HHS Public Access

Author manuscript

Circ Heart Fail. Author manuscript; available in PMC 2019 August 01.

Published in final edited form as:

Circ Heart Fail. 2018 August ; 11(8): e004886. doi:10.1161/CIRCHEARTFAILURE.117.004886.

Home delivered meals post-discharge from heart failure hospitalization: the GOURMET-HF pilot study

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Abstract

Background: In patients with heart failure (HF), malnutrition and dietary sodium excess are common and may worsen outcomes. No prior studies have provided low-sodium, nutritionally-complete meals following HF hospitalization.

Methods and Results: The Geriatric OUt-of-hospital Randomized MEal Trial in Heart Failure (GOURMET-HF) study randomized patients discharged from HF hospitalization to four weeks of home-delivered sodium-restricted Dietary Approaches to Stop Hypertension meals (DASH/SRD; 1,500 mg sodium/day) vs. usual care. The primary outcome was the between-group change in the Kansas City Cardiomyopathy Questionnaire (KCCQ) Summary Score from discharge to four weeks post-discharge. Additional outcomes included changes in the KCCQ Clinical Summary Score and cardiac biomarkers. All patients were followed 12 weeks for death/all-cause readmission and potential diet-related adverse events (symptomatic hypotension, hyperkalemia, acute kidney injury). 66 patients were randomized 1:1 at discharge to DASH/SRD vs. usual care (age 71±8 years, 30% female, ejection fraction 39±18%). The KCCQ Summary Score increased similarly between groups (DASH/SRD 46±23 to 59±20 vs. usual care 43±19 to 53±24, p=0.38) but the KCCQ Clinical Summary Score increase tended to be greater in DASH/SRD participants (47±22 to 65±19 vs. 45±20 to 55±26, p=0.053). Potentially diet-related adverse events were uncommon; 30-day HF readmissions (11% vs. 27%, p=0.06) and days rehospitalized within that timeframe (17 vs. 55, p=0.055) trended lower in DASH/SRD participants.

Conclusions: Home-delivered DASH/SRD following HF hospitalization appeared safe in selected patients, and had directionally favorable effects on HF clinical status and 30-day readmissions. Larger studies are warranted to clarify the effects of post-discharge nutritional support in patients with HF.

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Disclosures

None.

Clinical Trial Registration: https://clinicaltrials.gov/ct2/show/NCT02148679

Keywords

diet; sodium; nutrition; readmission; elderly

Introduction

Patients hospitalized for acutely decompensated heart failure (HF) commonly suffer functional decline, rehospitalization, and death. With the advent of financial penalties from the Centers for Medicare and Medicaid Services (CMS) for excess 30-day readmissions, most U.S. hospitals have instituted formal programs to reduce preventable rehospitalizations in patients with HF [1]. However, resulting declines in 30-day readmissions have plateaued, only 1/3 of readmissions are due to recurrent HF, and 30-day mortality has increased in recent years [2, 3].

Clearly, more effective strategies are needed to improve outcomes for patients with HF during the particularly vulnerable post-discharge period [4] and beyond. Dietary factors are thought to contribute to many HF hospitalizations [5], and dietary recommendations for patients with HF historically have focused on sodium restriction [6]. Yet this strategy has been associated with increased readmission rates and even mortality in several large clinical trials [7, 8]. One potential reason is that patients with HF instructed to eat less sodium may inadvertently worsen existing nutritional deficits [9]. In addition, patients with HF often face significant barriers to following healthy eating patterns [10].

In light of these challenges, we conducted the Geriatric OUt-of-hospital Randomized MEal Trial in Heart Failure (GOURMET-HF) pilot study. GOURMET-HF is the first trial to test the effects of home-delivered, nutritionally complete, sodium-restricted meals in patients following discharge from HF hospitalization. We hypothesized that this strategy would improve disease-specific quality of life at four weeks post-discharge. Given previous studies demonstrating adverse events with a low-sodium diet, important additional goals of GOURMET-HF were to assess the safety of the intervention, including effects on cardiac biomarkers and rehospitalization burden.

Methods

Study design and population

The study design and methods of GOURMET-HF have previously been published [11]. The data, methods used in the analysis, and materials used to conduct the research will not be made available to other researchers. In brief, GOURMET-HF was a randomized, controlled trial of 12 weeks total duration conducted at three sites (Michigan Medicine/University of Michigan, Ann Arbor Veterans Affairs Health System, both in Ann Arbor, MI, and Columbia University Medical Center/New York Presbyterian Hospital, in New York, NY). The trial was approved by the institutional review board at each site, and all enrolled participants gave written informed consent.

Patients ≥65 years of age having primary hospitalization for acute decompensated HF and meeting no exclusion criteria at hospital discharge (Table 1) were randomized to usual care vs. receiving four weeks of home-delivered meals. Due to slower-than-expected recruitment, the age of inclusion was later lowered to ≥55 years after discussion with NIH/NIA and the study Data and Safety Monitoring Board.

