A Randomized Controlled Trial to Improve Self-Care in Patients with Heart Failure Living in Rural Areas

Running title: Dracup et al.; Self Care in Rural Patients with Heart Failure

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Journal Subject Code: Heart failure:[110] Congestive
Abstract

**Background**—Patients with heart failure (HF) who live in rural areas have less access to cardiac services than patients in urban areas. We conducted a randomized clinical trial to determine the impact of an educational intervention on the composite endpoint of HF rehospitalization and cardiac death in this population.

**Methods and Results**—Patients (N=602, 66 ± 13 years old, 41% female, 51% systolic HF) were randomized to one of three groups: Control (usual care), Fluid Watchers LITE or Fluid Watchers PLUS. Both intervention groups included a face-to-face education session delivered by a nurse focusing on self-care. The LITE group received two follow-up phone calls, while the PLUS group received bi-weekly calls (mean 5.3±3.6, range 1-19) until the nurse judged the patient adequately trained. Over two years of follow-up, 35% of patients (n=211) experienced cardiac death or hospitalization for HF with no difference among the three groups in the proportion that experienced the combined clinical outcome (p=0.06). Although, patients in the LITE group had reduced cardiac mortality compared to patients in the control group over the two years of follow-up (7.5% and 17.7% respectively, p=0.003), there was no significant difference in cardiac mortality between patients in the PLUS group and control.

**Conclusions**—A face-to-face education intervention did not significantly decrease the combined end-point of cardiac death or hospitalization for HF. Increasing the number of contacts between the patient and nurse did not significantly improve the outcome.

**Clinical Trial Registration**—www.ClinicalTrials.gov. Identifier: NCT00415545.

**Key words:** heart failure, health education, self-management
Patients with heart failure (HF) present a multifaceted management challenge. Self-monitoring and timely response by HF patients to worsening symptoms caused by fluid overload (the primary reason for hospital admissions) is an important cornerstone of care in this population as prolonged periods of high cardiac filling pressure lead to increased damage to the myocardium and to further ventricular remodeling. Multidisciplinary disease management programs reduce morbidity and mortality in HF patients; however, these resource-intensive programs are primarily limited to major urban medical centers and are generally unavailable to elderly patients living in rural areas where resources and access to care are limited. Rural patients in the United States have lower incomes, less health insurance, more health risks, lower levels of education and health literacy, and less broadband Internet access than patients living in urban areas. When hospitalized for HF, they are less likely to have early physician follow-up (i.e., within 7 days of hospital discharge). These factors create special challenges for patients with a complex chronic illness like HF. Additionally, less is known regarding optimal treatment of patients with HF with preserved or normal ejection fraction (HFPEF), which accounts for approximately 50% of HF patients. The majority of guidelines for treating HF have focused on heart failure with reduced ejection fraction (HFREF) and the majority of educational interventions and disease management programs have been tested primarily in patients with HFREF.

Therefore, we conducted a multi-center randomized controlled trial to test an education and counselling intervention for use with rural patients diagnosed with either HFREF or HFPEF. The proposed intervention was designed to increase knowledge about heart failure symptoms and achieve enhanced self-care by patients. The intervention included all aspects of HF self-care, but focused particularly on establishing patients’ dry weight, monitoring daily weights and noting early warning sign of hypervolemia. Patients were encouraged to seek medical care promptly to
prevent HF exacerbations by calling their physician when signs and symptoms of HF began to increase.

The primary aim of the study was to compare the impact of two different intensity levels of HF patient education focused on volume overload prevention and self-care enhancement, with control (usual care) and with each other on the composite endpoint of cardiac death or HF hospitalizations. Patients were followed for two years. A secondary aim was to test the role of potential moderators (type of HF [i.e., with either reduced or preserved ejection fraction], age and gender) on clinical outcomes.

