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# Effect of an Early Palliative Care Telehealth Intervention vs Usual Care on Patients With Heart Failure
## The ENABLE CHF-PC Randomized Clinical Trial

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**IMPORTANCE** National guidelines recommend early palliative care for patients with advanced heart failure, which disproportionately affects rural and minority populations.

**OBJECTIVE** To determine the effect of an early palliative care telehealth intervention over 16 weeks on the quality of life, mood, global health, pain, and resource use of patients with advanced heart failure.

**DESIGN, SETTING, AND PARTICIPANTS** A single-blind, intervention vs usual care randomized clinical trial was conducted from October 1, 2015, to May 31, 2019, among 415 patients 50 years or older with New York Heart Association class III or IV heart failure or American College of Cardiology stage C or D heart failure at a large Southeastern US academic tertiary medical center and a Veterans Affairs medical center serving high proportions of rural dwellers and African American individuals.

**INTERVENTIONS** The ENABLE CHF-PC (Educate, Nurture, Advise, Before Life Ends Comprehensive Heartcare for Patients and Caregivers) intervention comprises an in-person palliative care consultation and 6 weekly nurse-coach telephonic sessions (20-40 minutes) and monthly follow-up for 48 weeks.

**MAIN OUTCOMES AND MEASURES** Primary outcomes were quality of life (as measured by the Kansas City Cardiomyopathy Questionnaire [KCCQ]: score range, 0-100; higher scores indicate better perceived health status and clinical summary scores ≥50 are considered "fairly good" quality of life; and the Functional Assessment of Chronic Illness Therapy–Palliative-14 [FACIT-Pal-14]: score range, 0-56; higher scores indicate better quality of life) and mood (as measured by the Hospital Anxiety and Depression Scale [HADS]) over 16 weeks. Secondary outcomes were global health (Patient Reported Outcome Measurement System Global Health), pain (Patient Reported Outcome Measurement System Pain Intensity and Interference), and resource use (hospital days and emergency department visits).

**RESULTS** Of 415 participants (221 men; baseline mean [SD] age, 63.8 [8.5] years) randomized to ENABLE CHF-PC (n = 208) or usual care (n = 207), 226 (54.5%) were African American, 108 (26.0%) lived in a rural area, and 190 (45.8%) had a high-school education or less, and a mean (SD) baseline KCCQ score of 52.6 (21.0). At week 16, the mean (SE) KCCQ score improved 3.9 (1.3) points in the intervention group vs 2.3 (1.2) in the usual care group (difference, 1.6; SE, 1.7; $d$ = 0.07 [95% CI, −0.09 to 0.24]) and the mean (SE) FACIT-Pal-14 score improved 1.4 (0.6) points in the intervention group vs 0.2 (0.5) points in the usual care group (difference, 1.2; SE, 0.8; $d$ = 0.12 [95% CI, −0.03 to 0.28]). There were no relevant between-group differences in mood (HADS-anxiety, $d$ = −0.02 [95% CI, −0.20 to 0.16]; HADS-depression, $d$ = −0.09 [95% CI, −0.24 to 0.06]).

**CONCLUSIONS AND RELEVANCE** This randomized clinical trial with a majority African American sample and baseline good quality of life did not demonstrate improved quality of life or mood with a 16-week early palliative care telehealth intervention. However, pain intensity and interference (secondary outcomes) demonstrated a clinically important improvement.

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Invited Commentary
Supplemental content

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Heart failure (HF) imposes a high symptom burden for more than 6 million persons in the United States that requires significant self-management, problem-solving, treatment decision-making, and care partner involvement for months to years.[1,2] Mounting evidence and numerous clinical guidelines highlight the benefits that supportive and palliative care can provide to patients with HF and their families.[2-6]

Unlike cancer, few models of integrated HF palliative care have been tested.[7,8] Fewer still have been designed to address unique palliative care sociocultural and access issues of underserved minorities and those who live in rural areas.[9] This problem is especially pernicious in the southeastern United States because this region has the highest rates of HF morbidity and mortality[10]; the highest proportions of rural, minority, and underserved patients[11,12]; and the lowest access to palliative care services.[13] We developed ENABLE CHF-PC (Educate, Nurture, Advise, Before Life Ends Comprehensive Heartcare for Patients and Caregivers), a culturally based, early palliative care telehealth intervention, to address these priority clinical[11,14,15] and research gaps.[16]

ENABLE CHF-PC is a nurse-led, predominantly telephone-based psychoeducational intervention for patients with advanced HF who are still months to years from the end of life.[17-20] The intervention is focused on teaching patients and family caregivers skills to help them cope with their serious illness (eg, problem solving, symptom and self-care management, communication, treatment and advance care decision-making, and life review). Quality of life (QOL) and mood were the primary outcomes of this single-blind randomized clinical trial comparing ENABLE CHF-PC with usual HF care. We hypothesized that patients receiving the ENABLE CHF-PC intervention would report better QOL and mood than patients receiving usual HF care. Secondary outcomes were pain, global health, and resource use (hospital days and emergency department visits). Family caregivers received a parallel intervention, reported separately.[17]

### Key Points

**Question** What is the effect of an early palliative care telehealth intervention vs usual care on the quality of life and mood of patients with heart failure over 16 weeks?

**Findings** In this randomized clinical trial of 415 adults (55% African American) with American College of Cardiology stage C or D heart failure, most had good baseline quality of life. There were no significant differences in the primary outcomes of quality of life and mood; however, secondary outcomes of pain intensity and pain interference with daily life were better in the intervention group.