The primary outcome of GOURMET-HF was the inter-group change in the Kansas City Cardiomyopathy Questionnaire (KCCQ) Summary Score between discharge and four weeks post-discharge [12]. The study diet (DASH/SRD) followed the Dietary Approaches to Stop Hypertension pattern, recommended for patients with hypertension [13], and was sodium-restricted to 1,500 mg/day, as per American Heart Association recommendations [14]. Randomization was stratified by gender and by left ventricular ejection fraction <50% vs. ≥50%. Investigators were blinded to treatment assignment. Participants were assessed in-person at hospital discharge and at one, four, and 12 weeks post-discharge, and their care was otherwise managed by their usual medical team.

Physical examinations, blood pressure measurements, and blood samples for renal function and electrolytes were performed at a safety visit one week post-discharge. At this visit, the investigator could adjust HF therapies as needed to maintain clinical stability and/or stop the dietary intervention if potentially diet-related adverse events occurred. These parameters were assessed again, along with the KCCQ, at the four week visit. In participants who were rehospitalized at the time of their four week visit, the KCCQ was administered as an inpatient. In patients who were unable to attend their four week visit, the KCCQ was obtained by mail.

Intervention

The DASH/SRD contains higher intake of whole grains, fruits and vegetables, nuts and legumes, and lower intake of red meat and sweets than the typical American diet [15]. As recommended by the National Kidney Foundation [16], the potassium content of the DASH/SRD in GOURMET-HF was reduced from 4,500 mg/day to 3,000 mg/day in patients with: 1) discharge estimated glomerular filtration rate (eGFR) <45 ml/min/1.73 m^2, 2) discharge eGFR 45–60 and potassium >4.5 mmol/L, and/or 3) discharge potassium >4.5 mmol/L and potassium-sparing diuretic use.

Meals were prepared, packaged for refrigerator storage, and home-delivered once weekly by Mom's Meals NourishCare (PurFoods LLC, Ankeny, IA), a commercial entity. Each week participants assigned to the study diet could choose their preferred menu items from a variety of options tailored to DASH/SRD specifications. Three daily meals, snacks, and some beverages were provided (see Supplementary Data for sample menus) for a daily calorie intake of 2,100. Both groups received a standardized educational pamphlet (see Supplementary Data) at hospital discharge with information on how to follow a sodium-restricted diet (standard of care advice at the three study sites). Meal delivery was paused for rehospitalization and resumed at hospital discharge.

Study outcomes

The KCCQ is a self-administered, 23-item instrument that assesses HF-related physical limitations, symptoms, self-efficacy, and social interference. The KCCQ Summary Score (primary outcome) and the individual KCCQ sub-domain scores range from 0–100, with higher scores indicating better quality of life. We also evaluated inter-group change in the KCCQ Clinical Summary Score, a composite of HF-related symptoms and physical limitations that is increasingly used as an endpoint in HF clinical trials [17].

Baseline dietary patterns and nutrient intake were assessed at hospital discharge using the 110-item Block Food Frequency Questionnaire as previously described [18]. Adherence to the study diet was assessed by meal delivery records from PurFoods and review of three-day food diaries recorded during weeks one and four post-discharge. Overall adherence was defined as the proportion of the total meals consumed from the home-delivered study food. Cardiac biomarkers (high-sensitivity troponin I and BNP), prealbumin, and C-reactive protein were measured at hospital discharge and at week four. 24-hour urine collections were also performed for sodium and potassium excretion at these time points.

We identified symptomatic hypotension requiring urgent medical attention, hyperkalemia (serum potassium >5.7 mmol/L), and worsening renal insufficiency (defined as decrease in estimated glomerular filtration rate [eGFR] by >50%) as adverse events of special interest that could potentially be related to DASH/SRD. Readmissions, deaths, and the composite of post-discharge days hospitalized or dead through 12 weeks post-discharge were recorded for all participants.

Power calculations and statistical analysis

Pre-study power calculations assumed a standard deviation of the change in KCCQ Summary Score of 8 points and a 10% dropout rate. Based on a 2-sample t-test, 66 randomized participants (33 per group) would provide >80% power to detect a six-point difference between groups in the change in KCCQ Summary Score between discharge and week four [19].

All study outcomes were evaluated in an intent-to-treat analysis. Between-group differences in baseline characteristics were assessed using chi-square tests for dichotomous variables and 2-sample t-tests for continuous variables. Within-group discharge-to-week four changes in KCCQ Summary Scores were evaluated using paired t-tests. Between-group comparisons were made using linear regression with week four KCCQ as the outcome and with treatment group and discharge KCCQ as covariates. The KCCQ Clinical Summary Score, cardiac biomarkers, and other quantitative parameters were similarly evaluated, with log-transformation for B-type natriuretic peptide, high-sensitivity troponin I, and C-reactive protein due to skewed distribution. Missing data due to study withdrawals, missed visits, and a death reduced the sample size for several of the tests.

The probabilities over time since discharge of all-cause rehospitalization and HF rehospitalization were visualized using Kaplan-Meier curves, with between-group comparisons made using log rank tests. The frequencies of potentially diet-related adverse events were compared between groups with Fisher’s exact test. Inter-group comparison of

the number of days hospitalized or dead between the index discharge and 30 days post-discharge was performed using 2-sample t-tests after log-x+1 transformation (i.e., in order to avoid zero values, adding one to the number of days for scale of 1–31, then log-transforming). Data were analyzed using SAS software (Cary, NC).

