.82-0.83$
Patient Assessment of Chronic Illness Care (PACIC) ⁵⁶	Consists of 5 Chronic Care Model dimensions: patient activation, delivery system/decision support, goal setting, problem solving, and follow-up/coordination; 20 items	Subscales $\alpha=0.62-0.90$
Memorial Symptom Assessment Scale-Heart Failure (MSAS-HF) ⁵⁷	Symptom burden measure targeting 32 HF-relevant symptoms (e.g., chest pain, difficulty breathing while lying flat, etc.)	Subscales $\alpha=0.83-0.92$ and $\alpha=0.73$ for HF-specific symptoms subscale
Family caregivers		
Montgomery Borgatta Caregiver Burden Scale (MBCB) ⁵⁸	Measure of caregiver burden with 3 domains: objective burden, stress burden, and demand burden; 14 items	Subscales $\alpha=0.75-0.88$
Hospital Anxiety and Depression Scale (HADS)	Same as above	Same as above
Quality of Life – Caregiver (QOLC) ⁵⁹	Quality of life measure with 3 domains: emotional and spiritual well-being, relationship quality with the patient, and satisfaction with sleep, daily routine, and family life; 35 items	$\alpha=0.91$

believe it will “kill them.” Clinicians reported that these barriers made it challenging to have conversations with patients about goals of care. While bringing up PC for some patients was a relief, other patients seem stunned or angry at the suggestion of PC. In addition, many primary care clinicians believed their colleagues lacked the communication skills necessary to talk to patients in a way that balanced giving truthful information without “squashing” hope. Moreover, clinicians thought many of their colleagues had misconceptions or lack of knowledge about the aims and scope of PC services, believing that PC is tantamount to hospice.

Clinicians talked about multiple triggers that led them to consider PC consultation. Some were objective, such as multiple hospitalizations or emergency department visits, while others were more subjective, such as noting that the “patient is getting tired.” Another trigger was the desire for a “second set of eyes” or assessment on overall patient condition and for suggestions in patient symptom management.

Clinicians identified positive features of the proposed intervention and suggestions for improvement. There was a strong belief that PC should be brought up at diagnosis and then again at occasional “check-ins” so that “it would not be such a shock” or “difficult to introduce” when it was really needed. Furthermore, providing “an extra layer of support” for family caregivers was seen as essential. Cardiologists commented that it was important to offer PC “early, but not too early.” They also expressed some mixed feelings about whether to offer PC support at the same time as offering “advanced therapies,” since though patients may need extra support, they may not be willing and able to hear about PC at that time. In general, clinicians found the proposed intervention to be “reasonable,” “nonthreatening,” and “com-

prehensive.” Lastly, there was some concern about involving PC up front and then having to transition to a whole new team when/if hospice gets involved. They expressed a desire to have the same team deliver PC across the continuum.

Clinicians expressed some concerns about delivering the intervention over the phone. They cited several challenges, including accommodating hearing difficulties in older adults; effectively establishing and maintaining rapport; carrying on sensitive dialogue without the aid of nonverbal cues; difficulties in assessing a participant’s understanding; and eliciting frank and open conversations from participants who

TABLE 2. DEMOGRAPHIC CHARACTERISTICS OF THE CLINICIAN EXPERT ADVISORY GROUP (N=15)

	<i>Count (%) or mean</i>
Age (mean), yr	53.5
Gender	
Female	8 (53)
Race	
White	13 (87)
Latino	1 (7)
No response	1 (7)
Discipline	
MD/DO	11 (74)
APRN	4 (26)
Total years in practice	25.4
Specialty	
Primary care	5 (33)
Internal medicine	4 (27)
Cardiology	4 (27)
Hospitalist	1 (7)
Family practice	1 (7)