**Meaning** An early palliative care telehealth intervention for patients with advanced heart failure did not improve quality of life or mood but did improve pain intensity and pain interference with daily life over 16 weeks.

## Methods

### Study Design and Oversight

Following the Consolidated Standards of Reporting Trials (CONSORT) reporting guideline,[21] this was a 2-site, single-blind randomized clinical trial comparing the effect of ENABLE CHF-PC with usual care among a sample of adults with a diagnosis of New York Heart Association (NYHA) class III or IV HF or American College of Cardiology stage C or D HF. The study protocol, including the statistical plan, has been published elsewhere[22] and is included in Supplement 1. The human participants protocol and data safety monitoring plan were approved by the University of Alabama at Birmingham and the Birmingham Veterans Affairs Medical Center Institutional Review Boards (NCT02505425). Patients provided written informed consent.

### Participants

Patients were identified by trained research coordinators using similar screening algorithms for University of Alabama at Birmingham and Birmingham Veterans Affairs Medical Center advanced HF clinicians' schedules (from October 1, 2015, to October 31, 2018 [participants were followed up until May 31, 2019]) for patients with the following eligibility criteria: (1) English-speaking, (2) 50 years or older, and (3) with clinician-documented NYHA class III or IV HF or American College of Cardiology stage C or D HF. If clinicians agreed, willing patients provided written informed consent and underwent additional screening to determine if they had reliable telephone access, a Callahan Cognitive Screener[23] score of 3 or more (range, 0-6, where 0 indicates severe cognitive impairment and 6 indicates normal cognitive function), and were able to complete telephone-administered baseline questionnaires. Patients were excluded if they had noncorrectable hearing loss or an untreated *Diagnostic and Statistical Manual of Mental Disorders* (Fourth Edition) Axis I diagnosis (eg, schizophrenia, bipolar disorder, or active substance use disorder).

### Randomization and Blinding

After completing baseline questionnaires, patients were randomized by the project manager (S.E.) to either the intervention or the usual care group. Computer-generated randomization was concealed and performed using a secure REDCap (Research Electronic Data Capture) database in a 1:1 ratio with block size of 2. Randomization was stratified by site (University of Alabama at Birmingham and Birmingham Veterans Affairs Medical Center) and race/ethnicity (white and African American). Participants, physicians, and nurse interventionists were not blinded. Trained research assistants who collected self-report questionnaire data, the principal investigator, and coinvestigators were blinded. All participants received a $10 incentive at each data collection time point.

### The ENABLE CHF-PC Intervention and Fidelity Monitoring

Using the Medical Research Council guidance for developing and evaluating complex interventions,[24] we conducted multiple formative evaluation pilot studies to translate our successful ENABLE (Educate, Nurture, Advise, Before Life Ends) nurse-led early palliative care telehealth model for patients

with cancer[18-20,25-27] to a population with HF.[22,28-32] In these studies, informed by literature reviews and medical record audits of patients with HF receiving palliative care consultations,[32] we translated the ENABLE *Charting Your Course-Patient* guidebook and nurse coach training materials and used patient and caregiver feedback to identify an acceptable and feasible intervention.[28,29] We then conducted a 2-site, single-group pilot trial (N = 61) to test outcome measures, study procedures, and to query patients and caregivers about intervention relevance.[28] Patients, caregivers, and advanced HF clinicians (who also served as coinvestigators) provided critical suggestions related to literacy, branding, and cultural norms that stimulated significant revisions of the *Charting Your Course-Patient* guidebook, study materials, and procedures. An extensive description of ENABLE CHF-PC is provided in the published protocol.[22]

Following guidelines outlined in the Template for Intervention Description and Replication[33] and integrating essential elements of the Chronic Care Model[34] and National Consensus Project Guidelines for Quality Palliative Care,[35] the adapted ENABLE CHF-PC intervention delivered comprehensive palliative care (eFigure 1 in Supplement 2) via (1) an in-person comprehensive consultation by a board-certified palliative care clinician; (2) 6 telehealth nurse coaching sessions (lasting approximately 30-40 minutes) focused on essential palliative care topics using a structured curriculum and guidebook, *Charting Your Course: An Intervention for Patients with Heart Failure and their Families*; and (3) monthly follow-up calls to assess patients' needs and to reinforce prior content through the end of data collection (48 weeks) or patient death. Session 1 introduced palliative care, elicited patients' understanding of their illness, discussed problem-solving and COPE (creativity, optimism, problem solving, and expert information) frameworks.[36,37] Session 2 reviewed self-care topics (ie, healthy eating, exercise, smoking cessation, relaxation, and asking for help). Session 3 addressed physical and emotional symptom management, including how to self-assess and report pain and other symptoms so that clinicians would glean the patients' priorities, and spirituality. Session 4 introduced values elicitation, advance care planning, and decision aids. Sessions 5 and 6 comprised life review and creating legacy: the Outlook intervention of Keall et al.[38]

We used National Institutes of Health-recommended fidelity strategies to ensure validity and reliability of intervention delivery,[39] including (1) interventionist training and weekly supervision by study investigators (M.A.B. and J.N.D.-O.; use of study IDs maintained investigator blinding during supervision), (2) *Charting Your Course* session scripts and documentation templates, and (3) fidelity monitoring. All sessions were digitally recorded and 10% were randomly selected for external audit using a study team-developed fidelity checklist. A fidelity checklist rating less than 80% was discussed with the individual nurse coach. However, 3 consecutive ratings less than 80% were considered a pattern of protocol nonadherence and was cause for intensive remediation. During the course of the study, there were no patterns of protocol nonadherence.