Results

A total of 107 patients were originally consented to participate in the study, and 66 were randomized 1:1 to DASH/SRD vs. usual care at hospital discharge. The flow of participants through the study is shown in Figure 1. The most common reasons for being consented but not randomized at hospital discharge were hypotension, hyperkalemia, and/or renal insufficiency during the index admission. Of the randomized participants, six (9%) did not complete the KCCQ primary outcome measure at week four, three due to formal withdrawal from active participation and three who did not attend the visit and declined to complete the questionnaire by mail. By week 12, one participant died and six others withdrew from active participation in the study. All 66 randomized participants, including those who withdrew from active participation, were followed for 12 weeks by telephone and medical record review for rehospitalization or death.

Baseline characteristics of the study population are shown in Table 2. In general, randomized participants were older adults, frequently were obese, and had multiple comorbid illnesses. Renal dysfunction, anemia, and elevated levels of BNP and high-sensitivity troponin I were common. The enrolled cohort was approximately one-third female and of diverse race and ethnicity. Most patients (64%) had left ventricular ejection fraction <50%. There were no significant between-group differences in baseline characteristics.

In available Food Frequency Questionnaire data (n=57 participants) obtained during the index hospitalization, estimated energy intake was 1,602 (IQR 1,192–2,154) kcal/d, sodium intake was 2,987 (2,148–3,561) mg/d, and potassium intake 2,557 (1,911–3278) mg/d. There were no significant between-group differences in estimated calorie, sodium, or potassium intake. Energy and sodium intake were highly correlated ($r=0.93$, $p<0.001$).

Participants assigned to DASH/SRD received home-delivered meals for an average of 27±1 days post-discharge. Per review of three-day food diaries, available in 29 of 33 participants assigned to DASH/SRD, 77% of all meals consumed consisted of complete or partial home-delivered study meals. Information on the nutrient content of study meals is shown in the *Supplementary Data*. Compared with baseline intake, the study diet was ~50% lower in sodium content while providing ~25% more calories and a ~25–45% increase in potassium content. Medication changes between hospital discharge and week 4 were similar between groups (see Supplementary Data). There were no significant changes in urinary sodium or potassium excretion between discharge and week four in either group (see Supplementary Figure).

The baseline KCCQ Summary Score was similar to other previously reported cohorts at hospital discharge [20] and was not statistically different between groups ($p=0.38$). This was also the case with the KCCQ Clinical Summary Score ($p=0.70$). The KCCQ results are

illustrated in Figure 2. The KCCQ Summary Score increased in both groups from hospital discharge to week four (DASH/SRD: 46±23 to 59±20, change 13±19; usual care: 43±19 to 53±24, change 10±16; both p<0.001). The mean increase in KCCQ Summary Score was three points greater in the DASH/SRD group, but this difference was not statistically significant (p=0.37). The KCCQ Clinical Summary Score also increased in both groups from hospital discharge to week four (DASH/SRD: 47±22 to 65±19, change 18±20; usual care: 45±20 to 55±26, change 10±18; both p<0.001). The mean increase in the KCCQ Clinical Summary Score was nine points greater in the DASH/SRD group, nearing but not achieving statistical significance (p=0.053). Results were similar in patients with left ventricular ejection fraction <50% vs. ≥50% (*Supplementary Figure*).

There were no deaths during the first 30 days post-discharge. In the DASH/SRD group at this time point four all-cause rehospitalizations had occurred in four patients, as compared to 12 total all-cause hospitalizations in nine participants in the usual care group (p=0.12). Over the same timeframe, in the DASH/SRD group three patients had three HF rehospitalizations, as compared to nine patients with a total of 11 HF rehospitalizations in the usual care group (p=0.055). Within the first 30 post-discharge days, the DASH/SRD group spent 17 cumulative days rehospitalized, as compared to 55 cumulative days in the usual care group (p=0.06 for between-group comparison after log-transformation of days hospitalized). This relationship, along with a Kaplan-Meier curve showing the probability of avoiding hospitalization or death over time since index hospital discharge, is shown in Figures 3a and 3b. By 12 weeks post-discharge, 11 DASH/SRD patients had 15 total all-cause rehospitalizations, while 14 usual care patients had a total of 22 all-cause hospitalizations and one death (p=0.45 for comparison). At 12 weeks there were eight HF rehospitalizations in seven DASH/SRD patients, as compared to 18 HF rehospitalizations in 13 usual care patients (p=0.11).

Changes in safety measures and serological biomarkers over the four-week intervention period in participants with paired samples at both time points are shown in Table 3. There were no significant changes in serum potassium, serum creatinine, or systolic blood pressure between discharge and week four in either group. B-type natriuretic peptide (BNP) levels were elevated, as expected in this cohort, and increased from baseline to week four in the DASH/SRD group while not changing in the usual care group. High-sensitivity troponin I decreased from baseline to week four in the DASH/SRD group, but not in the usual care group. Prealbumin levels increased in both groups; C-reactive protein levels decreased significantly in the control group, but not in the DASH/SRD cohort. There were no significant between-group changes in any of these parameters between discharge and week four.