TABLE 3. DEMOGRAPHIC CHARACTERISTICS OF HF PARTICIPANTS AND FAMILY CAREGIVERS

	<i>HF patients</i> (<i>n</i> = 11)	<i>Family caregivers</i> (<i>n</i> = 11)
Age (mean), yr	68	60
Gender, <i>n</i> (%)		
Male	7 (64)	9 (82)
Marital status, <i>n</i> (%)		
Married or living with partner	9 (82)	11 (100)
Divorced or separated	2 (18)	
Race, <i>n</i> (%)		
White	11 (100)	11 (100)
Education		
Less than high school graduate	2 (18)	2 (18)
High school graduate	2 (18)	2 (18)
College graduate	7 (64)	7 (64)
Employment status, <i>n</i> (%)		
Full-time	0 (0)	4 (36)
Part-time	1 (9)	1 (10)
Homemaker	0 (0)	1 (9)
Retired	9 (82)	4 (36)
Unemployed due to disability or illness	1 (9)	1 (9)
AHA stage, <i>n</i> (%)		
C	9 (82)	NA
D	1 (9)	NA
Unknown	1 (9)	NA
NYHA class, <i>n</i> (%)		
II/III	1 (9)	NA
III	5 (45)	NA
III/IV	2 (18)	NA
IV	2 (18)	NA
Unknown	1 (9)	NA
Ejection fraction (mean)	35%	NA
Devices, <i>n</i> (%)		
ICD	7 (64)	NA
BiV-ICD	3 (27)	NA
Seattle Heart Failure Model		
Predicted Mortality		
1-year survival, %	33% [0–98]	NA
median [range]		
Life expectancy, median [range], yrs	6.29 [0–18.5]	NA
Medications, <i>n</i> (%)		
ACE-I	4 (36)	NA
ARB	4 (36)	NA
Aldosterone blocker	5 (45)	NA
Beta-blocker	7 (64)	NA
Statin	9 (82)	NA
Allopurinol	2 (18)	NA
Diuretics, <i>n</i> (%)		
Furosemide	4 (36)	NA
Torsemide	5 (45)	NA
Metolazone	2 (18)	NA
Lab data, median [range]		
Hemoglobin	12.6 [10.1–16.2]	NA
Lymphocyte %	21.2 [6.0–18.3]	NA
Uric acid	8.6 [4.9–11.2]	NA
Total cholesterol	143 [94–295]	NA
Sodium	137 [129–143]	NA

ACE-I, angiotensin-converting-enzyme inhibitor; AHA, American Heart Association; ARB, angiotensin receptor blocker; BiV-ICD, biventricular implantable cardioverter-defibrillator; ICD, implantable cardioverter-defibrillator; NYHA, New York Heart Association.

may have (or think they have) others listening in on their conversations. However they agreed that those concerns were minor in comparison to the logistical convenience of doing the bulk of the intervention over the phone given the lengthy distances between patients' homes and the clinic. Combined with the one-time in-person PC assessment and the option of seeing a clinician in person when needed, overall, clinicians believed the net benefit was greater in favor of telephone care.

Phase II: Patient and caregiver participant feasibility evaluation

Table 3 shows the demographic characteristics of the 11 HF participant/caregiver dyads (22 total participants). Mean age of HF patient participants (*n* = 11) was 68 years, 36% (*n* = 4) were female, 100% (*n* = 11) were white, 82% (*n* = 9) were retired, and 64% (*n* = 7) had a college education. Mean age of caregiver participants (*n* = 11), all of whom were the patients' spouse, was 60 years, 18% (*n* = 2) were female, 100% (*n* = 11) were white, 36% (*n* = 4) were retired, 36% (*n* = 4) worked full time, and 64% (*n* = 7) had a college education. Medications and median lab values were those closest to the time of study entry and were used to estimate the Seattle Heart Failure Model prognostic scores.⁴⁸ All 11 patient participants completed a PC assessment; all patient and caregiver participants completed baseline efficacy measures; 10 patient participants completed all 6 CYC phone sessions (1 patient participant died suddenly before beginning phone sessions); and 10 caregiver participants completed 3 CYC phone sessions. HF participant sessions lasted an average of 43 minutes and caregiver sessions lasted an average of 37 minutes. Completion rates for satisfaction and efficacy measures are noted below.