## Usual Care

Patients randomized to the usual care group continued to receive the same outpatient management as prior to enrolling in the study. Based on national HF guidelines,[40] patients were followed up in an HF disease management program by subspecialty HF cardiologists. Patients were seen in the clinic at intervals determined by the physician based on clinical evaluation, and had telephone access to HF nurses between visits. Heart failure education was provided verbally and through printed materials by physicians and nurses based on perceived patient needs. Additional consultative services, such as palliative care, were requested based on clinical evaluation. Hospitalized patients were managed by their admitting service (cardiology or hospitalist).

## Primary End Points

Outcome measures were collected by telephone using trained, blinded data collectors, every 8 weeks through 48 weeks. Primary outcomes were QOL measured by the HF-specific 23-item Kansas City Cardiomyopathy Questionnaire (KCCQ) (score range, 0-100; higher scores indicate better perceived health status; clinical summary scores ≥50 are considered "fairly good" QOL[41,42] and a change of 5 points is considered a clinically important difference[43]) and the 14-item Functional Assessment of Chronic Illness Therapy–Palliative-14 (FACIT PAL-14) (score range, 0-56; higher scores indicate better QOL).[44] Mood was measured by the 14-item Hospital Anxiety and Depression Scale (HADS),[45] where 7 items measure anxiety symptoms and 7 items measure depressive symptoms (subscale ranges, 0-21; scores >8 indicate clinically high symptoms[46]; and a change of 1.7 is considered a clinically important difference).[47]

## Secondary End Points

Secondary outcomes included 3 Patient Reported Outcome Measurement System measures: Global Health-10,[48] which measures general domains of health including physical, mental, and social health, symptoms, and overall quality of life, and the 3-item Pain Intensity and 2-item Pain Interference Scales.[49] For Patient Reported Outcome Measurement System tools, summed scores are converted to a T-score where the mean is 50 and the SD is 10 (higher scores indicate better health). For pain intensity and interference, higher scores indicate more pain and interference with daily life[50] and 2-point to 3-point change in T-scores is considered a clinically important difference. Self-reported resource use (hospital days and emergency department visits) was an additional secondary outcome. Other baseline measures included: health literacy, demographic information, spiritual or religious coping, results of the Brief Cope Inventory,[51] and reciprocal relationships.

## Sample Size

Our primary hypothesis was that patients receiving the ENABLE CHF-PC intervention would report a higher QOL and mood at 16 weeks compared with patients receiving usual care. We anticipated enrollment of 380 patients to detect a standardized mean effect size difference between the intervention and usual care groups of $d = 0.3$, estimated as 6.4 for KCCQ,

1.22 for HADS-anxiety, and 1.19 for HADS-depression using SDs from the literature.[52,53] We assumed 80% power, α = .01 (a conservative parameter owing to multiple comparisons), an exponential survival distribution with a median of 2 years, and independent 2-year 10% attrition. Owing to higher than anticipated data attrition at week 16, we recruited an additional 35 participants to achieve a final total sample of 415.

### Statistical Analysis

Data from all participants were included regardless of intervention participation, consistent with an intent-to-treat analysis. We used descriptive statistics and measures of effect size (Cohen *d* or *d*-equivalent: small, approximately 0.2; medium, approximately 0.5; and large, approximately 0.8[54]) to examine between-group balance on baseline characteristics and outcomes. We examined patterns of missing data due to participant withdrawal or skipping data collection time points (eTable 1 in Supplement 2). We used measures of effect size to examine associations between patient consistency in data collection and baseline characteristics among patients alive at 32 weeks. For each study outcome we fitted longitudinal models with linear or generalized linear mixed models including coefficients for time, group, and time by group interaction terms and adjusting for covariates associated with patterns of missing data (eTable 1 in Supplement 2). We used linear contrasts to estimate intervention effects calculated as a mean of weeks 8 and 16 combined minus baseline. We rescaled these estimates into standardized intervention effects (Cohen *d*) using the outcomes' baseline SDs. Owing to higher than anticipated proportions of participants with NYHA class III HF and baseline KCCQ of 50 or more (indicating fairly good QOL), we conducted an unplanned sensitivity analysis of primary outcome effects in intervention participants with baseline KCCQ clinical summary scores of less than 50 (poorer HF-related QOL)[41,42] (eFigure 2 and eTable 2 in Supplement 2). All *P* values were from 2-sided tests and results were deemed statistically significant at *P* = .01.