Methods

Trial Design and Participants

The randomized clinical trial (Rural Education to Improve Outcomes in Heart Failure [REMOTE-HF]) was approved by the Institutional Review Board of each participating institution. Patients were recruited from 12 clinics or hospitals in California, Kentucky, and Nevada. To be eligible for the study, patients had to be 18 years or older and live in a rural area defined as a town of < 2,500 persons, a metropolitan center of < 50,000 persons, or open country. They also must have been hospitalized for HF within the past 6 months, been able to read and write English, and be living independently (i.e., not living in an institutional setting and having primary decision-making ability over health issues). Patients were excluded if they had a complicating serious co-morbidity (e.g., a psychiatric illness, untreated malignancy or renal failure requiring dialysis), were currently participating in a HF disease management program, or had a neurological disorder that impaired cognition. Cognitive status was determined by using the Mini-Cog Exam and a clock-drawing test. The clock-drawing component of the test
provided a quick assessment of cognitive function, memory, language comprehension, visual-motor skills, and executive function and as such screened out patients with dementia or mild cognitive impairment. Patients with a word recall score of 0 (range 1-3) or a word recall of \( \leq 2 \) with an abnormal clock drawing were excluded. Reading difficulty secondary to eyesight problems was not a cause for exclusion and large print questionnaires and diaries as well as digital scales with large numbers were available to all enrolled patients.

**Procedures**

After written informed consent was obtained from each patient, sociodemographic (i.e., age, gender, race/ethnicity, education, annual household income, marital status, and number of people living in the household) data were collected using structured questionnaires. Clinical data were abstracted from hospital medical records by trained research personnel using a standardized form and medication reconciliation was performed at that time. Echocardiograms were obtained if not conducted in the previous six months. Assessment of New York Heart Association (NYHA) class was determined by the patient's physician or research nurse prior to randomization.

Patients were randomized to 1 of the 3 groups at each site using random selection techniques available in SPSS 18.0 with 1:1:1 fixed allocation randomization using blocks of 5 patients. Randomization assignment was placed in sealed envelopes in sequential order at each site. The study nurse opened the envelope to determine group assignment following the patient’s completion of baseline testing. Patients and their physicians were blind to group assignment. Research assistants and investigators also remained masked to study arm assignment. Contamination of groups was minimized because none of the medical practices had heart failure clinics or patient group sessions, patients lived in geographically diverse areas, and the intervention in both experimental groups was delivered in the patient’s home or a private room in
one of the participating clinics. Data were collected at baseline, 3, 12 and 24 months, entered directly onto teleforms and faxed to the Clinical Trials Coordinating Center.

Patients in all three groups were provided with educational brochures about HF from the American Heart Association, as well as health care logs to document telephone calls to physicians, medical appointments (both scheduled and unscheduled) and emergency department admissions and hospitalizations. Physicians were not told of the group assignment of their patients. Patients in the two intervention groups were given daily weight and HF symptom diaries to be completed, as well as weight scales. Both the health care logs and diaries were returned monthly in stamped, self-addressed envelopes to the appropriate project director. All patients were compensated $25.00 per visit. Follow-up data were collected in person by a research nurse either in the patient’s home or the physician’s office or clinic.

Patients in the two experimental arms met with a nurse for an educational session lasting approximately 50 minutes. The education was enhanced by a structured flipchart to promote intervention fidelity across sites, but every effort was made to make the session as interactive as possible using the strategies of "teach-back" where patients are asked to repeat what they have been taught. The intervention session was based on current clinical guidelines and included information about HF; a discussion of common barriers to seeking care; a review of the patient's dry weight and signs and symptoms of fluid overload; tailored messages on the importance of medication adherence, diet, and self-monitoring of symptoms; and supportive coaching to identify barriers to seeking care and develop action plans. The rationale for the emphasis on weight monitoring and, if appropriate, diuretic self-adjustment was based on research demonstrating that adherence to this area of self-care is associated with fewer HF-related hospitalizations. Nurses in the intervention session had a list of the patients’ medications, and
they tailored the medication teaching accordingly. Based on our pilot study in which patients kept a daily log but did not use the data to alert their physician when they experienced weight gain or increased HF symptoms, we provided all patients in the two experimental arms with a script to use when calling their physicians, and we reviewed the importance of contacting a physician when they experienced weight gain or increased HF symptoms. A similar script was tested in a randomized controlled trial in cancer patients and found to improve clinical outcomes related to pain management.

