Heart Failure Care Management Programs A Review of Study Interventions and Meta-Analysis of Outcomes

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Background: The objective of this systematic review and meta-analysis was to describe and quantify individual interventions used in multicomponent outpatient heart failure management programs. Methods: MEDLINE, CINAHL, and the Cochrane Central Register of Controlled Trials between 1995 and 2008 were searched using 10 search terms. Randomized controlled trials evaluating outpatient programs that addressed comprehensive care to decrease readmissions for patients with heart failure were identified. Forty-three articles reporting on 35 studies that reported readmissions separately from other outcomes were included. Three investigators independently abstracted primary study characteristics and outcomes. Results: In the 35 studies, participants included 8071 subjects who were typically older (mean [SD] age, 70.7 [6.5] years) and male (59%). Using our coding scheme, the number of individual interventions within a program ranged from 1 to 7 within individual studies; the most commonly used interventions were patient education, symptom monitoring by study staff, symptom monitoring by patients, and medication adherence strategies. Most programs had a teaching component with a mean (SD) of 6.4 (3.9) individual topics covered; frequent teaching topics were symptom recognition and management, medication review, and self-monitoring. Fewer than half of the 35 studies reviewed reported adequate data to be included in the meta-analysis. Some outcomes were infrequently reported, limiting statistical power to detect treatment effects. Conclusion: A number of studies evaluating multicomponent HF management programs have found positive effects on important patient outcomes. The contribution of the individual interventions included in the multicomponent program on patient outcomes remains unclear. Future studies of chronic disease interventions must include descriptions of recommended key program components to identify critical program components.

KEY WORDS: heart failure, meta-analysis, randomized controlled trials

Chronic heart failure (HF) is 1 of the most common reasons for hospitalization in patients aged 65 years and older. However, many hospitalizations

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This study is funded in part by the Department of Veterans Affairs Health Services Research and Development Center for Comprehensive Access and Delivery Research and Evaluation, Iowa City VA Medical Center, Iowa.

The authors have no conflicts of interest to disclose.

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DOI: 10.1097/JCN.0b013e318239f9e1

for HF are potentially preventable² if the warning signs of decompensation are recognized and treated before the situation becomes emergent.³ Heart failure is a prevalent and costly disease with significant effects on quality of life. Successful management of HF is complex and requires ongoing monitoring on the part of clinicians, as well as education of patient and family regarding appropriate medication use, adherence to dietary and physical activity guidelines, self-monitoring, and symptom management.⁴ Effective outpatient HF programs may improve clinical outcomes and reduce hospital readmissions by making better use of outpatient resources.

Multicomponent outpatient HF management programs have been the focus of numerous studies. More recently, these types of interventions have been referred to as "bundled" interventions. Bundled interventions combine several individual interventions that are implemented simultaneously. Probably the most widely recognized types of bundled interventions are sepsis bundles intended to prevent hospital-acquired infections. ⁵ Bundled interventions, such as multicomponent

outpatient HF management programs, are used when complex problems are treated. However, determining the active ingredient of the bundle is challenging⁷ particularly when different bundles are created and tested.

Despite the proliferation of studies testing multicomponent outpatient HF management programs, no previous quantitative synthesis has examined individual interventions comprising these programs or the effective combination of these individual interventions needed to improve outcomes. Thus, the primary purpose of this study was to describe and quantify individual interventions used in multicomponent outpatient HF management programs. We used meta-analysis to assess the effects of the multicomponent programs on outcomes of readmissions, emergency department (ED) visits, clinic/physician office use, reported costs, mortality, HF-specific and generic quality of life (QOL), satisfaction with care, mood, adherence, knowledge, self-efficacy, and symptom management.

Methods

We conducted a comprehensive computerized search of MEDLINE, CINAHL, and the Cochrane Central Register of Controlled Trials using 10 search terms for English language articles published between 1995 when the Rich et al⁸ seminal study was published and 2008 (see Figure). The reference lists from previously published meta-analyses and narrative reviews were hand searched for additional articles. In an attempt to include higher quality studies, study inclusion was limited to randomized controlled trials comparing intervention and control subjects. Studies that evaluated multicomponent outpatient disease management programs where multiple interventions were used to systematically manage HF⁹ to decrease readmissions for patients with HF were included. We excluded studies that focused only on 1 aspect of HF care (eg, solely on pharmacist/medication interventions), delivered an intervention in the control group beyond attention control, or did not focus on patient outcomes (eg, studies focused on changing staff behavior as the only outcome). Only studies that reported readmissions separately from other outcomes were included, that is, studies that reported only a combined endpoint of mortality and readmission were excluded. Studies were not excluded based on sample size (ie, there was no minimum number of subjects required to be included). Although small studies lack statistical power to detect treatment effects, they can contribute to meta-analysis findings. A full review of potentially eligible studies ensured both that they met the inclusion and exclusion criteria and that the study methodology and findings were reported in sufficient detail to describe and evaluate in the current review.