## Results

### Study Participants

All 415 patients randomized to receive the ENABLE CHF-PC intervention (n = 208) or usual care (n = 207) were included in the intent-to-treat analysis (**Figure**). Baseline characteristics were balanced between groups (**Table 1**). The total sample mean (SD) age was 63.8 (8.5) years, and most were male (221 [53.3%]), African American (226 [54.5%]), and Protestant (378 [91.1%]), and had a high-school education or less (190 [45.8%]). Patients had been living with their HF diagnosis for a mean (SD) of 5.1 (5.3) years, with a mean (SD) ejection fraction of 41.0% (15.8%). A total of 402 participants (96.9%) had NYHA class III HF, with a mean (SD) KCCQ clinical summary score of 52.6 (21.0), indicating a "fairly good" baseline HF-specific QOL.[41,42] Similarly, participants' mean (SD) baseline FACIT Pal-14 score (36.4 [9.5]) demonstrated moderate QOL[44] and the mean (SD) HADS-anxiety (6.7 [3.6]) and HADS-depression (5.7 [4.3]) scores reflected low anxiety or depression.[47] Mean (SD) global physical (38.3 [8.0]) and mental health (45.2 [8.6]) T-scores and pain intensity T-score (45.9 [10.7]) were below the population mean of 50; however, the mean (SD) pain interference T-score (54.9 [10.8]) was higher than the population mean score.

### Study End Points

Models estimated within-group and between-group change from baseline through week 16 (calculated as a mean of weeks 8 and 16 combined minus baseline). As shown in **Table 2**, the mean KCCQ clinical summary score improved a mean (SE) of 3.9 (1.3) points in the intervention group and 2.3 (1.2) points in the usual care group (difference, 1.6; SE, 1.7; *d* = 0.07 [95% CI, −0.09 to 0.24]). The mean (SE) FACIT-Pal-14 score improved 1.4 (0.6) points in the intervention group vs 0.2 (0.5) points in the usual care group (difference, 1.2; SE, 0.8; *d* = 0.12 [95% CI, −0.03 to 0.28]). We also observed small between-group effect size differences for HADS-anxiety (*d* = −0.02 [95% CI, -0.20 to 0.16]) and HADS-depression (*d* = −0.09 [95% CI, -0.24 to 0.06]).

For secondary outcomes, we observed small between-group differences for global health (mental health, *d* = 0.06; and physical health, *d* = 0.08; **Table 3**) and resource use (days in hospital: mean ratio, 1.65 [95% CI, 0.90-3.03]; *P* = .11; and emergency department visits: mean ratio, 1.32 [95% CI, 0.86-2.01]; *P* = .21; **Table 4**) that were also unlikely to be clinically relevant. However, pain intensity T-scores (difference, −2.8; SE, 0.9; *d* = −0.26 [95% CI, −0.43 to −0.09]) and pain interference T-scores (difference, −2.3; SE, 1; *d* = −0.21 [95% CI, −0.40 to −0.02]) demonstrated small between-group effect size reductions through week 16 (Table 3). No relevant between-group differences were observed in resource use (Table 4). No significant differences were noted in week 24 and 32 measures after baseline).

Because mean baseline KCCQ clinical summary scores were higher than expected, we conducted sensitivity analyses of participant subgroups (n = 195: intervention n = 92 vs usual care n = 103) with baseline KCCQ clinical summary score of less than 50 indicating fair-to-poor QOL.[41,42] We observed a mean (SE) change of 5.0 (2.5) points (*d* = 0.46), considered a clinically important difference in the KCCQ clinical summary score, in the intervention group[43] (difference, 9.7; SE, 1.9) compared with the usual care group (difference, 4.8; SE, 1.7) at 16 weeks after baseline. For the FACIT Pal-14 we observed a small beneficial effect at 16 weeks after baseline (difference, 1.6; SE, 1.1; *d* = 0.21) (eTable 2 in Supplement 2).

## Discussion

Given the lack of culturally based, accessible palliative care interventions for patients with advanced HF, we conducted the largest, most racially diverse randomized clinical trial to date, to our knowledge, to address this disparity. The results showed that ENABLE CHF-PC, a nurse-led, early palliative care telehealth intervention, did not demonstrate significant differences in QOL or mood compared with usual care over 16 weeks. The secondary outcomes of pain intensity and pain interference demonstrated improvement, whereas global health and

resource use were not different between the groups. Although the ENABLE CHF-PC intervention did not demonstrate benefit to primary outcomes over 16 weeks, we gleaned critical insights that will guide future work on integrating early palliative care in HF.

