PALLIATIVE CARE RESEARCH COOPERATIVE GROUP

PCRC De-identified Data Repository (DiDR) Study Summary

TITLE: **Patient-Centered Disease Management for Heart Failure Trial (PCDM)**		
PRINCIPLE INVESTIGATOR(S):	**John Rumsfeld, MD, PhD** **David Bekelman, MD, MPH**	SITE(S) (if applicable): **4 VA Medical Centers (Denver, Palo Alto, Richmond, and Seattle)**
COORDINATING SITE:	**VA Eastern Colorado Health Care System**	
STUDY PERIOD		
START:	**May 2009**	
LAST SUBJECT CONTACT:	**June 2012**	

OBJECTIVES:
To evaluate a Patient-Centered Disease Management (PCDM) intervention that includes case finding, collaborative care management for both CHF and comorbid depression, and home telemonitoring.

PARTICIPANTS		
	ENROLLMENT	ELIGIBILITY CRITERIA
Patients:	**392**	**Inclusion:** • **Diagnosis of Chronic Heart Failure** • **Low health status** • **18 years or older** • **Assigned VA primary care physician with at least one primary care visit in the 12 months prior to study enrollment** **Exclusion:** • **Cognitive impairment** • **Nursing home resident** • **Irreversible non-cardiac medical condition likely to affect 6-month survival or ability to execute protocol** • **Prior heart transplant** • **Alcohol abuse**
Informal Caregivers:	**n/a**	**n/a**
Health Care Providers:	**n/a**	**n/a**

METHODOLOGY:
A multi-site randomized study

INTERVENTION (if applicable):
The PCDM intervention will include evaluation of CHF care by the collaborative care team, with diagnostic and therapeutic treatment recommendations based on current ACC/AHA national clinical practice guidelines, daily telemonitoring and patient self-care support utilizing the VA telemonitoring system, and screening and treatment for comorbid depression. The Collaborative Care (CC) team at each site will consist of a primary care provider, cardiologist, and psychiatrist, who are local opinion leaders, as well as a nurse site coordinator and pharmacist. For a given intervention patient, there will be an initial assessment of care by the CC team following the enrollment visit. Each intervention patient will be re-reviewed by the CC team a minimum of 2 additional times (at 6-weeks and 6 months). In addition, patients will have daily telemonitoring, and their care will be reviewed by the CC team if the telemonitoring data suggests clinical deterioration.

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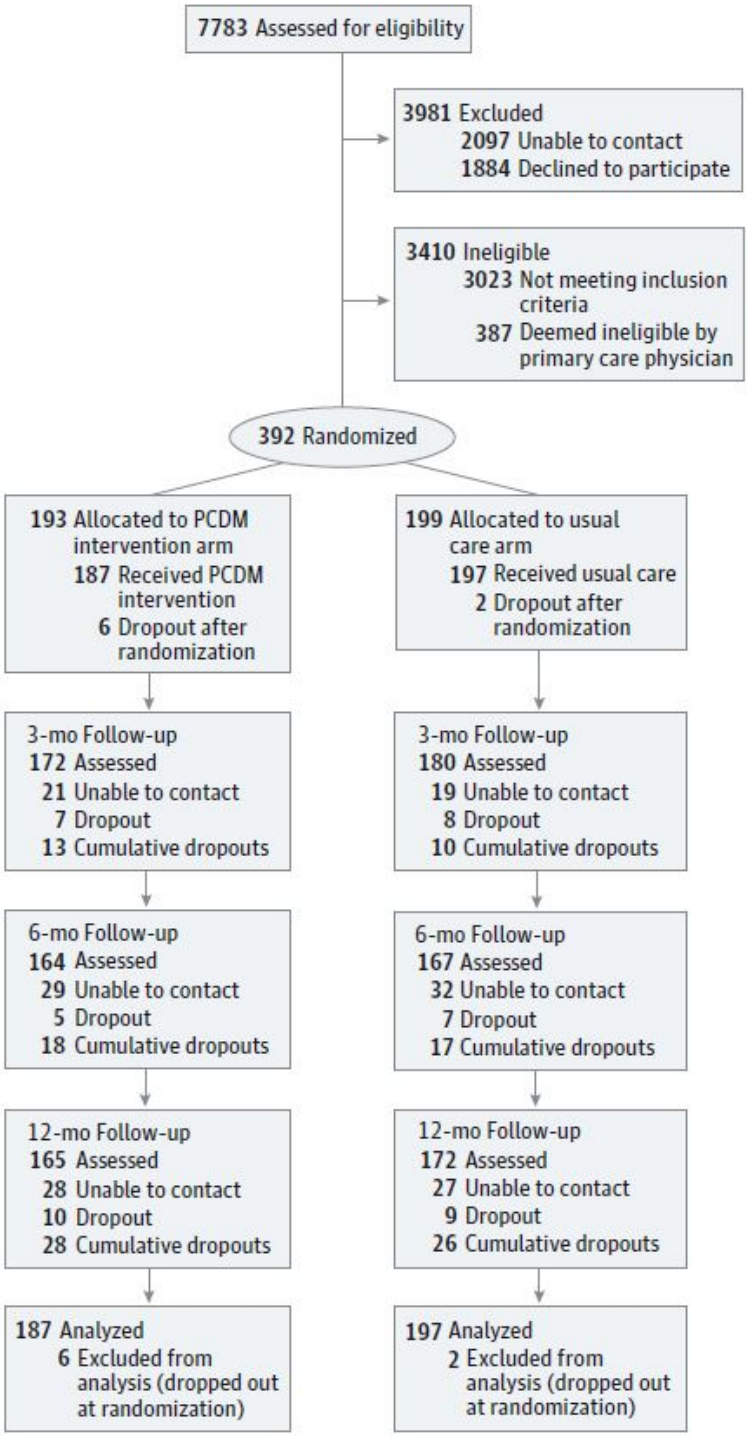
MEASURES:

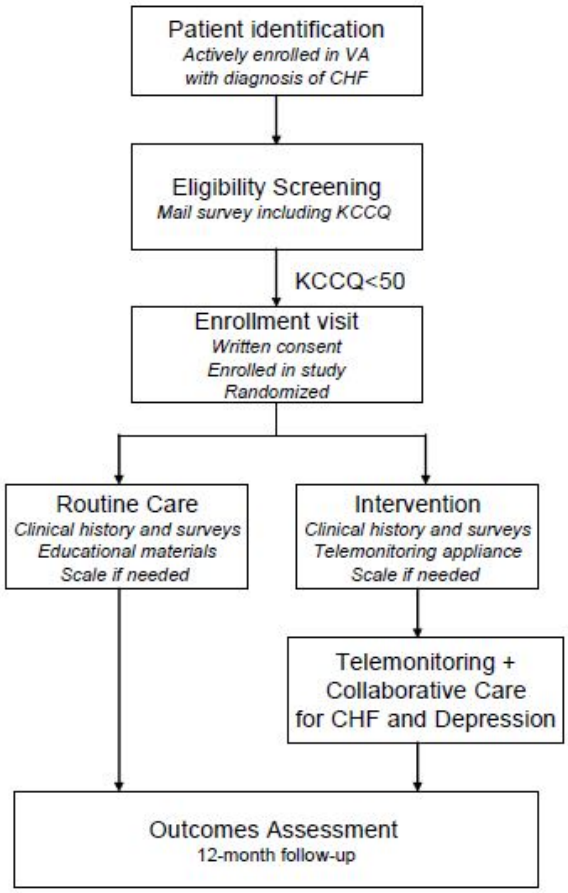
- **Chronic Heart Failure Health Status, by the Kansas City Cardiomyopathy Questionnaire (KCCQ)**
- **Depression, by Patient Health Questionnaire (PHQ-9)**
- **Anxiety, by Generalized Anxiety Disorder survey (GAD-7)**
- **Signs and symptoms survey**

SUBJECT FLOW (CONSORT):



PCRC De-identified Data Repository (DiDR) Study Summary

STUDY CALENDAR:



BASELINE CHARACTERISTICS (TABLE 1)

Table 1. Baseline Characteristics of 384 Participants Enrolled in the Patient-Centered Heart Failure Trial[a]