Three potentially diet-related adverse events occurred in the DASH/SRD group within the first 30 days post-discharge (one each of presyncope, acute renal insufficiency, and hyperkalemia) and zero such events in the usual care group (p=0.24 for comparison by Fisher's exact test). None of the events directly resulted in rehospitalization. The presyncopal episode occurred during an upper respiratory infection, and rapid heart rate was noted on home blood pressure monitoring. The participant sought medical attention three days later and was hospitalized for atrial fibrillation with rapid ventricular response. These

events were judged unlikely related to diet. The acute renal insufficiency event was noted on post-discharge day one in a participant who was seen for concern of dehydration. The patient had not yet received study meals. Loop diuretics were discontinued, angiotensin-converting enzyme inhibitor was temporarily held, and renal function returned to baseline two days later. The hyperkalemia episode was identified at the week 1 safety visit and treated in the emergency department. The intervention was stopped by the blinded site primary investigator. After review of the event, the patient had been randomized to meals but mistakenly not been assigned by the study team to the lower-potassium version of DASH/SRD.

Discussion

The GOURMET-HF study is the first randomized trial to evaluate the safety and efficacy of home-delivered DASH/SRD meals post-discharge from HF hospitalization. Home delivery of meals was feasible, participants largely adhered to the study diet, and diet-related adverse events were uncommon. While not meeting its primary outcome, this pilot study demonstrated trends for efficacy in several domains important to recently hospitalized patients with HF and their providers. These outcomes included symptoms and physical limitations related to HF as well as rehospitalization burden.

Most previous dietary interventions in patients with HF have focused on sodium restriction as the primary intervention. In a series of such studies performed by Italian investigators, patients with HF and reduced ejection fraction were assigned at hospital discharge to dietitian-guided moderate vs. intensive sodium restriction (120 vs. 80 mmol, or 2,800 vs. 1,800 mg/day) at hospital discharge. Contrary to initial expectations, patients assigned to lower sodium intake had higher readmission and mortality rates [8, 21]. These concerning findings were reinforced by the Heart Failure Adherence and Retention Trial (HART). In HART, 902 U.S. patients with HF randomized to self-management counseling vs. usual care self-reported their sodium intake with a questionnaire. Following propensity-matching, patients with estimated sodium intake <2500 mg/day had a 44% higher risk of HF hospitalization [7].

One possible reason for these results would be if dietary sodium restriction compromises overall nutritional status, an aspect not considered in the studies above. When assessed with validated screening instruments, the prevalence of malnutrition in patients hospitalized for HF is at least 15%, and is up to 90% in patients with advanced HF. Malnourishment has significant clinical consequences in hospitalized patients with HF, increasing length of stay and readmission rate while approximately tripling long-term mortality [22–24]. In addition, malnutrition contributes to and overlaps with frailty, sarcopenia, and reduced mobility, each individually associated with poor outcomes in patients with HF [25–28]. National survey data indicate that the correlation between sodium and calorie intake is ~0.7 in most U.S. populations [29]. The substantially higher correlation in GOURMET-HF implies that patients with HF attempting to restrict sodium may consume insufficient calories for daily energy needs. Well-intentioned sodium restriction may also inadvertently contribute to micronutrient deficiencies in patients with HF [9], another risk factor for poor outcomes [30].

When compared with healthy older adults, patients with HF have additional factors affecting food intake and hence nutritional status. Mobility limitations, transportation difficulties, economic concerns, and symptoms such as dyspnea, nausea, anxiety, depression, and fatigue can greatly impact the motivation and ability to follow healthy eating patterns [10, 31]. We hypothesized that home delivery of DASH/SRD meals during the particularly vulnerable post-discharge period [4] could overcome some of these challenges. The results of the GOURMET-HF pilot study suggest that this strategy is feasible and associated with a low rate of adverse events. Overall, there was no significant change in blood pressure, serum creatinine, or serum potassium in either group. In contrast to prior studies of sodium restriction post-discharge, we did not observe progressive neurohormonal activation or azotemia [21]. This may be because medical therapy in GOURMET-HF was guided by clinical status rather than a standardized protocol, or could be related to the relatively short duration of the DASH/SRD intervention.

The GOURMET-HF study was not powered or intended to determine the effect of home-delivered meals on readmission rates. However, the trend toward fewer 30-day HF readmissions and total days rehospitalized in the DASH/SRD group is encouraging. These findings are consistent with previous literature both in plausibility and magnitude. In particular, the PICNIC study (Nutritional Intervention Program in Hospitalised Patients with Heart Failure who are Malnourished) provides important context. The PICNIC study randomized 120 patients discharged from HF hospitalization at two large Spanish hospitals to an intensive, team-based six-month nutritional intervention vs. usual care. At 12 months post-discharge, the combined mortality and HF rehospitalization in the nutritional intervention group was substantially lower (27 vs. 61%, $p<0.001$). These results were consistent across key subgroups and the number needed to treat was 2.5 to prevent one event; the survival curves began to separate within the first 30 days post-discharge and continued to diverge throughout the six-month intervention period [32]. The Kaplan-Meier curves in GOURMET-HF (Figure 3a) diverge during the meal delivery period, but converge after this period, suggesting that a longer intervention might be needed for sustained benefits of nutritional support.