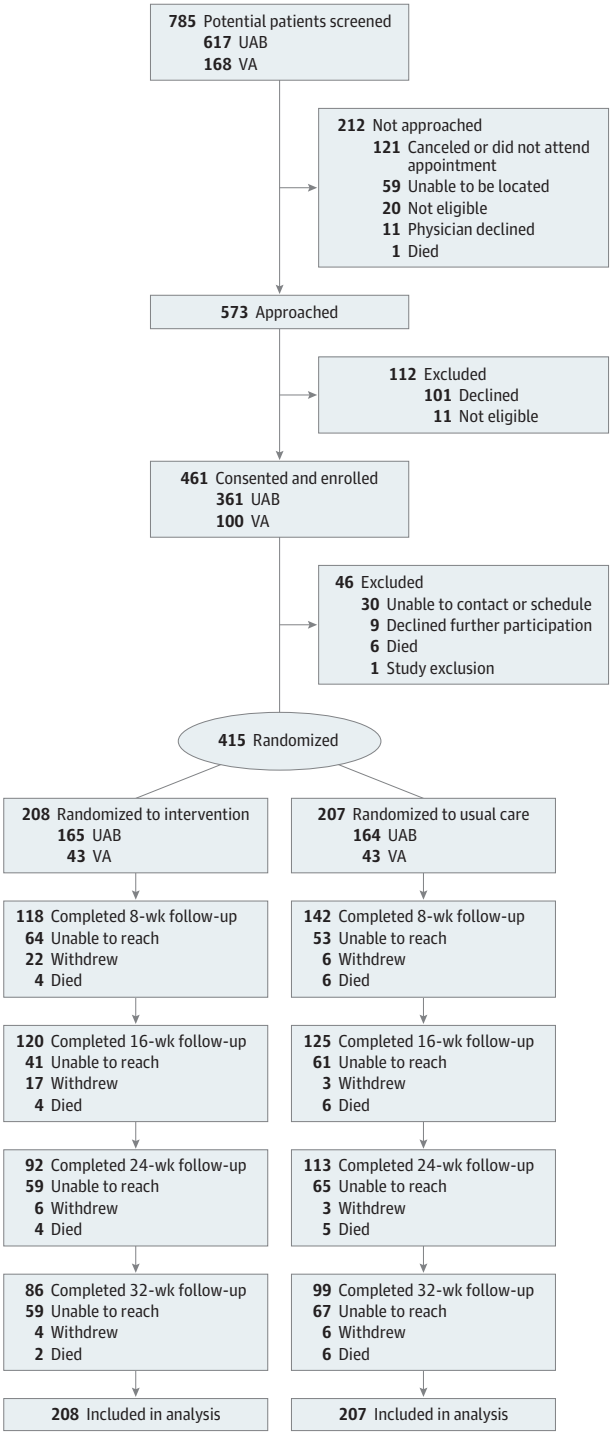
One potential explanation for the lack of a detectable intervention effect may reflect the high proportion of patients with NYHA class III status (96.9%) and the sample's fairly good baseline QOL (mean [SD] KCCQ clinical summary score, 52.6 [21.0] [≥50 indicates fairly good QOL[41,42]] and mean FACIT Pal-14 score, 36.4 [a FACIT Pal-14 score >33.7 indicates a high functional status and >6-month prognosis]).[44] The proportion of patients with NYHA class III HF and baseline KCCQ scores in our study was considerably higher than in other palliative care HF trials that demonstrated positive outcomes—specifically, the study by Rogers and colleagues[5] (patients with NYHA class III HF, 75%; mean baseline KCCQ score, 33.7) and the study by Bekelman and colleagues[4] (patients with NYHA class III HF, 47%; mean baseline KCCQ score, 47). Hence, our lack of results may represent a possible "ceiling effect," indicating that there was little room for improvement by our intervention.

Our sensitivity analysis of participants with KCCQ scores of less than 50 (identified as fair-to-poor QOL)[41,42] did show a clinically meaningful effect size difference ($d$ = 0.46) at 16 weeks benefiting the intervention group. This finding suggests that the ENABLE CHF-PC intervention may positively affect patient QOL outcomes among those with poorer baseline QOL. An analysis of prior ENABLE cancer trials demonstrated that patients with higher depression scores at baseline showed the greatest survival and intervention effect compared with those with low depression scores.[55] A key implication for future intervention work should be the selective screening and identification of patients with HF who have higher distress from symptom burden and poorer QOL.

Another explanation for the lack of positive outcomes in the present study might be attributed to participants receiving a lower "dose" of the ENABLE CHF-PC intervention than that specified in the protocol. Nearly half of intervention patients were unable to attend the in-person palliative consultation and 39% did not receive the full (6 telephone sessions) "dose" of Charting Your Course. This lower adherence to the study protocol may suggest a dose effect (ie, patients receiving more of the intervention would be more likely to have better QOL); we are exploring this hypothesis in our data and as a future area of study.[56] Noncompletion of all intervention components might also suggest that the ENABLE CHF-PC intervention was too burdensome or perceived as not needed for individuals who had relatively high physical and mental function.

It is notable that pain intensity T-scores (difference, −2.8; SE, 0.9) and pain interference T-scores (difference, −2.3; SE, 1.0) secondary outcomes demonstrated a statistically significant and clinically important decrease (defined as 2-3 T points) at 16 weeks and remained stable thereafter.[50] Bodily pain in patients with HF is underreported, underassessed, understudied, and often overshadowed by other HF-related symptoms such as dyspnea and fatigue.[57] In a recent review of

Figure. Patient Screening, Enrollment, Allocation, and Data Collection




Participants were randomized into 2 groups: intervention, in which usual heart failure care and the Educate, Nurture, Advise Before Life Ends Comprehensive Heartcare for Patients and Caregivers (ENABLE CHF-PC) intervention was provided, and the usual, standard heart failure care group, in which usual heart failure care was provided but the ENABLE CHF-PC intervention was not provided. Primary end points were quality of life and mood over 16 weeks. To maximize potential data points, participants could remain in the study after 1 missed data collection window, which contributed to higher 16-week questionnaire completion in participants randomized to the usual care group. All available data were included in the analysis. UAB indicates University of Alabama at Birmingham; and VA, Birmingham Veterans Affairs Medical Center.