Satisfaction interviews. Content analysis of the satisfaction interviews from both HF patients—week 3, *n* = 6; week 6, *n* = 8; and caregivers, *n* = 8—revealed three primary themes. The first and most prominent theme emphasized nearly unanimously by all participants was that the intervention would have been more helpful if received earlier. A number of caregivers expressed feeling “burned out” from the length of time being a caregiver and that they were already familiar with many of the skills and content presented in the CYC sessions. The second main theme was the value of having the nurse coach to talk to and vent with regarding their experiences. Some talked about how it helped to have someone to help them think things through. In particular, they found the last three sessions focused on life review of particular value in this regard. As stated by one male patient, “It kind of helps you put things in perspective and it changes your attitude more towards life. Hopefully giving you a better positive outlook.” The final key theme related to making intervention modifications, e.g., suggested shortening CYC chapter length and density, noting that it took over an hour to review some chapters.

Efficacy outcome measures. Efficacy measures for both HF participants and caregivers took approximately 30 minutes to complete. Out of 66 possible sets of measures (11 dyads × 2 persons/dyad × 3 time points), 44 sets (67%) were completed; 12 (18%) measures were not completed due to the HF participant's death, and 10 (15%) were not completed due to failure to reach/loss to follow-up.

TABLE 4. PATIENT AND CAREGIVER OUTCOME MEASURES

Group	Measure	Baseline mean score (SD) (N=11)	Mean standardized effect size (d) from baseline	
			Week 12 (N=6)	Week 24 (N=5)
HF participants	HADS Total	25.11 (4.38)	0.54	0.01
	Anxiety	12.67 (3.66)	0.36	-0.16
	Depression	12.44 (1.67)	0.66	0.41
	PACIC summary score	3.49 (0.53)	0.47	-0.08
	Patient activation	3.48 (0.84)	0.39	0.68
	Decision support	4.11 (0.51)	0.73	-0.12
	Goal setting	3.51 (0.62)	0.41	-0.23
	Problem solving	3.75 (0.87)	0.12	-0.23
	Care coordination	2.89 (0.78)	0.26	-0.14
	KCCQ summary score	51.94 (18.95)	0.31	0.06
Family caregivers	MSAS summary score	2.04 (0.46)	-0.22	0.33
	HADS total	24.89 (7.2)	0.05	0.12
	Anxiety	10.67 (3.68)	-0.06	0.23
	Depression	14.22 (3.81)	0.14	-0.06
	MBCB total	45.78 (6.3)	0.25	0.28
	Objective burden	17.67 (5.27)	0.04	0.41
	Stress burden	15.89 (2.58)	0.01	-0.96
	Demand burden	12.22 (1.52)	0.64	0.96
	QOLC total	82.06 (22.2)	-0.06	0.33

HADS, Hospital Anxiety and Depression Scale; PACIC, Patient Assessment of Care for Chronic Conditions; KCCQ, Kansas City Cardiomyopathy Questionnaire; MSAS, Memorial Symptom Assessment Scale; MBCB, Montgomery Borgalia Caregiver Burden Scales; QOLC, caregiver quality of life.

Table 4 displays the results of the generalized estimating equations used to compute observed effect sizes at 12 and 24 weeks in comparison to baseline. Given the large number of measures and small sample size, these analyses are useful only for descriptive purposes.

Discussion

HF and PC organizations recommend early PC to improve the quality of life of the over five million individuals living with HF. We conducted a rigorous, formative evaluation study to translate ENABLE, a telehealth model of concurrent PC, from an oncology population to a rural-dwelling population of adults with NYHA Class III-IV HF and their primary caregivers. The results of this formative evaluation demonstrate that the first iteration of the ENABLE: CHF-PC intervention was feasible and well received by clinicians and HF patient/caregiver dyads. Feasibility was ascertained by clinician willingness to refer HF patients and patient and caregiver willingness to participate and complete all study sessions and measures. Our evaluation identified several modifications for future ENABLE: CHF-PC trials. As recommended by the MRC, this evaluation study was a necessary first step prior to conducting an efficacy trial.

Based on input from clinicians, we were able to elicit their concerns about HF patient referral to a concurrent PC intervention. Difficulty predicting prognosis is one potential barrier to this model of care.² A related challenge is that patients often lack an appreciation of the fatality of HF which can also interfere with their ability to see the value of defining goals of care or having the participation of PC until very late in their disease trajectory.