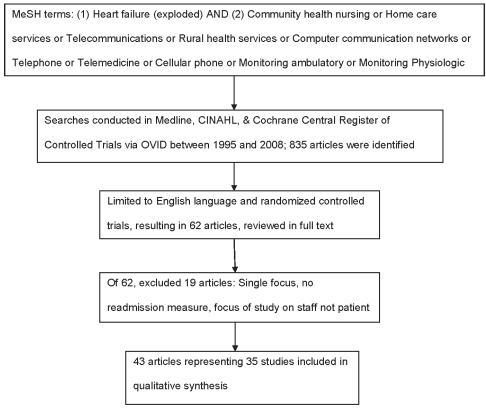


FIGURE. Outline of search.

Data Abstraction

A coding frame to extract primary study characteristics (eg, report features, descriptions of samples, methodological features) and outcomes was developed from 1 author's (VC) previous experience with meta-analysis, 10 published meta-analyses on similar topics, narrative review articles addressing HF outpatient management programs, intervention components reported in the literature, and the authors' previous research in HF. 11-13 Within this coding frame, year of publication, number of publications reporting separate findings for an individual study, and study funding were coded as report features. Gender, age, ethnicity, and HF severity measures (New York Heart Association [NYHA] classification, left ventricular ejection fraction [LVEF]) were coded from descriptions of samples. Methodological features included individual specific interventions delivered within the disease management program; control group management (attention control vs true control group description); intervention target (individual with HF, informal caregivers); intervention delivery mode (eg, face to face, telemonitoring); recruitment site; whether patient education was delivered and, if so, specific topics covered; settings (hospital component, clinic/physician office, patient homes); personnel involved in the intervention; and outcome measures (readmissions, ED visits, clinic/physician office use, costs, mortality, HF-specific and generic quality of life, satisfaction with care, mood, adherence, knowledge, selfefficacy, and symptom management). Outcome data coded included baseline and outcome sample sizes, means, measures of variability, and P values from t tests or χ^2 statistics.

To establish intercoder agreement, 5 studies were coded and discussed among 3 reviewers to reach agreement on coding. All studies were coded independently by 2 reviewers and then discussed to reach 100% agreement on coding. The primary author (BJW) coded all studies with 2 coauthors (SAB, PSG), each coding half of the studies. Coded data were double-entered and checked for accuracy. Ancillary reports—additional publications about the same subjects in the same study—were used to enhance coding completion.

Data Analysis

Descriptive statistics were used to describe the reports, methodological features, and nature and frequency of specific interventions used in the programs. For the meta-analysis, a standardized mean difference (*d*) effect size (ES) was calculated (an odds ratio was calculated for mortality, all other ES are *d* ES). A *d* ES is calculated from the difference between the treatment and control groups at outcome assessment divided by the pooled standard deviation. This creates a unitless data point, which can be aggregated across studies

using diverse measures for the same construct. Confidence intervals were constructed to provide a range of possible values, which denotes the uncertainty around the point estimate of the ES. Effect sizes were weighted by the inverse of the variance to give larger sample studies more influence. ¹⁴ Random-effects models were used to acknowledge that ESs vary both because of subject-level sampling error and because of other sources of study-level error such as variations in samples or interventions. ¹⁵ Effect sizes were adjusted for bias.

A conventional homogeneity statistic (Q) was used to address between-study heterogeneity. Q is distributed approximately as χ^2 on k-1 df, where k is the number of observed ESs. Both clinical and statistical heterogeneity is common in health behavior change research. 10,16 Heterogeneity is typical in studies, such as interventions to improve HF outcomes, because of differences in sample characteristics, disease variations, diverse intervention content, varied interventionist characteristics, variable intervention dose, nonidentical study measures, and variable study implementation and quality. Heterogeneity was expected and handled in 3 ways: (a) random-effects models were used because they take into account unexplained heterogeneity; (b) heterogeneity was quantified, along with the location parameter; and (c) discovered heterogeneity was included in the interpretation of findings.

Results

Comprehensive searches resulted in 43 published journal articles representing 35 studies (Table 1). The results for 6 studies were published in more than 1 article. We used data from all publications to assess each study. Most (n = 32; 91.4%) of the studies had some funding support.