Characteristic	Intervention Arm (n = 187)	Usual Care Arm (n = 197)
Demographics		
Age, mean (SD), y	67.3 (9.6)	67.9 (10.6)
Male sex, No. (%)	178 (95.2)	193 (98.0)
White race/ethnicity, No. (%)	149 (79.7)	165 (83.8)
Medical History, No. (%)		
Myocardial infarction	71 (38.0)	85 (43.1)
Percutaneous coronary intervention	31 (16.6)	48 (24.4)
Coronary artery bypass graft	44 (23.5)	64 (32.5)
Atrial fibrillation	73 (39.0)	70 (35.5)
Implantable cardiac defibrillator	37 (19.8)	42 (21.3)
Biventricular pacemaker	7 (3.7)	14 (7.1)
Other pacemaker	21 (11.2)	26 (13.2)
Diabetes mellitus	99 (52.9)	93 (47.2)
Hypertension	158 (84.5)	159 (80.7)
Chronic obstructive pulmonary disease	57 (30.5)	59 (29.9)
Obstructive sleep apnea	85 (45.5)	83 (42.1)
Peripheral vascular disease	22 (11.8)	26 (13.2)
Heart Failure Characteristics		
Nonischemic etiology, No. (%)	97 (51.9)	96 (48.7)
Left ventricular ejection fraction, No. (%)[b]		
Normal	78 (45.6)	84 (47.5)
Mildly reduced	34 (19.9)	34 (19.2)
Moderately reduced	46 (26.9)	32 (18.1)
Severely reduced	13 (7.6)	27 (15.3)
New York Heart Association classification, No. (%)[c]		
1	16 (8.9)	16 (8.5)
2	77 (42.8)	85 (45.0)
3	82 (45.6)	82 (43.4)
4	5 (2.8)	6 (3.2)
6-min Walk, median (IQR), yd	765 (510-1125)	822 (356-1140)
Medications, No. (%)		
Angiotensin-converting enzyme inhibitor or angiotensin receptor blocker	122 (65.2)	117 (59.4)
β-Blocker	132 (70.6)	129 (65.5)
Eplerenone	5 (2.7)	5 (2.5)
Spironolactone	49 (26.2)	46 (23.4)
Health Status and Depression		
Kansas City Cardiomyopathy Questionnaire score, mean (SD)	37.9 (13.3)	36.9 (14.6)
Positive depression screen, No. (%)	78 (41.7)	77 (39.1)
Patient Health Questionnaire 9 score, median (IQR)	9 (4-13)	8 (4-11)

Abbreviation: IQR, interquartile range.

[a] There were no statistically significant differences between groups at baseline.

[b] Left ventricular ejection fraction was available for only 177 usual care patients and 171 intervention patients. Normal is at least 50%, mildly reduced is 40% to 49%, moderately reduced is 30% to 39%, and severely reduced is less than 30%.

[c] New York Heart Association classification was available for only 189 usual care patients and 180 intervention patients.

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PCRC STANDARDIZED DATA ELEMENTS

Please see the separate information sheet "DISC Standardized Data Elements" for the exact wording and format of the data elements.

DATA ELEMENT	Collected?	Var Name(s)	Data source (e.g. self-report, EHR) or reason not applicable
1. Site ID (if multi-site)	☐		
2. Who is the research participant? (e.g., patient, caregiver, etc.)	☐		only patients enrolled
3. Sex	☒	gender	EHR
4. Ethnicity	☒	CRF_ETH	EHR
5. Race	☒	CRF_RAWH, CRF_RABL, CRF_RARAAS, CRF_RAAI, CRF_RAOT	EHR
6. Age in years	☒	age	EHR
7. Current Marital Status	☐		
8. Primary life-limiting diagnosis/illness	☒		heart failure as eligibility criteria
9. Performance status (AKPS)	☐		
10. Enrolled in Hospice	☐		
a. If yes to hospice, where is hospice care provided?	☐		
11. Receiving Palliative Care (PC)?	☐		
a. If yes to receiving PC, where is PC provided?	☐		
12. Source of Death information	☐		
13. Location of Death	☐		
14. Enrolled in Hospice at time of death?	☐		
15. Receiving PC at time of death?	☐		

Cells in blue only need to be collected for patient research participants. Cells in orange should be collected regardless of participant type.

PATIENT-REPORTED OUTCOME INSTRUMENTS

CONTENT *(e.g., PS)*	ABBREV *(e.g., AKPS)*	INSTRUMENT NAME *(e.g., Australian Modified Karnofsky Performance Status)*
Health Status	KCCQ	Kansas City Cardiomyopathy Questionnaire
Depression	PHQ-9	Patient Health Questionnaire (9 item)
Anxiety	GAD-7	Generalized Anxiety Disorder survey (7 item)
Symptoms	SS	Signs and Symptoms