Patients in the Fluid Watchers LITE group received two phone calls at two week intervals to reinforce the information in the educational session. Patients in the Fluid Watchers PLUS group received an audiotape of the education session for future review as well as bi-weekly follow-up phone calls by the research nurse until content competency was demonstrated. The expected level of knowledge competency was a focus of staff training and reinforced through role playing. The nurses were encouraged to use the teach-back technique in the educational sessions to determine patients’ understanding of the concepts taught. The mean number of follow-up telephone calls was 5.3 ± 3.6 (range 1 to 19). Family members were invited to participate in the educational session and did so approximately one-third of the time (in the LITE group 35% and in the PLUS group 37% of the time).

Co-morbidities were assessed using the Charlson Co-morbidity Index (CCI). Knowledge about heart failure was assessed using a 20-item HF Knowledge Scale. Health literacy was measured using the Short Test of Functional Health literacy in Adults (S-TOFHLA), which is a 36-item, 7-minute timed test of reading comprehension. The instrument measures the ability to read and understand actual health-related passages. Based on the number of correct answers, patients are categorized as having inadequate (0–16 correct answers), marginal (17–22
correct answers), and adequate health literacy (23–36 correct answers). The S-TOFHLA has good internal consistency (Cronbach's alpha = 0.98) and demonstrated concurrent validity compared to the long version (r = 0.91).25

The nine-item European HF Self-care Behavior Scale26 was used to measure HF-related self-care. Sample items include: ‘I weigh myself every day’ and ‘If my shortness of breath increases, I contact my doctor or nurse.’ Responses on each item are measured on a 5-point Likert scale ranging from 1 (completely agree) to 5 (don’t agree at all). The total score can range from 9 to 45, with lower scores indicating better self-care. The scale has excellent data supporting its validity and reliability,26 and in our sample internal reliability was acceptable with a Cronbach’s alpha of .72.

Hospitalizations were determined at each data collection point by questioning patients and their physicians. Cause of hospitalizations was determined by medical record review. Mortality was determined by medical record review using a blinded adjudication process to determine cause of death, and interview of the patient’s family member and/or physician for out-of-hospital deaths. All deaths were confirmed using Social Security Death Index and copies of death certificates were obtained.

No changes in the criteria for enrollment or study procedures were made once the trial was initiated. We collected participant contact information, including two alternate contacts, at enrollment to minimize loss to follow-up.

Sample Size

Based on data from previous trials,4,5,27,28 we estimated the proportion of patients who would experience either cardiac death or HF rehospitalisation over the two-years of follow-up in the control group at 72%. An absolute 15% decrease in the composite end-point in the LITE group
(57%) and an absolute 30% decrease in the PLUS group (42%) was considered both realistic and clinically relevant. With a power of 80% and an alpha level of 0.05 for the overall Chi-square test and more specifically an alpha of 0.017 (0.05/3) for the three subsequent pair-wise contrasts, 212 patients were required in each arm.

Statistical Analysis

Data were analysed using SPSS® for Windows (version 18.0, SPSS, Inc., Chicago, IL). Comparability of the groups on baseline measures was examined using Chi-square or one-way ANOVA depending on the level of measurement. All analyses followed an intent-to-treat strategy, that is, the analyses included all patients in the groups to which they were randomly assigned, regardless of their level of adherence to the intervention or subsequent withdrawal from the study. All significance levels used and p-values presented are two-sided.