Sample Description

Across the 35 studies, participants included 8071 subjects who were typically older (mean [SD] age, 70.7 [6.5] years) and male (59%). Ethnicity/race was reported in 37% (n = 13) of studies, mostly those conducted in the United States. In the 13 studies reporting ethnicity/race, 58.8% of participants were white and 34.2% of participants were African American. Slightly more than half (51%; n = 18) of the studies were conducted outside of the United States, primarily in Europe and Australia. About one-fourth were conducted in US academic medical centers (25.7%; n = 9). Many studies reported NYHA classification levels (n = 23; 66%) and LVEF (n = 21; 60%), although almost none classified participants as having systolic or diastolic dysfunction. Most participants were recruited while in the hospital (n = 27; 77%), and 46% of the studies (n = 16) also provided some interventions while the

MARIE II Summary of Studies	of Studies								
Study (Year)	Treatment, n	Control, Mean n Age	Mean Age	%Men	Caregiver Delivery Included Mode		Intervention Length, in days	Interventions	Outcomes ^a
Benatar et al (2003) ¹⁷	108	108	63	37	No	4	06	Education, symptom monitoring by staff and patient	QOL, HF QOL, MOOD,
Blue et al (2001) ¹⁸	84	81	75	28	No	1,3,8	365	Education, guideline concordant care	MORT
Capomolla et al (2002) ¹⁹	112	122	99	84	No	1,2	365	Education, guideline concordant care, exercise recommendation	QOL, MORT
Cleland et al (2005) ²⁰	168	85	29	81	No	4,7,8	240	Education, symptom monitoring by staff	MORT
Cline et al (1998) ²¹	80	110	9/	53	Yes	1,2,8	240	Education, symptom monitoring by patient,	OFF, QOL, HF QOL,
;								problem solving	MORT, COST
Dansky et al (2008)	127	112	77 N	Not reported	No	4	09	Symptom monitoring by staff and patient	ED, MORT
DeBusk et al (2004) ²³	228	234	72	51	No	1,7	365	Education, symptom monitoring by staff,	ED, MORT
DeWalt et al (2006) ²⁴	62	9	63	49	No	1,2,7	180	Education, symptom monitoring by patient,	HF QOL, MORT,
į								fluid management, problem solving	KNOW, SE
Doughty et al (2002) ²⁵	197	97	73	09	Yes	1,2,8	180	Education, symptom monitoring by patient, quideline concordant care,	hf qol, mort
								problem solving	
Dunagan et al (2005) ²⁶	92	75	70	44	No	7,8	365	Education, symptom monitoring by staff,	QOL, HF QOL, MORT,
77 (1000)27	C C	7	C	C	(7	0	diet, guideline concordant care	MOOD, SAT
בצווומוו פר מו (דששס)	5	6/	0	00	0	0,7,2,1	00	education, symptom morning by start and patient, medication management,	Z O S
000								goal setting, problem solving	
Goldberg et al (2003)²8	138	142	29	89	No	1,4,6	180	Education, symptom monitoring by staff and patient	QOL, HF QOL, MORT
Grancelli et al (2003) ²⁹	760	758	65	71	No	7	488	Education, symptom monitoring by staff	HF QOL, MOOD
								and patient	
Harrison et al $(2002)^{30}$	26	103	9/	52	No	1,3,8	14	Education	QOL, HF QOL
Jaarsma et al (1999) عَا	84	92	73	28	Yes	1,3,8	10	Education	ED, MORT
Jaarsma et al (2008) ³²	344	339	71	62	<u>8</u> :	1,3,7,8	549	Education, sodium restriction	MORT
Jerant et al (2003, 2001) 2,34		17	0/	84	No	1,3,5,8	09	Education, symptom monitoring by staff,	ED, QOL, HF QOL, ADH,
Kashem et al (2006) ³⁵	24	24	54	74	No	4,6,8	365	medication management, goal setting Symptom monitoring by staff and patient,	SAI, COSI ED, OFF, MORT
98/0000/ 1- + //	,	Ċ	(Ç		, , ,	6	guideline concordant care	F000 F1
Nasper et al (2002)	701	y S	70	00	0	8,1,5,1,8	081	restriction exercise recommendation	HF QUE, MIUKI, CUSI
Krumholz et al (2002) ³⁷	4	44	74	57	No	1,2,3,7	365	Education, symptom monitoring by patient	MORT, COST
Kwok et al (2008) ³⁸	49	26	78	45	No	1,3,7,8	180	Education, symptom monitoring by staff, medication management sodium	MORT, MOOD, COST
								restriction, diet, exercise recommendation	
Laramee et al (2003) ³⁹	141	146	71	54	Yes	1,7,8	06	Education, symptom monitoring by staff and patient, sodium restriction,	MORT, ADH, SAT, COST
								problem solving	