The GOURMET-HF results are supported by the recent Mediterranean DieT in Acute Heart Failure (MEDIT-AHF) analysis. In this prospective cohort study, Spanish patients hospitalized for acutely decompensated HF who were more adherent to a Mediterranean diet, which shares many characteristics with DASH, had a lower risk of death and rehospitalization for HF over the subsequent 12 months [33]. Our findings are also generally aligned with large cohort studies indicating that the DASH dietary pattern is associated with reduced incidence of HF and improved long-term outcomes in HF [34–36].

The mechanisms underlying any potential benefits of post-discharge nutritional support with DASH/SRD in HF are not clear from our results. Although controversy exists, reduced sodium and increased potassium intake (as expected with DASH/SRD) have been generally associated with improved cardiovascular function and outcomes [37]. Protein-calorie malnutrition, also potentially addressed by the study diet, is a strong risk factor for death and readmission in older patients hospitalized for HF [38, 39]. We did not note a differential increase in prealbumin levels in the DASH/SRD group, but this commonly used biomarker

may not be an accurate index of nutritional status during acute illness [40]. Cardiac biomarkers did not demonstrate a clear trend, with BNP increasing and high-sensitivity troponin I decreasing in the DASH/SRD group and no change in either parameter in usual care patients.

Limitations

The standard deviation of the between-group change in KCCQ Summary Score was more than twice as large as predicted, reducing the power of the study for its primary outcome. In addition, the magnitude of the between-group change in KCCQ Summary Score (3 points) was not in a range considered clinically significant (typically >5 points). However, the magnitude of change in the DASH/SRD group was substantially greater in the domains most likely to respond to nutritional support, i.e. HF symptoms and physical limitations, and negligible in less directly related domains (general quality of life and social limitations).

In most cases, food diary records were sufficient to gauge the proportion of home-delivered meals consumed by participants assigned to DASH/SRD. We could not definitively analyze the nutrients consumed during GOURMET-HF participation, as some three-day food records had inadequate detail despite prompting from study personnel. Because of this limitation, we cannot provide direct comparison between the provided meals and the diet consumed post-discharge by usual care group participants.

We hypothesized that urinary sodium would decrease and urinary potassium would increase in the DASH/SRD group and serve as a supplementary measure of adherence, but did not find any changes in these parameters. Others have found poor reproducibility of 24-hour urine electrolytes over a one-month period in stable outpatients with HF [41], and this issue may be compounded by diuretic dose and administration route changes prior to discharge in hospitalized patients.

Any small treatment trial carries the risk of important between-group differences despite randomization. While there were no statistically significant differences in baseline characteristics, it is possible that the trend toward fewer hospitalizations relates to a lower inherent risk in the DASH/SRD cohort. Due to limited prior safety and efficacy data with the DASH diet in HF [42, 43], we enrolled only participants with a history of systemic hypertension, the focus of most prior DASH diet studies. While most patients with HF have a history of hypertension, our findings may not be generalizable to patients who do not have a history of hypertension.

The GOURMET-HF results are hypothesis-generating, and establish the rationale for conducting a larger study of direct dietary support in patients with HF following hospital discharge. Such a trial would ideally be powered to assess this strategy’s impact on hospital readmission burden. In addition, the complexity and costs of this intervention, as well as its feasibility and efficacy across patients of diverse demographics and socioeconomic status, would be important considerations in a future trial.

Conclusions

Home delivery of low-sodium, nutrient-dense meals following discharge from HF hospitalization is feasible and safe. While not meeting its primary outcome, the GOURMET-HF pilot study suggests that post-discharge nutritional support has the potential to improve HF symptoms and reduce readmissions. Larger studies are warranted to explore these concepts further.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

Acknowledgments

Sources of Funding

The GOURMET-HF pilot study was jointly funded by the National Institute of Aging/National Institutes of Health (R21-AG047939) and PurFoods, LLC (Ankeny, IA).

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What is new?

- Dietary factors are believed to be an important cause of hospitalizations in patients with heart failure (HF), but few dietary interventions have been performed in this population.
- Malnutrition is common in HF and associated with adverse outcomes, and the standard recommendation to restrict dietary sodium could contribute to dietary nutritional deficiencies.
- The GOURMET-HF pilot study is the first randomized trial to examine the effects of direct dietary support in patients with HF following hospital discharge.

What are the clinical implications?

- GOURMET-HF randomized patients with HF at hospital discharge to four weeks of home-delivered, low sodium, nutritionally complete meals vs. usual care.
- Disease-specific quality of life (primary outcome) did not improve more in patients assigned to home-delivered meals.
- However, secondary analyses suggest potential benefits of this strategy on HF symptoms, physical limitations, and readmission reduction.
- Larger studies are warranted to clarify the effects of home-delivered meals on rehospitalization burden and quality of life in recently hospitalized patients with HF.