Differences in self-care scores among the groups over the study period were tested using a linear mixed models analysis. The analysis examined the main effects of group and time as well as the group by time interaction. The within patient covariance structure was set at unstructured. Pair-wise comparisons between groups at each time point were tested using the Bonferroni correction for multiple comparisons at a total alpha of 0.05, i.e., in order to be significant the p-value of a pairwise comparison would need to be <0.017 (.05/3). The difference in the proportions of HF hospital admissions or cardiac death was tested using Chi-square analysis with significance set at p<0.05 and potential pairwise differences between groups set at p<0.017. Differences among groups in time to first occurrence of the combined endpoint of HF hospital admission or cardiac death, as well as individual endpoints of HF hospitalization and cardiac death, were analysed using Cox proportional hazards estimates of the survival curves. Gender, age and ejection fraction (≤40% or >40%) were used as covariates. The Wald statistic
was used to compare survival curves.

**Results**

We screened patients from September 2006 through December 2010 with the last follow-up completed in January 2012. Of the 636 patients eligible for enrollment, 12 did not meet eligibility criteria for cognitive function and 10 chose not to participate (Figure 1). Of the 614 HF patients who were enrolled, twelve (2%) were lost to follow-up prior to the first follow-up at three-months and we could not obtain data about their clinical outcomes. The remainder of those who withdrew (n=97 or 15.8%) gave us written permission to follow their outcomes. The rate of withdrawal from the treatment groups was lowest in control (13.6%) and highest in the LITE group (19.2%), but these percentages were not significantly different across the three groups (p=0.096). Patients who withdrew from the study were not significantly different than patients who remained in the study on any of the demographic or clinical characteristics measured at baseline including health literacy scores with significance set at <0.05.

Of the 602 patients available for analysis of clinical outcomes at two years (98% of the enrolled sample), they were on average 66 (±13.0) years of age; the majority were male (58.7%) and married (56.6%). Sixty-five per cent had combined household incomes of less than $40,000 per year. Fifty one percent had HFREF. The majority of patients were classified as NYHA class II or III (85.4%). The mean score on the S-TOFHLA was 70.9±24.6, with a range from 2.8 to 100, with 18.8% scoring as inadequate, 15.7% marginal, and 61.3% adequate.

Demographic and clinical characteristics of patients by total sample and group assignment are summarized in Table 1. There were no significant differences among the three groups on any demographic or clinical characteristic with the exception of history of
hypertension.

Given that the intervention focused on enhancing patients' self-care of their HF regimen, we examined self-care scores over time. The linear mixed models analysis found a non-significant main effect of group (p=.062), a significant main effect of time (p<.001), and a significant group by time interaction (p=.003). Pairwise comparisons among the groups at each time were examined. The means and standard errors of each group at each time are presented in Table 2. At baseline, there were no significant differences among the groups. At 3 and 12 months, there were some significant differences among the groups (p<0.05). At 3 months and 12 months, both LITE and PLUS groups had significantly lower (better) self-care scores than control (p<0.05), with no difference between the two intervention groups. At 24 months, the improvement in the two intervention groups in self-care behavior was sustained but no longer significantly different from the control group (Control vs. PLUS, p=0.095; Control vs. LITE, p=0.116).

Over two years of follow-up, 35% of patients (n=211) experienced either cardiac death or hospitalization for HF (Table 3). Groups did not differ significantly in the proportion that had the combined clinical outcome of cardiac death or hospitalization for HF (p=0.058). There was a trend favoring the Fluid Watchers LITE group compared to control (p=.048) and to PLUS (p=.033), but neither comparison met the criteria of p <0.0167 using the Bonferroni correction for multiple comparisons. There were no differences among the groups in time to HF hospitalization or cardiac death (Chi-square 3.577, p=0.167; Figure 2). When age, gender, and type of HF, all characteristics that have been identified by previous investigators as potentially affecting this combined clinical outcome,28,29 were also included in the Cox survival analysis, there were still no significant differences among the groups (p=.154). We also tested the effect
of site on the primary clinical endpoint and demonstrated no significant interaction between treatment group and site (p=0.169).