INTERPOLE SUMMARY OF STUDIES, CONTINUED	or studies,	continu	e d						
Study (Year)	Treatment, Control, Mean n Age	Control, n	Mean Age	%Men	Caregiver Delivery Included Mode	Delivery Mode	Intervention Length, in days	Interventions	Outcomes ^a
Ledwidge et al (2003), ⁴⁰ McDonald et al (2002) ⁴¹	51	47	71	99	Yes	1,2,7,8	06	Education, symptom monitoring by staff and patient, quideline concordant care	MORT, KNOW, COST
Naylor et al (2004) ⁴²	118	121	92	43	Yes	1,3,8	06	Education, symptom monitoring by staff and patient, goal setting, problem solving	ED, OFF, HF QOL, MORT, SAT, COST
Nucifora et al (2006) ⁴³	66	101	73	62	No	1,2,8	180	Education	OFF, HF QOL, MORT, ADH
Rich et al (1995), ⁸ Rich et al (1993) ⁴⁴	142	140	79	37	Yes	1,3,7,8	09	Education, symptom monitoring by staff and patient, medication management, fluid management, diet	HF QOL, MORT, COST
Riegel et al (2006) ⁴⁵	70	65	72	46	Yes	7	180	Education, symptom monitoring by staff, medication management	QOL, HF QOL, MORT, MOOD, COST
Riegel et al (2002) ⁴⁶	130	228	72	49	Yes	7	180	Education, symptom monitoring by staff, medication management	ED, OFF, MORT, SAT, COST
Schwarz et al (2008) ⁴⁷	51	21	78	48	Yes	4,6	06	Symptom monitoring by staff and patient	ED, HF QOL, MORT, MOOD, COST
Stromberg et al (2003) ⁴⁸	52	54	78	61	Yes	1,2,8		Education, social support	MORT
Stewart and Horowitz (2002a, 2002b), ^{49.50} Stewart et al (1999, 1998, 1999) ^{51–53}	149	148	75	29	Yes	1,3,7,8	180	Education, symptom monitoring by patient, medication management, fluid management, exercise recommendation	MORT, COST
Thompson et al (2005) ⁵⁴	28	48	72	72	Yes	1,2,3,8	180	Education, symptom monitoring by staff, fluid management	QOL, HF QOL, MORT
Tsuyuki et al (2004) ⁵⁵	140	136	72	28	ON N	1,7,8	180	Education, symptom monitoring by patient, medication management, fluid management, sodium restriction, guideline concordant care, exercise recommendation	MORT, COST
Wakefield et al (2009, 2008) ^{12,56}	52	49	69	66	N O	2,8	06	Education, symptom monitoring by staff and patient, medication management, fluid management, sodium restriction, diet	HF QOL, MORT, ADH, KNOW, SE, SAT
Woodend et al (2008) ⁵⁷	62	29	29	72	No	4,5,8	06	Symptom monitoring by staff and patient	QOL, HF QOL
	:		-		-			-	

Delivery mode: 1 = face to face, 2 = clinic/MD office visits, 3 = home visits, 4 = remote vital signs monitoring, 5 = remote videophone, 6 = remote messaging, 7 = scheduled telephone calls, 8 = telephone availability of staff (unscheduled).

Outcomes measured: ADH, adherence; COST, costs; ED, emergency department visits; SE, self-efficacy; KNOW, knowledge; OFF, office visits; HF QOL, heart failure—specific quality of life measure; SAT, satisfaction; SYMPT, symptoms.

ADRT, mortality; QOL, generic quality of life measure; SAT, satisfaction; SYMPT, symptoms.

All studies measured readmission as an outcome.

patient was in the hospital before discharge. The mean (SD) planned intervention period was 204 (135) days, with a range of 10 days to more than 1 year. The most common intervention period was 180 days (n = 12 studies; 34%) followed by 90 days (n = 7; 20%) and 365 days (n = 6; 17%).

Intervention Features

To describe the content and frequency of specific interventions used in multicomponent outpatient HF management programs, data were extracted on specific study interventions used within the program (Table 2). We assessed studies for data on 14 individual interventions; the number of specific interventions described in a study ranged from 1 to 7 within individual studies, with a mean (SD) of 3.4 (1.6) interventions delivered across studies. The most common intervention was patient education (n = 31; 89%) followed by symptom monitoring by study staff (n = 21; 60%), symptom monitoring by patients (n = 19; 54%), medication adherence strategies (n = 10; 29%), and guideline concordant care established at study enrollment (n = 8; 23%), that is, use of recommended medications for HF. Table 2 shows which studies delivered each intervention; sleep enhancement and contracting were included in the coding scheme, but none of the reviewed studies included these interventions. Scales to monitor weight at home were provided to participants in some studies $(n = 12; 3\overline{4}\%)^{8,12,17,20,24,26,28,35,36,39,44,47,56,57}$; a blood pressure cuff^{12,17,20,35,56,57} and medication organizer^{21,36,39,49–52,55} were provided in 5 (14%) studies. Care provided for the usual care/control group patients was typically only briefly described (n = 15; 43%)^{8,17,20,23,28,30,35,39}–42,44–46,48–52,54 or not described at all; 3 studies^{17,28,34} used an attention control group, consisting of home visits,^{17,34} specific instructions for follow-up care, ²⁸ and use of a weight log. ²⁸