Table 1. Baseline Characteristics of Participants

| Characteristic | Participants, No. (%) | | Effect size, Cohen *d* |
|---|---|---|---|
| | Intervention (n = 208) | Usual care (n = 207) | |
| Age, mean (SD) [range], y | 63.5 (8.0) [50.0-89.0] | 64.1 (9.1) [50.0-92.0] | 0.07 |
| Sex | | | |
| Male | 111 (53.4) | 110 (53.1) | 0.0 |
| Race/ethnicity | | | |
| White | 92 (44.2) | 92 (44.4) | 0.0 |
| African American | 113 (54.3) | 113 (54.6) | |
| Other | 3 (1.4) | 2 (1.0) | |
| Marital status | | | |
| Married or living with partner | 105 (50.5) | 96 (46.4) | 0.11 |
| Divorced or separated | 52 (25.0) | 56 (27.1) | |
| Never married | 29 (13.9) | 22 (10.6) | |
| Widowed | 21 (10.1) | 33 (15.9) | |
| Employment status | | | |
| Employed | 19 (9.1) | 11 (5.3) | 0.09 |
| Retired or homemaker | 82 (39.4) | 93 (44.9) | |
| Disability | 101 (48.6) | 97 (46.9) | |
| Not employed | 8 (2.9) | 5 (2.4) | |
| Educational level | | | |
| Less than high school graduate | 29 (13.9) | 30 (14.5) | 0.27 |
| High school graduate or GED | 82 (39.4) | 49 (23.7) | |
| Some college or technical school | 61 (29.3) | 84 (40.6) | |
| College graduate | 29 (13.9) | 26 (12.6) | |
| Graduate degree | 7 (3.4) | 17 (8.2) | |
| Urban residence | 150 (72.1) | 157 (75.8) | 0.09 |
| Religious preference | | | |
| Protestant | 194 (93.8) | 184 (88.9) | 0.12 |
| Catholic | 3 (1.4) | 9 (4.3) | |
| Other | 4 (1.9) | 7 (3.4) | |
| None | 6 (2.9) | 7 (3.4) | |
| Attend religious services | | | |
| Regularly | 103 (49.5) | 97 (46.9) | 0.02 |
| Occasionally | 85 (40.9) | 85 (41.1) | |
| Never | 18 (8.7) | 23 (11.1) | |
| Not applicable | 2 (1) | 2 (1) | |
| Ever prayed for your own health? | | | |
| Yes | 191 (91.8) | 184 (88.9) | 0.04 |
| If yes, prayed in past month? | 183 (95.8) | 170 (92.4) | 0.12 |
| Medical history | | | |
| New York Heart Association class | | | |
| III | 200 (96.2) | 202 (97.6) | 0.06 |
| IV | 6 (2.9) | 5 (2.4) | |
| Uncertain | 2 (1.0) | 0 (0.0) | |
| Ejection fraction at enrollment, mean (SD), % | 40.9 (16.4) | 41.2 (15.2) | 0.02 |
| <40% | 90 (43.3) | 86 (41.5) | 0.06 |
| ≥40% | 117 (56.3) | 121 (58.5) | |

(continued)

Table 1. Baseline Characteristics of Participants (continued)

| Characteristic | Participants, No. (%) | | Effect size, Cohen *d* |
|---|---|---|---|
| | Intervention (n = 208) | Usual care (n = 207) | |
| Seattle Heart Failure Model, mean (SD), % | | | |
| Predicted survival, y | | | |
| 1 | 86.8 (11.3) | 86.3 (13.9) | 0.04 |
| 2 | 76.3 (17.8) | 75.6 (19.7) | 0.04 |
| 5 | 52.5 (24.8) | 52.8 (23.3) | 0.01 |
| Years since advanced HF diagnosis, mean (SD), y | 5.1 (5.1) | 5.1 (5.4) | 0.0 |
| Charlson Comorbidity Index, mean (SD) | 3.2 (1.9) | 3.4 (1.9) | 0.10 |
| Palliative care clinical outcomes | | | |
| Hospice program enrollment in last 2 mo | 9 (4.3) | 15 (7.2) | 0.13 |
| Had advance directive | 50 (24.0) | 53 (25.6) | 0.02 |
| Had DNR order | 28 (13.5) | 37 (17.9) | 0.09 |
| **Patient-reported outcomes, mean (SD)** | | | |
| Primary | | | |
| KCCQ clinical summary[a] | 54.2 (20.5) | 51.1 (21.5) | 0.15 |
| FACIT Pal-14[b] | 36.8 (9.3) | 36.1 (9.7) | 0.07 |
| HADS[c] | | | |
| Anxiety | 6.6 (3.5) | 6.8 (3.7) | 0.06 |
| Depression | 5.7 (4.3) | 5.8 (4.2) | 0.02 |
| Secondary | | | |
| PROMIS Global[d] | | | |
| Physical health T score | 38.6 (8.0) | 38.1 (8.0) | 0.06 |
| Mental health T score | 45.8 (8.6) | 44.9 (8.7) | 0.1 |
| PROMIS Pain[e] | | | |
| Intensity T score | 46.8 (10.8) | 45.1 (10.5) | 0.16 |
| Interference T score | 55.4 (10.9) | 54.5 (10.7) | 0.08 |
| Secondary, resource use, mean (SD) | | | |
| Days in hospital, last 2 mo | 2.6 (5.23) | 2.76 (6.61) | 0.02 |
| Emergency department visits, last 2 mo | 0.43 (0.85) | 0.4 (0.77) | 0.04 |

Abbreviations: DNR, do not resuscitate; FACIT Pal-14, Functional Assessment of Chronic Illness Therapy–Palliative-14 items; GED, General Educational Development Certification; HADS, Hospital Anxiety Depression Scale; HF, Heart Failure; KCCQ, Kansas City Cardiomyopathy Questionnaire; PROMIS, Patient-Reported Outcomes Measurement System.

[a] The KCCQ ranges from 0 to 100; higher scores indicate better perceived health status; clinical summary scores 50 or higher are considered fairly good quality of life.