During two-years of follow-up, 75 (12.5%) patients died from a cardiac cause. Cardiac mortality was significantly different among the groups (p=0.008). The proportion of patients who experienced a cardiac death was significantly less in the LITE group (7.5%) compared to control (17.7%) (p=0.003). Differences in cardiac deaths between LITE and PLUS (p=0.172) and control and PLUS (p=0.123) groups were not significant. Cox survival analysis of time to cardiac death also showed a significant difference among groups (Chi-square = 8.741, p=.013). Survival was significantly better for the LITE group than for the control group (p=.005) (Figure 3). Cardiac mortality was not significantly different between PLUS and control or PLUS and LITE. Including age, gender, and type of HF did not alter the test of the group effects. Eight percent of patients (n=50) died from non-cardiac causes.

We also examined number of scheduled and unscheduled office visits made by patients to their physicians over the study period. Patients in the LITE group made the fewest visits (11.5%) compared to control (12.9%) and PLUS (23.8%) (p=0.001) (Table 3). Finally, we examined the potential role of family presence in the intervention sessions and identified no significant difference between the two intervention groups with 35% of the LITE group and 37% of the PLUS group sessions attended by family members (p=0.68).

**Discussion**

Patient education designed to achieve optimal self-care in HF such as monitoring daily weight and maintaining adherence to medication and dietary regimens is recommended in all HF guidelines.\(^\text{14,15}\) Self-care is also a fundamental component of comprehensive HF disease
management programs, which in turn are documented to improve all-cause hospitalization and survival. However, such programs are usually not available to patients living in rural areas who are geographically distant from specialty care. Moreover, urban-rural differences in mortality, morbidity, access to care and cost of care have been documented in a variety of clinical conditions, including HF, with rural populations disadvantaged on every dimension. These differences may be compounded by the demographic differences between rural and urban populations, which include lower incomes and educational levels, less medical insurance and access to health care, and higher health care risk factors. Thus patients living with HF in rural areas of the U.S. pose specific challenges for the health care system given the demands related to having a complex chronic condition combined with minimal personal resources and geographic distance from medical support.

To date, the special population of rural HF patients has not been the subject of an educational intervention study designed to enhance self-care. We enrolled 614 HF patients living in rural areas of Appalachia, central California and Nevada and randomized them to one of three treatment groups to determine whether a face-to-face, one-time educational intervention designed to improve knowledge and enhance self-care would reduce HF-related hospitalization or cardiac death. We designed the trial to see whether the intensity of the intervention, as reflected by additional telephone reinforcement sessions and provision of an audiotape of the educational session, would make a significant difference in the hypothesized clinical outcomes over the two-years of follow-up.

The results demonstrated a lack of significant difference across the three groups in the combined endpoint of HF hospitalization or cardiac death, although there was a trend favouring the LITE treatment group. One potential explanation for the unexpected finding of no difference
in the composite endpoint between groups might be that approximately half of the patients in the study had HFPEF by echocardiogram. The evidence related to optimal self-care in patients with HFPEF is limited and self-care measures are not proven effective in this group of patients. However, a Cox analysis using type of HF as a covariate demonstrated no significant difference in the composite endpoint by group, suggesting that type of HF did not play a significant role in the findings. Also, the proportion of patients with HFPEF compared to patients with HFREF was not significantly different among groups.

Another potential explanation of our finding of a lack of difference among groups in the combined outcome of cardiac mortality and rehospitalization for HF may be the lack of integration of the patients' physicians in the trial. Keeping the physicians blind to patient assignment reduced a potential bias in the trial, but the lack of collaboration between the nurses who provided the educational intervention and the physicians who cared for the patients might explain the smaller beneficial effects that accrued. This observation was made by both Jaarsma regarding the COACH trial\textsuperscript{33} and Angermann regarding the INH trial\textsuperscript{34}; both tested a nurse-coordinated intervention and had similar findings to ours. It may be that the strong benefit noted in HF interdisciplinary disease management programs\textsuperscript{4,5} is a result of the collaboration that occurs between physicians and nurses and the uniformity of their approach to patients and their caregivers.