One of the key points that we emphasized in the adapted intervention is that palliative care in general and this intervention in particular is not about end of life but rather about living well with serious illness. Educational efforts for both clinicians and patients are an important component of any future concurrent PC intervention in HF. Of interest is the ambivalence of clinicians to involve PC in patients seeking advanced therapies. This is similar to oncologists' concerns about involving PC when patients are still seeking active and investigational therapies.⁴⁹ Ironically, this is just the time when patients and their caregivers likely need the most support—as disease is advancing and decision support could be of greatest value. Hence, stressing the extra layer of support that PC provides to patients with life-limiting illness who are actively undergoing treatment, especially in terms of symptom management, is an important consideration as this intervention is implemented in the broader HF population.

It is important that clinicians' suggestions are actively incorporated into any newly developed intervention. Clinicians expressed some concern over telephone supportive care, but agreed that the net benefit of this approach for access outweighed potential downsides of phone-based care. Contrary to concerns expressed by clinicians about introducing PC “too early,” individuals with HF and caregivers stated in satisfaction surveys that they wished the intervention had been introduced earlier in their care, particularly at the time of diagnosis of advanced HF. Other studies have reported similar findings pertaining to the earlier timing of PC.^{50–52} This point was further emphasized in our formative evaluation by the fact that two patients experienced sudden, unexpected cardiac death within two weeks of enrollment, before the CYC sessions were started, and another died six weeks

after enrollment just after completing sessions. Though the sample size was small, we experienced an almost 30% sudden death rate. This compares to more recent sudden death estimates of 5%–10%. The deaths occurred in a sample that was specifically chosen with a clinician-estimated prognosis of at least a year, so that participants would be able to complete all study procedures. In our opinion, PC could be ideally introduced at the time of diagnosis of advanced disease. However, the illness trajectory of HF is known to be notoriously difficult to predict.^{2,53} Hence, future trials of EN-ABLE: CHF-PC will need to emend the eligibility criteria and recruitment protocol in such a way as to identify HF patients and caregivers earlier in the illness trajectory at the time of advanced HF diagnosis.

Patients and caregivers noted in satisfaction interviews that they found it extremely helpful having a nurse coach to talk to about their experiences and that the CYC topics were quite relevant; however the draft of the CYC manual (which lacked graphics in its draft form) was dense and difficult to get through. We have incorporated patients' suggestions by simplifying and abbreviating the patient and caregiver CYC manual's content and format and have added more interactive discussion activities. Of great interest to us in adapting the intervention was the patients' responses regarding the relevance of the session topics in general as they dealt with advanced HF, and in particular the last three sessions on life review (the OUTLOOK component of the intervention).⁵⁴ Patients specifically reported the value of these sessions in helping them to reflect on their lives and consider all of their past experiences—positive and negative—and how they might approach some activities differently moving forward. In general participants described how they often found themselves being more reflective in general outside of the actual sessions.

Efficacy measures for HF patients and caregivers were administered at baseline, 12 weeks, and 24 weeks for the purpose of determining the ability of patients and caregivers to complete them and to explore whether an intervention effect could be determined in this small sample. Effect sizes ranged from small to medium.⁵⁵

This was an intervention development study, using the MRC framework, designed to translate an existing, effective intervention from cancer to a HF population; therefore the sample size was appropriate for that purpose. However, as noted by Kraemer, readers should exercise caution using pilot study data to guide sample size calculations for future randomized control trials, due to both over- and underestimation of intervention effect.⁵⁶ Though participants had to meet certain inclusion and exclusion criteria, participants were also sought who would be able to provide critical feedback. An important limitation was that we did not determine the sample's health literacy. Education level, which in our sample was quite high, could limit the generalizability of our results. In our next pilot we intend to measure that construct as a potential mediator of intervention effect.⁵⁷ Another limitation of our study was that all participants were white; however this was expected given the demographic homogeneity of Vermont and New Hampshire.

The data from our study allowed us to translate an intervention that was previously determined to be effective in cancer to an HF population. In preparation for a larger randomized clinical trial to determine intervention efficacy, we have obtained funding from the National Palliative Care

Research Center to pilot test the intervention with a larger sample of participants who are more racially diverse.

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Address correspondence to:
 Marie Bakitas, DNSc, CRNP
 University of Alabama at Birmingham
 School of Nursing
 Office 2M024
 1720 2nd Avenue South
 Birmingham, AL 35294-1210
 E-mail: mbakitas@uab.edu