[b] The FACIT-PAL ranges from 0 to 56; higher scores indicate better quality of life; a score of 33.7 corresponds to high functional status and more than 6-month prognosis.

[c] The HADS subscale ranges from 0 to 21; scores higher than 8 indicate caseness for clinically high symptoms.

[d] The PROMIS Global Physical and Mental health mean (SD) score is 50 (10); higher scores indicate better health.

[e] The PROMIS Pain Intensity and Pain Interference mean (SD) scores are 50 (10); higher scores indicate higher pain intensity and more pain interference with daily life.

65 HF studies that mentioned pain as a symptom, pain prevalence ranged from 23% to 85%, with higher ranges in older patients with lower ejection fraction.[57] Our intervention was designed to empower patients to report and seek relief of symptoms that were most important to them. It is possible that even though pain is not considered a typical HF symptom, the nurse coach support may have empowered participants to bring this issue to their clinicians and receive management suggestions that offered relief. Ongoing qualitative interviews may reveal deeper insights about this finding.

## Strengths and Limitations

Our study has some strengths. First, this study represents the largest proportion and absolute number of HF palliative care trial participants who report African American race/ethnicity. Our recruiters were mostly African American; racial concordance has demonstrated greater trust and more likely positive responses when the recruiter "looks like the person they are recruiting." This finding is particularly salient given our proximity to Tuskegee, Alabama, where the memory of the unethical experimentation in African American prisoners is still quite fresh.[58] This study provided us with specific insights on successful recruitment strategies.[58,59] Second, rigorous fidelity procedures allowed us to monitor and ensure protocol-adherent intervention delivery, and to note the proportion of patients who did not receive the intended intervention "dose."

We also acknowledge several study limitations. First, we experienced higher than expected data attrition at our primary end point (16 weeks). Despite many strategies, including a $10 incentive, seeking emergency contact telephone numbers at enrollment, following up with physicians, and making up to 10 contact attempts on different days and times, we had difficulty contacting patients. Missing data are common in palliative care trials owing to patient illness; however, we believe some unique socioeconomic factors (eg, temporary loss of cell phone access) and lack of regular health care appointments may have also influenced our ability to contact some participants. To account for attrition, we overrecruited to 415 participants from our planned sample of 380 and adjusted our primary analyses to account for variables associated with missing data. Second, a minority of patients were not able to adhere to the study protocol, missing either the in-person

Table 2. Outcomes From Baseline to 16 Weeks (Intervention vs Usual Care)

| Outcome, No. of weeks after baseline | Intervention group | | | Usual care group | | | Between-group difference in change from baseline[a] | | |
|---|---|---|---|---|---|---|---|---|---|
| | No. | Mean (SE) | Mean (SE) change from baseline | No. | Mean (SE) | Mean (SE) change from baseline | Mean (SE) | *P* value | Effect size, Cohen *d* (95% CI) |
| KCCQ clinical summary | | | | | | | | | |
| 0 | 208 | 54.3 (1.6) | NA | 206 | 50.9 (1.6) | NA | NA | NA | NA |
| 8 | 118 | 56.6 (1.8) | 3.9 (1.3) | 142 | 51.8 (1.7) | 2.3 (1.2) | 1.6 (1.7) | .37 | 0.07 (−0.09 to 0.24) |
| 16 | 120 | 59.7 (1.8) | | 125 | 54.8 (1.8) | | | | |
| FACIT Pal-14 | | | | | | | | | |
| 0 | 208 | 36.9 (0.7) | NA | 206 | 36 (0.7) | NA | NA | NA | NA |
| 8 | 117 | 38.1 (0.8) | 1.4 (0.6) | 142 | 35.8 (0.8) | 0.2 (0.5) | 1.2 (0.8) | .12 | 0.12 (−0.03 to 0.28) |
| 16 | 119 | 38.5 (0.8) | | 123 | 36.8 (0.8) | | | | |
| HADS-anxiety | | | | | | | | | |
| 0 | 208 | 6.6 (0.3) | NA | 206 | 6.8 (0.3) | NA | NA | NA | NA |
| 8 | 116 | 6.5 (0.3) | 0 (0.2) | 142 | 6.7 (0.3) | 0.1 (0.2) | −0.1 (0.3) | .83 | −0.02 (−0.20 to 0.16) |
| 16 | 119 | 6.6 (0.3) | | 122 | 7.1 (0.3) | | | | |
| HADS-depression | | | | | | | | | |
| 0 | 208 | 5.7 (0.3) | NA | 206 | 5.8 (0.3) | NA | NA | NA | NA |
| 8 | 116 | 5.2 (0.3) | −0.7 (0.2) | 142 | 5.5 (0.3) | −0.3 (0.2) | −0.4 (0.3) | .24 | −0.09 (−0.24 to 0.06) |
| 16 | 119 | 4.9 (0.3) | | 122 | 5.6 (0.3) | | | | |

Abbreviations: FACIT Pal-14, Functional Assessment of Chronic Illness Therapy–Palliative-14 items; HADS, Hospital Anxiety Depression Scale; KCCQ, Kansas City Cardiomyopathy Questionnaire; NA, not applicable.

[a] Intervention minus usual care group, calculated as a mean of weeks 8 and 16 combined minus baseline. *P* values from time by group interaction term in longitudinal models; *d* = mean difference in change from baseline divided by baseline pooled SD.