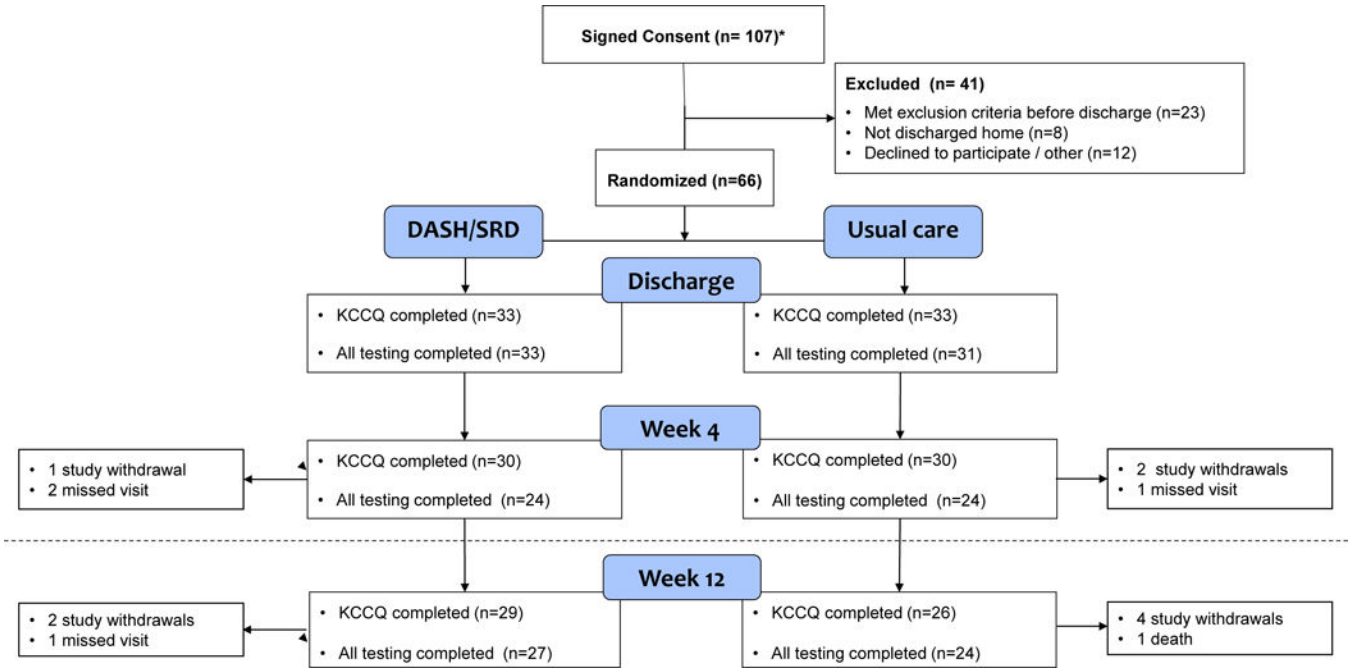

Figure 1:
Study participant flow

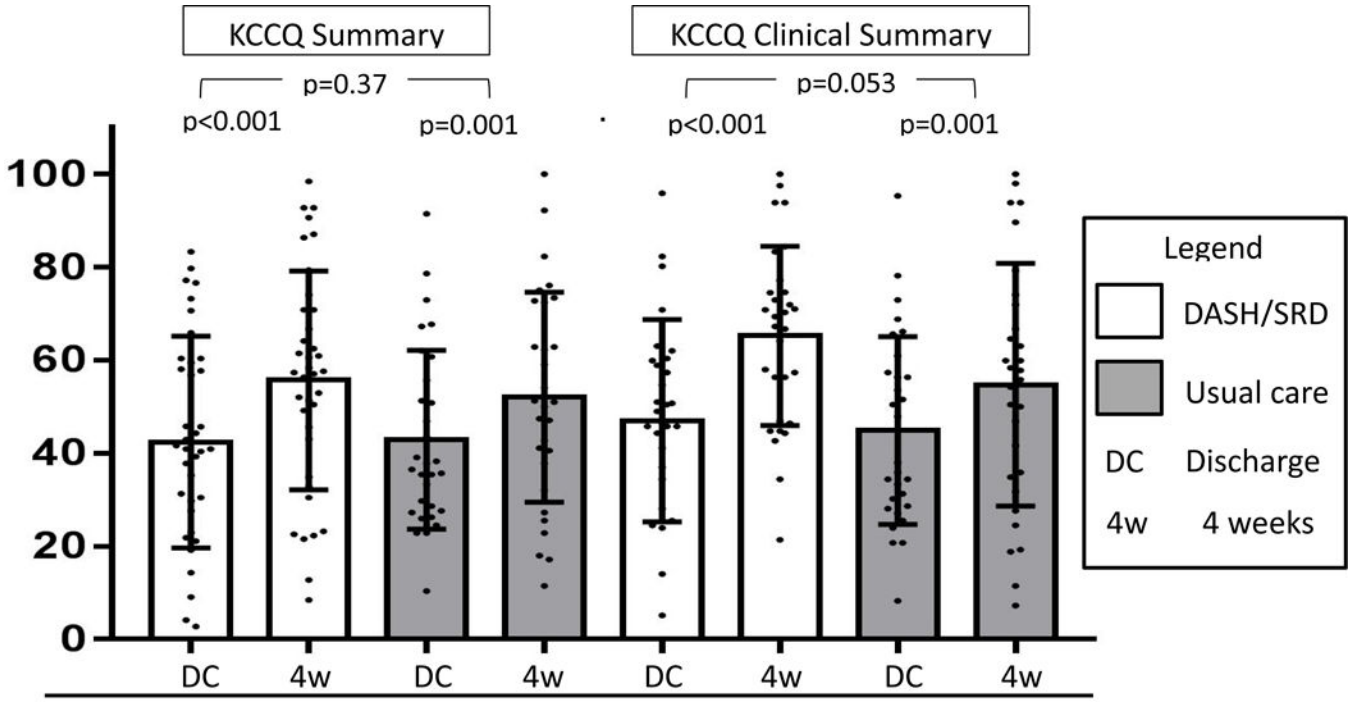

Figure 2: KCCQ Summary and Clinical Summary Scores.

Abbreviations: DASH/SRD, sodium-restricted Dietary Approaches to Stop Hypertension eating pattern; KCCQ, Kansas City Cardiomyopathy Questionnaire

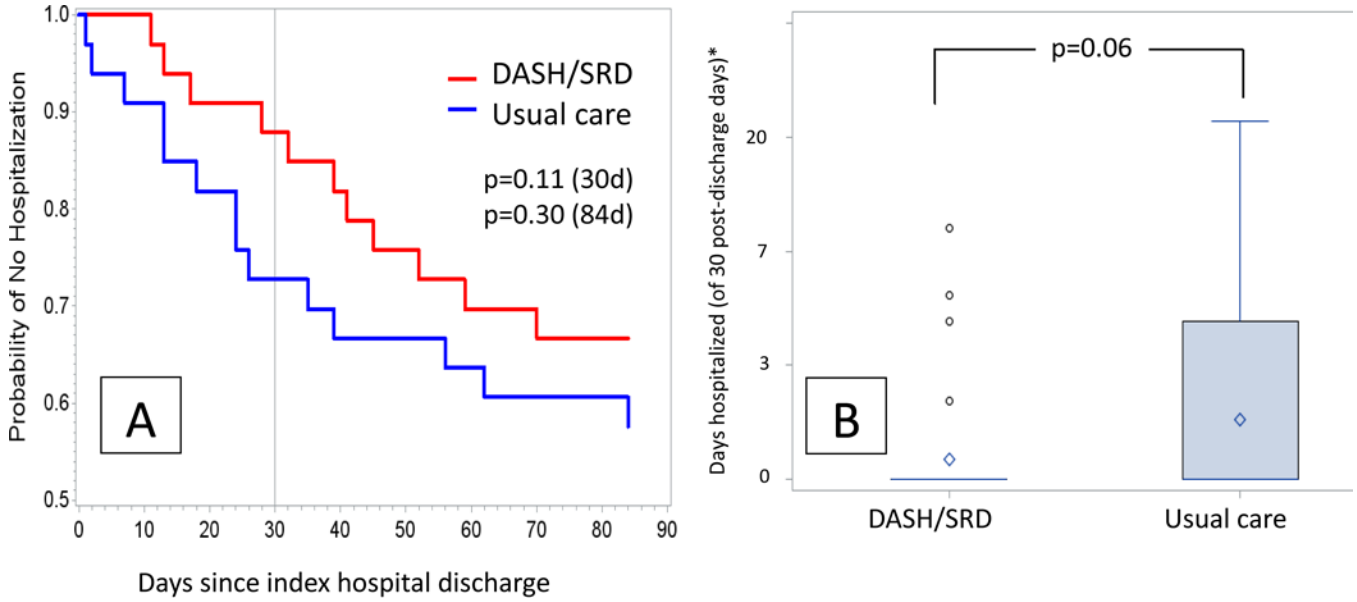

Figure 3: (A) Kaplan-Meier curve for freedom from hospitalization following index hospital discharge, (B) Boxplots by treatment group of days hospitalized from index discharge to day 30.
*Tick marks correspond to one-unit increase in log-days hospitalized, numbers on axis indicate days hospitalized rounded to the nearest day; diamond indicates mean, box inter-quartile range, whiskers 5–95%, and circles outliers

Table 1:

Inclusion and exclusion criteria

Inclusion Criteria
Age ≥ 55 years old
History of systemic hypertension
Patient being discharged to home
Admission for acute decompensated HF, with criteria: ≥ 1 symptom of HF: • dyspnea, fatigue, orthopnea, PND
≥ 2 signs of HF: • pulmonary congestion on exam or chest x-ray, jugular venous distension, edema or rapid weight gain, elevated BNP (>100 pg/ml)
Change in medical treatment specifically targeting HF: • diuretics, vasodilators, and/or neurohormonal agents
No other apparent cause of patient's signs and symptoms
Exclusion Criteria
Hypotension during hospitalization: persistent systolic BP <100
Hyperkalemia: • ≥ 2 serum potassium > 5.0 mmol/L during hospitalization
• History serum potassium > 6.0 mmol/L
Severe anemia (hemoglobin < 9.0 g/dL)
Length of stay < 48 hours or > 14 days
Expected survival < 12 months
Active alcohol or substance abuse
Dementia or history of nonadherence to treatment
Exclusions at Discharge:
Blood pressure (persistent within 24 hr prior to discharge): • Systolic BP > 180 mmHg or diastolic BP > 100 mmHg
• Hypotension (persistent systolic BP < 110 mmHg)
Need for intravenous inotropic therapy
Severe renal insufficiency (eGFR < 30 ml/min/1.73 m^2)