Examining mortality from cardiac causes specifically, patients in the Fluid Watchers LITE group had significantly fewer cardiac deaths (7.5\% vs. 17.7\%) over the two-years of follow-up compared to either the control or PLUS group. Since the groups were equivalent on all demographic and clinical variables, with the exception of hypertension history, and HF hospitalization rates were not significantly different across groups in the two-years of follow-up,
we examined the data for other potential explanations of differences in cardiac deaths. Patients in the PLUS group had almost twice as many physician visits as patients in the LITE group. On reflection, this higher number of visits is not surprising in that nurses focused on reviewing the daily logs with the patients and encouraged them to call their physicians if they experienced an increase in weight or HF symptoms, particularly in the extra telephone reinforcement sessions of the PLUS group. Although not significant, hospital admissions for HF were highest in the PLUS group compared to either control or LITE, suggesting that physicians may have responded to patients’ concerns or changes in weight and/or symptoms by recommending hospitalization.

A recent comparative effectiveness research study\textsuperscript{35} evaluated a similar HF self-care training intervention with both intervention groups receiving a single face-to-face training session and patients then randomized to either the single-session or a multisession group that received 5 to 8 phone calls over 4 weeks. The primary hypothesis was a decrease in all-cause death and hospitalization in the multisession group and data were collected over 12 months. The investigators found no differences between the two groups until an analysis was conducted by literacy levels. Among those with higher literacy, the multisession intervention yielded a higher incidence of all-cause hospitalization and death. The investigators suggested that for these patients “the additional phone calls may have led to closer attention to symptoms and subsequently more admissions.” (p. 2860). Although the setting was urban, their findings partially confirm our experience with worse outcomes in the intervention group when patients received multiple reinforcement calls. Baseline testing revealed no differences in literacy levels in our study and the majority of patients demonstrated adequate literacy, but the findings of DeWalt and colleagues\textsuperscript{35} suggest that literacy is an important characteristic to be assessed in any test of an education intervention.
Ultimately, the primary hypothesis of our trial was based on a composite endpoint, and the hypothesis was rejected. Composite endpoints have been used in many HF trials to increase statistical power.\textsuperscript{36,37} However, composite endpoints only increase statistical power if the intervention has a similar effect on multiple aspects of the composite. The inclusion of factors in the composite end point that are not impacted by the intervention, or even impacted negatively, dilutes the observed treatment effect and decreases the overall statistical power. Although hospitalizations for HF have been a target for intervention over the past several decades because of the high cost incurred by the health care system, particularly for Medicare patients, investigators may want to reconsider the wisdom of using this target as an outcome variable. Hospitalizations as an end point are sensitive to the judgement of the clinician and the unique situation of each HF patient and family, and as such they may not be an accurate assessment of the effect of a particular intervention. Also, with the exception of the first 30 days following hospitalization for HF in Medicare patients, the current system incorporates powerful forces that encourage hospitalization of HF patients for both financial and legal reasons, which are not necessarily influenced by an intervention focused on increasing HF patient’s self-care.

The heterogeneity in the results of various trials testing educational interventions for the HF population may be partially explained by methodological variances in length of follow-up, category of outcomes measured and type of intervention tested (e.g., disease management, one-time education session, telephonic follow-up, remote monitoring), as well as the demographic and clinical variances in patients. Other investigators who have documented reductions in mortality with increases in health care resources, particularly hospitalizations, that were similar to ours have noted that heterogeneity in outcomes makes it difficult to recommend a single educational model to promote self-care and improve clinical outcomes.\textsuperscript{38,39}
Cardiac mortality is clinically relevant, simple, and relatively inexpensive to measure. It is also unambiguous. From the patient’s perspective, cardiac mortality may not be as relevant as all-cause death, and from the investigator’s standpoint it implies the added burden of expanding a study’s sample size with a concomitant demand for increased funding. However, a test of an intervention such as the one in this trial that is focused specifically on preventing HF exacerbations is best evaluated using the specific outcome most germane to the intervention, which is cardiac death.