Table 3. Secondary Outcomes From Baseline to 16 Weeks (Intervention vs Usual Care)

| Outcome, No. of weeks after baseline | Intervention group | | | Usual care group | | | Between-group difference in change from baseline[a] | | |
|---|---|---|---|---|---|---|---|---|---|
| | No. | Mean (SE) | Mean (SE) change from baseline | No. | Mean (SE) | Mean (SE) change from baseline | Mean (SE) | *P* value | Effect size, Cohen *d* (95% CI) |
| PROMIS global physical health T-score | | | | | | | | | |
| 0 | 208 | 38.6 (0.6) | NA | 206 | 38 (0.6) | NA | NA | NA | NA |
| 8 | 116 | 40.6 (0.7) | 1.3 (0.5) | 142 | 38.7 (0.6) | 0.7 (0.5) | 0.7 (0.7) | .35 | 0.08 (−0.09 to 0.25) |
| 16 | 119 | 39.4 (0.7) | | 122 | 38.8 (0.7) | | | | |
| PROMIS global mental health T-score | | | | | | | | | |
| 0 | 208 | 45.9 (0.6) | NA | 206 | 44.9 (0.6) | NA | NA | NA | NA |
| 8 | 116 | 46.1 (0.7) | 0 (0.5) | 142 | 44.1 (0.7) | −0.5 (0.5) | 0.5 (0.7) | .49 | 0.06 (−0.10 to 0.22) |
| 16 | 119 | 45.6 (0.7) | | 122 | 44.7 (0.7) | | | | |
| PROMIS pain intensity T-score | | | | | | | | | |
| 0 | 208 | 46.9 (0.7) | NA | 205 | 45.1 (0.7) | NA | NA | NA | NA |
| 8 | 115 | 45.5 (0.9) | −1.3 (0.7) | 142 | 46 (0.8) | 1.5 (0.6) | −2.8 (0.9) | .003 | −0.26 (−0.43 to −0.09) |
| 16 | 119 | 45.8 (0.9) | | 122 | 47.4 (0.9) | | | | |
| PROMIS pain interference T-score | | | | | | | | | |
| 0 | 208 | 55.5 (0.8) | NA | 203 | 54.6 (0.8) | NA | NA | NA | NA |
| 8 | 115 | 55.2 (0.9) | −0.7 (0.8) | 142 | 54.8 (0.9) | 1.5 (0.7) | −2.3 (1.0) | .03 | −0.21 (−0.40 to −0.02) |
| 16 | 119 | 54.3 (0.9) | | 122 | 57.7 (0.9) | | | | |

Abbreviations: NA, not applicable; PROMIS, Patient Reported Outcomes Measurement System.

[a] Intervention minus usual care group; change = mean of 8 and 16 weeks combined minus baseline; *P* values from time by group interaction term in longitudinal models; *d* = mean difference in change from baseline divided by baseline pooled SD.

Table 4. Secondary Outcomes: Resource Use From Baseline to 16 Weeks (Intervention vs Usual Care)

| No. of weeks after baseline | Intervention group | | | Usual care group | | | Mean ratio: intervention vs usual care | |
|---|---|---|---|---|---|---|---|---|
| | No. | Mean (95% CI) | Combined mean (95% CI) | No. | Mean (95% CI) | Combined mean (95% CI) | Estimate (95% CI) | *P* value |
| **Days in hospital, last 2 mo** | | | | | | | | |
| 0 | 208 | 2.59 (1.64-4.07) | NA | 206 | 2.75 (1.74-4.34) | NA | 0.94 (0.49-1.80) | .85 |
| 8 | 118 | 1.77 (0.96-3.26) | 1.64 (1.06-2.53) | 139 | 0.74 (0.41-1.32) | 0.99 (0.65-1.52) | 1.65 (0.90-3.03) | .11 |
| 16 | 119 | 1.51 (0.82-2.77) | | 124 | 1.29 (0.71-2.38) | | | |
| **Emergency department visits, last 2 mo** | | | | | | | | |
| 0 | 208 | 0.30 (0.23-0.40) | NA | 206 | 0.28 (0.21-0.37) | NA | 1.10 (0.75-1.60) | .63 |
| 8 | 118 | 0.23 (0.16-0.34) | 0.20 (0.15-0.28) | 142 | 0.12 (0.08-0.19) | 0.15 (0.11-0.21) | 1.32 (0.86-2.01) | .21 |
| 16 | 119 | 0.17 (0.11-0.26) | | 125 | 0.19 (0.13-0.28) | | | |

Abbreviation: NA, not applicable.

palliative care consultation or some *Charting Your Course* sessions. An inadequate dose may explain the lack of QOL and mood effects—outcomes that were previously responsive to the intervention. We are currently conducting research and clinical evaluations of video rather than in-person consultation to increase accessibility to the palliative consultation.[60]

## Conclusions

Few palliative care programs exist in the southeastern United States and there has been limited attention to providing effective, guideline-concordant palliative care to underserved, rural, minority patients and their families.[35] This trial addressed this gap by using a nurse-led, telehealth model to bring culturally based palliative care to persons with HF who would not be able to access such care in their communities. Furthermore, this trial raises a key question about the likely influence of baseline QOL as a key element in determining which populations might show the greatest benefit from the scarce palliative care specialty resource. Future analyses and studies will examine both the patient factors and intervention components to find the right palliative care dose, for the right patient, at the right time.

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