All interventions were targeted at individual patients (there were no group approaches used in these studies), and only slightly more than one-third (n = 13; 37%) included the patient's informal caregiver in the intervention, primarily teaching both patients and caregivers about HF by including them in study training. The most common intervention mode was face-to-face interaction (n = 24; 69%; typically these were inhospital study visits or visits to the clinic/physician's office for study related care), followed by use of scheduled telephone contacts (n = 17; 49% of studies), and home visits (n = 10; 29%), and these communication modes were often used in combination. Telehealth approaches varied from remote monitoring of vital signs only (n = 7; 20%), devices that both monitored vital signs and delivered content through use of a messaging device (n = 5; 14%), and use of interactive videophones (n = 3; 9%). Only 11 (31%) studies included physician office visits in the study design. Many studies provided telephone availability of clinical study staff, that is, patients could call study staff with questions about their care (n = 24; 69%; see Table 1).

Patient Education

About half (n = 19; 54%) of the studies identified specific teaching content. $^{8,21,23,25-28,30,31,33,34,37,39-41}$, $^{43-45,48-52,54,55}$ We assessed studies for data on 33 education topics; of the 31 studies that provided patient education, the number of specific topics in a study ranged from 1 to 16 within individual studies, with a mean (SD) of 6.4 (3.9) topics covered. When specific topics were identified, the most common teaching topics were symptom recognition and management (n = 22; 63%) and medication review (n = 19; 54%; Table 3). Fewer than 20% of studies included teaching on the following topics (data not shown in table): weight management, management of dyspnea and fatigue, coping skills, alcohol intake, tobacco cessation, and adjusting diuretic dose. Importantly, none of the studies provided teaching content about recognizing and/or managing mood disturbances, although depression and

Individual Interventions Included in Multicomponent Heart Failure Management Programs

Intervention	No. of Studies ^a (%), $n = 35$
Patient education ^{8,12,17–21,23–34,36,37,39–45,47–50,52–57}	31 (89)
Symptom monitoring by staff ^{8,12,17,20,22,23,26–29,33–35,38–42,44–47,54,56,57}	21 (60)
Symptom monitoring by patient ^{8,12,17,21,22,24,25,27} –29,35,37,39,40–42,44,47,49,50,52,53,55–57	19 (54)
Medication management (adherence) ^{8,12,27,33,34,36,38,44} –46,49,50,52,53,55,56	10 (28)
Guideline concordant medicines at baseline 18,19,23,25,26,35,40,41,55	8 (23)
Fluid management (adherence) ^{8,12,24,44,49,50,52–56}	6 (17)
Sodium restriction (adherence) ^{12,32,36,38,39,55,56}	6 (17)
Problem solving ^{21,24,25,27,39,42}	6 (17)
Exercise recommendation ^{19,36,38,49,50,52,53,55}	5 (14)
Diet adherence ^{8,12,26,38,44,56}	4 (11)
Goal setting ^{27,33,34,42}	3 (9)
Social support ⁴⁸	1 (3)

a Note: some studies were reported in multiple publications; all publications reporting the study are included here; thus, there may be a greater number of referenced studies than is reflected in the column.

TABLE 3 Teaching Topics Included in Heart Failure Management Programs	
Teaching Topic	No. of Studies (%), n = 35
Symptom recognition and management 17,18,20,21,24–29,31,33,34,37,39,40,41,43,45,46,48–50,52–55	22 (63)
Medication review ^{8,17–21,23,25,29,3} 0,33,34,36,37,39–41,44,48–50,52–55	19 (54)
Self monitoring and adherence 12,18,19,21,23,25,29,31,37–39,42,43,45,48–50,52–56	18 (51)
Diagnosis 18,19,21,26,29,31,33,34,37,39–41,43,48–50,52–55	15 (43)
Diet 8,12,18,19,23,25,27–30,33,34,36,39,44,46,56	14 (40)
Daily weight measurement 12,19-21,24,25,28,29,33,34,39,40,41,43,55,56	13 (37)
Physical activity 18,19,25,29,30,33,34,36,39,43,55	10 (29)
Sodium restriction 12,28,29,31,33,34,36,40,41,43,48,55,56	10 (29)
Fluid balance 19,28,29,31,39–41,43,46,48,55	10 (29)
How to access a physician/knowing when to call ^{25,27,29,31,32,37,39–41,55}	9 (26)
Social interaction and support ^{8,18,30,31,39,44,48–50,52–54}	8 (23)
Follow up care advice ^{8,18,23,25,29,33,34,44,49,50,52,53}	7 (20)
Aims of treatment ^{8,18,26,43,44,48,55}	6 (17)

anxiety are common in people with HF. 58,59 More than half (n = 22; 62.9%) of studies provided printed information to participants, for example, printed teaching materials. $^{8,18,21-27,29-32,36,37,39,42-46,48,55}$