Table 2:

Demographics and baseline characteristics

Parameter	Overall cohort	Usual care	DASH/SRD	p value
Age (years)	71±8	70±8	71±8	0.57
Gender (% female)	30%	33%	27%	0.59
BMI (kg/m2)	32.6±7.7	34.0±7.9	31.3±7.1	0.15
Race				
-White	36 (55%)	18 (55%)	18 (55%)	1.0
-Black	20 (30%)	10 (30%)	10 (30%)	
-Other	10 (15%)	5 (15%)	5 (15%)	
Ethnicity				
- Hispanic	24 (36%)	11 (33%)	13 (39%)	0.61
- Non-Hispanic	38 (64%)	22 (67%)	20 (61%)	
Cardiovascular parameters				
-Systolic blood pressure (mmHg)	124±20	121±20	126±21	0.37
-Diastolic blood pressure (mmHg)	72±11	71±11	72±11	0.84
-Heart rate (beats/minute)	76±17	80±19	74±14	0.16
-Left ventricular ejection fraction	39±18	39±18	39±18	0.91
Comorbidities				
-Hypertension	65 (98%)	33 (100%)	32 (97%)	1.0
-Diabetes mellitus	37 (56%)	20 (61%)	17 (52%)	0.46
-Ischemic etiology of heart failure	30 (45%)	15 (45%)	15 (45%)	1.0
Laboratory parameters				
-eGFR (ml/min/1.73 m^2)	54±17	55±18	53±17	0.66
-Hemoglobin (g/dl)	12.4±1.7	12.4±1.7	12.4±1.7	0.94
-BNP (pg/ml) *	188 (82, 580)	190 (104, 604)	176 (68, 501)	0.43
-hs-Troponin I (pg/ml) *	148 (86, 253)	138 (73, 275)	148 (87, 230)	0.80

Abbreviations: BNP, B-type natriuretic peptide; eGFR, estimated glomerular filtration rate; hs-Troponin I, high-sensitivity troponin I

Values expressed as percentage, mean ± standard deviation, or median (interquartile range) for log-transformed variables

* Statistical tests were performed on the log scale for BNP and hs-Tropopnin I due to skewness

Table 3:

Selected clinical and laboratory values (paired samples)

Parameter	Usual Care				DASH/SRD				Between group difference DASH/SRD vs. Usual Care	
	Discharge	Week 4	p	Within group change	Discharge	Week 4	p	Within group change	p	Estimate (SE) or Log Effect (%)
Systolic blood pressure (mmHg)	123±22	123±22	0.99	0±20	126±22	121±19	0.17	-5±18	0.46	-3.6 (4.8)
Serum potassium (mmol/L)	4.3±0.4	4.2±0.5	0.84	0.0±0.5	4.3±0.4	4.3±0.7	0.98	0.0±0.8	0.60	0.09 (0.16)
Serum creatinine (mg/dL)	1.4±0.4	1.3±0.5	0.53	0.0±0.3	1.4±0.4	1.4±0.4	0.49	0.0±0.3	0.87	0.01 (0.08)
BNP (pg/mL) *	190 (125,624)	237 (143,917)	0.44	61 (−94,133)	176 (68,501)	232 (112,606)	0.041	36 (−13,169)	0.59	11% higher *
hs-Troponin I (pg/mL) *	162 (76,362)	183 (76,347)	0.84	-7.5 (−30,76)	150 (109,230)	131 (74,219)	0.025	-21 (−65,31)	0.23	20% lower *
C-reactive protein (mg/L) *	14.2 (5.4,28.5)	5.2 (2.8,9.2)	0.001	-6.6 (−19.3,−2.0)	6.2 (4.6,14.3)	4.9 (1.5,9.0)	0.10	-0.9 (−3.9,0.5)	0.35	37% higher *
Prealbumin (mg/dL)	21.2±6.3	25.9±8.3	0.008	4.7±7.1	23.2±6.6	25.6±6.5	0.025	2.5±5.2	0.36	-1.6 (1.8)

Abbreviations: BNP; B-type natriuretic peptide; hs-troponin I; high sensitivity troponin I. Within-group changes are Week 4 minus Discharge, with values expressed as mean ± standard deviation, or median (interquartile range) for log-transformed variables.

* Statistical tests were performed on the log scale for BNP and hs-Tropopnin I and on the log(x+1) scale for C-reactive protein; all transformations were made due to skewness. Estimates are presented on the percent scale (approximate percent scale for C-reactive protein). Because confidence intervals are asymmetrical and thus SEs are not useful, we present 95% confidence intervals for estimates: BNP (−25% lower to 55% higher); hs-Troponin I (43%lower to 14% higher); C-reactive protein (29% lower, 162% higher)