Personnel

Almost all of the interventions were primarily delivered by a registered nurse (n = 29; 83%) 8,12,17,18,20 , $^{22,23,26,27,29-35,37-52,54,56,57}$; many of these were advanced practice nurses or nurses who were considered specialists for HF patients. Physicians were rarely directly involved in intervention delivery (5 studies included a cardiologist 8,17,35,38,43,44,48 and 3 studies included a primary care physician 24,38,43 in the intervention delivery). Furthermore, information about patient progress during the study was sent to physicians in fewer than half of the studies (study staff sent information to primary care physicians in 49% [n = 17] of the studies $^{12,20,23-27,33,34,36,38,39,42,43,45-47}$, $^{49-52,56}$ and to cardiologists in 37% [n = 13] of the studies $^{18,19,21,28,29,35,36,38,39,42,47-52}$; information was

sent to both the primary care provider and the cardiologist in some studies).

Meta-analysis Results: Overall Effects of Interventions on Outcomes

The number of studies that reported adequate data on outcomes to calculate an effect size is shown in Table 4. Positive ESs in Table 4 indicate better outcomes for treatment subjects than control subjects. Confidence intervals reported in Table 4 provide a range of possible values that denotes the uncertainty around the point estimate of the ES. All ESs, except adherence, were positive (the adherence ES is extremely small). Mortality rates were lower for treatment subjects (21 of 30 studies reported lower rates for treatment subjects) than for control subjects. Readmission rates were significantly lower in treatment subjects than control subjects (ES = 0.157, P < .001). Heart failure–specific quality of life was significantly better in treatment than control subjects after interventions (ES = 0.231, P = .007). Cost was significantly lower among treatment

TABLE 4 Random Effects Outcome E	stim	ates and	Tests				
Outcome Variable	k	Effect Size ^a	P (ES)	95% Confidence Interval	Standard Error	Q	P (Q)
Mortality ^{a,8,12,18–21,23–50,52–56}	30	1.27 ^a	.112	1.085, 1.487	_	38.504	.112
Readmissions ^{8,12,21,22,27,28,33–35,43–48,54,56}	14	0.157	<.001	0.071, 0.244	0.044	13.563	.405
QOL HF-specific ^{8,12,17,21,28–30,33,34,36,43–45,47,56}	12	0.231	.007	0.064, 0.399	0.086	43.05	<.001
ED visits ^{22,23,30,31,33} –35,42,46,47,55	10	0.123	.254	-0.089, 0.335	0.108	38.313	<.001
Cost ^{8,26,33,34,37,42,44–47}	8	0.17	.008	0.045, 0.296	0.064	8.847	.264
Satisfaction 12,33,34,39,42,46,56	5	0.338	.003	0.118, 0.558	0.112	8.167	.086
Clinic visits ^{21,31,42,43,46}	5	0.148	.054	-0.002, 0.298	0.077	4.909	.297
QOL generic ^{17,19,21,45}	4	0.283	.14	-0.093, 0.659	0.192	18.68	<.001
Mood ^{17,26,45,47}	4	0.215	.145	-0074, 0.504	0.147	8.466	.037
Adherence ^{39,43,55}	3	-0.005	.951	-0.168, 0.158	0.083	1.028	.598
Knowledge ^{12,40,41,56}	2	0.759	.186	-0.367, 1.885	0.574	6.859	.009
Self-efficacy ^{12,17,56}	2	0.267	.723	-1.205, 1.738	0.751	25.302	<.001
Symptom management ^{22,24}	2	0.725	.137	-0.230, 1.680	0.487	9.715	.002

Abbreviations: ED, emergency department; HF, heart failure; k, number of comparisons; Q, standard heterogeneity statistic; QOL, quality of life. ^aES, effect size; reported as d except for mortality. For mortality, an odds ratio ES is reported.

subjects compared with control groups (ES = 0.17, P = .008). Treatment subjects reported significantly higher satisfaction with care than control subjects reported (ES = 0.338, P = .003). There were significantly fewer clinic/physician office visits with intervention (ES = 0.148, P = .05). Several outcomes resulted in positive ES that did not achieve statistical significance; power was very low for comparisons with small k.

Several ES outcomes were significantly heterogeneous (Q in Table 4): QOL HF-specific, ED visits, satisfaction, QOL generic, knowledge, self-efficacy, and symptoms. A random-effects model was used to account for the expected heterogeneity. Heterogeneity was expected given the variations in interventions, samples, and procedures. Another approach to exploring heterogeneity, continuous and dichotomous moderator analyses, was not conducted because few studies were retrieved with data for each outcome.

Discussion

The primary focus of this study was to describe the content and frequency of use of interventions contained in multicomponent outpatient HF management programs and to assess the effects of these interventions on patient outcomes. Using our coding scheme, the number of individual interventions within a program ranged from 1 to 7 within individual studies; the most commonly used interventions were patient education, symptom monitoring by study staff, symptom monitoring by patients, and medication adherence strategies. Most programs had a teaching component with a mean of 6.4 individual topics covered; frequent teaching topics were symptom recognition, medication review, and self-monitoring.

There are several systematic reviews and meta analyses of HF disease management programs. We reviewed these and found that earlier studies^{60–62} included far fewer studies than ours. In cross-checking studies included in these reviews, we found three more recent reviews that included a large number of the studies in our review, ranging from 22^{62,63} to 25 studies⁶⁴ of the same studies. These reviews included studies with mixed samples as well, that is, studies that included patients without HF in the sample. One study with a similar purpose to ours used different inclusion criteria, and only 15 of the 21 studies reviewed were included in our review. Although all concluded that HF disease management programs have a beneficial effect on rehospitalization and mortality, none of these reviews provided a detailed analysis of specific interventions or patient teaching topics as the review reported here. Thus, areas for improvement in future studies include detailed descriptions of the intervention, inclusion of evidence-based interventions, and outcome reporting.

Intervention Description

Disease management programs were not completely described in many research reports. Eight domains should be routinely reported to describe chronic disease management programs⁶⁵: (1) risk status, demographics, and comorbidities of the sample; (2) the primary targets of the program (patients, informal caregivers, clinicians, and/or systems of care); (3) individual components of the intervention, for example, patient education, medication management, postdischarge care; (4) who is involved in intervention delivery, both clinical and nonclinical staff; (5) method of communication, such as face to face, audiovisual, and/or electronic or telecommunication technology; (6) frequency of provision of the intervention delivery components, duration of the intervention, and the mix of program components for each intervention target; (7) locations where each intervention component is delivered, including the hospital, clinic, patient home, or community based; and (8) outcomes, including clinical, resource, and patient-centered measures, such as adherence. The intervention descriptions in most of the reviewed studies did not include detailed descriptions of all of these recommended components; others have also found descriptions of interventions in published reports lacking.66 Thus, it is difficult to examine the effects of specific intervention components on patient outcomes, for example, determining the minimum number, type, duration, and combination of specific intervention needed to improve outcomes. These factors should be routinely described so that programs can be compared for effectiveness across studies. 65 Most of the studies included in previous reviews, as well as the studies we reviewed, were published before availability or widespread use of online supplementary files in journal publications, which can now be used to provide more detailed descriptions of interventions.

Intervention Mode

Most of the programs reviewed here were delivered using traditional methods, that is, face-to-face, clinic and home visits, and telephone calls. Over the past several years, home-monitoring technologies are emerging to improve patient outcomes, and HF is a frequently targeted condition for home technology monitoring. A wide range of technologies can be used to facilitate ongoing communication between the person with HF, the informal caregiver, and the healthcare team. One type of technology, remote monitoring, enables a communication link between the patient's home and clinicians. These technologies use scripted content, usually a question-and-answer format addressing patient symptoms, behavior, and knowledge, and can include outcomes assessments to track patient's progress.

Use of home technologies is becoming widespread, yet development of content for the disease management program is often being driven by device manufacturers. The development of standardized evidence-based communication protocols is key to successful implementation of telehealth-based interventions that can be delivered by nurses. Detailed data are needed from studies such as the ones included in this review to develop and validate evidence-based content for HF homemonitoring technologies. Thus, future studies need to provide an adequate description of the interventions included in multicomponent programs.

Use of Evidence-Based Interventions

Self-management in HF is key because patients are responsible for most of their HF care. 4 Self-care includes medication taking, symptom monitoring, adhering to diet recommendations (especially sodium reduction), restricting fluid, limiting alcohol intake, losing weight, exercising, having preventive behaviors (immunizations, dental health), and judiciously using nonprescription medications.⁴ Unfortunately, only half (54%) of the studies reviewed included symptom monitoring by patients as an intervention component. Even fewer studies (29%) included medication adherence strategies, and fewer than 20% of studies addressed the remaining behaviors. Other than teaching patients about symptom recognition, self-monitoring, and daily weights, less than a third of the reviewed studies included teaching content on these self-care needs.

Only about a third of the reviewed studies included the patient's informal caregiver in the intervention, a component identified as critical in other reviews. A review of 16 articles published through 2003 examined the role of informal caregiving in HF.⁶⁷ These authors found that emotional distress (eg., depression) in HF caregivers was comparable to other chronic conditions known to increase caregiver stress; higher patient impairment was related to higher levels of caregiver burden. If spouses got help from others (family, friends, and healthcare professionals), appreciation from the patient, and opportunities for involvement in decision making about care, the caregiving experience was perceived more positively. A more recent review found that caregiver self-efficacy and problem-solving skills influence patient self-care and outcomes.⁶⁸ Thus, more attention needs to be focused on supporting informal caregivers in this population of patients.

None of these studies focused on system issues such as communication between physicians and nurses, medication reconciliation, or hand-offs between care settings. Sochalski et al⁶⁹ pooled data from 10 studies and found that team care and in-person communication are associated with lower resource use. Future studies need to address these important issues.

Outcome Reporting

Findings from the meta-analysis verify and expand current nursing knowledge regarding HF intervention programs. A subset of the programs included in this review significantly reduced admissions, clinic visits, and cost as well as improved HF-specific quality of life and satisfaction. Previous meta-analyses of similar studies also showed significant reductions in readmissions ranging from 21% to 32% as well as significant reductions in mortality. 60-62,70,71 Several ESs were significantly heterogeneous. The variety of intervention characteristics documented in the studies likely contributed to heterogeneity. Study procedures also varied considerably. Unfortunately, fewer than half of studies reviewed were included in the meta-analysis because they did not report adequate data to calculate ES. Some outcomes were infrequently reported, limiting statistical power to detect treatment effects. Future meta-analyses may be able to conduct moderator analyses to explore sources of heterogeneity, for example, the number and type of individual interventions delivered, in an effort to identify characteristics of interventions associated with better outcomes.

Limitations

Although valuable evidence regarding the effects of multicomponent outpatient HF management programs was gleaned from this review, the authors discovered limitations in the available literature. Fewer than half of the 35 studies reviewed reported adequate data to be included in the meta-analysis. These studies did not report sample size, means, and SD or SE for outcome variables and thus could not be converted to ES estimates. We had planned to conduct moderator analyses by type of individual intervention to provide evidence for practice about which interventions (or combination of interventions) in multicomponent programs are most effective. We were unable to conduct moderator analyses because many studies did not report adequate data to be included in the meta analysis. Frequently, the interventions were poorly described and lacked transparency; therefore, they were not necessarily reproducible. It can be difficult to compare different interventions when the description and understanding are incomplete. The published intervention descriptions could be improved and provided in a standardized format so that the evidence can be systematically assessed. Meta-analyses are limited by the retrieved studies and the information accurately reported in the eligible studies. Several outcomes were synthesized across small numbers of studies and should be interpreted cautiously. Findings from heterogeneous ES should generate future research to explore intervention and study procedure sources of variations in outcomes. Further completed

Clinical Pearls

- Although there have been many studies evaluating heart failure management programs, the individual interventions used in the program are not described in sufficient detail to permit program replication.
- Programs tend to rely on clinician monitoring of symptoms; only half of reviewed studies included symptom monitoring by patients. Only one-third of reviewed studies included the patients informal caregiver in the intervention.
- Future studies should address system issues, such as hand offs between settings, communication between physicians and nurses, and medication reconciliation during care transitions.

research with completely detailed interventions is essential to move both science and practice forward.

Conclusions

Current published literature describing trials of multicomponent outpatient HF management programs does not provide sufficient detail on individual program components to enable identification of the appropriate number and combination of interventions needed to improve outcomes or translate findings to practice. Well-designed evidence-based multicomponent outpatient management programs for people with chronic illnesses are critical to maintain quality of life and manage resource use. The development of standardized evidence-based protocols is key to successful implementation of chronic disease management interventions delivered by nurses. Data are needed from well-designed trials to develop and validate evidencebased content for HF home management programs. A number of studies evaluating HF management programs have found positive effects on important patient outcomes. This study provides the most detailed analysis to date of the individual components of multicomponent outpatient HF management programs.

Recommendations

Future studies of chronic disease interventions must include detailed descriptions of recommended key program components to identify critical program components. Professional associations such as the American Heart Association could endorse the standard set of program components and outcomes developed by Krumholz et al⁶⁵ as well as a measure of intensity and complexity⁷² to be used when evaluating outpatient HF management programs and reporting results. Study data should be either shared for postpublication pooling or report key statistics to enable subsequent meta-analyses. For replication and implementation into practice, details of interventions need to be clearly described in online supplementary files. Finally, future studies need to address outcomes beyond resource use, especially patient-centered outcomes and systems issues.

Acknowledgments

The authors thank Stephanie Scrivner, MPH, for assistance with manuscript preparation and Douglas Wakefield, PhD, for review of the manuscript.

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