Limitations
First, the rural population targeted for this trial was unique and the ability to generalize our results to other HF populations, particularly those in urban settings or in countries other than the United States, is therefore limited. Second, any face-to-face encounter is difficult to standardize. Intervention fidelity was enhanced by training sessions with all nurse educators and the use of flip charts and checklists in the intervention session; moreover, the fact that the same nurse provided education to patients in both intervention groups at the various sites suggests that the approach and content were similar across the two groups and any differences in outcome are based on the reinforcement strategies. Nonetheless, the intervention is complex and there may have been differences between the two groups that were not appreciated by the investigators. Third, follow-up extended over two years and it can be assumed that physicians changed medication regimens or other aspects of treatment over that time. Medications were only recorded at baseline. Although there were no differences between the groups in the proportion of patients on specific medications upon enrollment, we cannot be sure that the difference in cardiac mortality between the LITE and control groups was not related to changes in patients’
medical regimen. Nonetheless, given that physicians were blinded to patient assignment, it would seem that such changes should be random and therefore not linked to the positive outcome of one group. Finally, it is recognized that efforts to distinguish cardiovascular deaths from other lethal events are not always successful.\(^4^0\) Although we used the usual blinded adjudication process and death certificates to determine cause of death, some mortality events may have been misclassified.

In summary, a face-to-face education and counseling intervention delivered by a nurse and focused on increasing knowledge about HF and self-care in patients with HF living in rural areas did not significantly decrease the combined end-point of cardiac death or re-hospitalization for HF, although self-care behaviors increased in both intervention groups and cardiac mortality was significantly decreased. Increasing the number of contacts between the patient and nurse did not significantly improve the outcome.

**Funding Sources:** This study was funded by the National Heart, Lung, and Blood Institute (NHLBI) and the National Institute of Nursing Research (NINR): 5R01HL83176-5

**Conflict of Interest Disclosures:** None.

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Table 1. Comparison of baseline characteristics across the three study arms (N=602)

<table>
<thead>
<tr>
<th></th>
<th>Total N=602</th>
<th>Control group (n=209)</th>
<th>Fluid Watchers LITE group (n=200)</th>
<th>Fluid Watchers PLUS group (n=193)</th>
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<tbody>
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<td>Sociodemographics</td>
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<tr>
<td>Mean age (+SD)</td>
<td>66.1 ± 12.9</td>
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<td>87.6 (183)</td>
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<td>.73</td>
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<td>Education:</td>
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<td>- less than high school</td>
<td>18.8 (113)</td>
<td>22.0 (46)</td>
<td>17.5 (35)</td>
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<td>- high school graduate only</td>
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<td>44.5 (93)</td>
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<td>48.7 (94)</td>
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<td>33.1 (199)</td>
<td>33.5 (70)</td>
<td>31.0 (62)</td>
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<td>Health literacy score, % correct</td>
<td>70.9 ± 25.5</td>
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<td>4.9 (9)</td>
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<td>11.7 (20)</td>
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<tr>
<td>Don’t know/Refused to report</td>
<td>11.8 (71)</td>
<td>12.9 (27)</td>
<td>11.0 (22)</td>
<td>11.4 (22)</td>
<td></td>
</tr>
<tr>
<td>Marital status: currently married/cohabitating</td>
<td>56.6 (341)</td>
<td>57.4 (120)</td>
<td>55.0 (110)</td>
<td>57.5 (111)</td>
<td>.85</td>
</tr>
<tr>
<td>Number living at home:</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>.87</td>
</tr>
<tr>
<td>Alone</td>
<td>23.4 (141)</td>
<td>23.0 (48)</td>
<td>24.5 (49)</td>
<td>22.8 (44)</td>
<td></td>
</tr>
<tr>
<td>= 1</td>
<td>52.3 (315)</td>
<td>51.2 (107)</td>
<td>51.5 (103)</td>
<td>54.4 (105)</td>
<td></td>
</tr>
<tr>
<td>≥ 2</td>
<td>24.3 (146)</td>
<td>25.8 (54)</td>
<td>24.0 (48)</td>
<td>22.8 (44)</td>
<td></td>
</tr>
<tr>
<td>Employed</td>
<td>14.5 (87)</td>
<td>11.5 (24)</td>
<td>13.0 (26)</td>
<td>19.2 (37)</td>
<td>.07</td>
</tr>
<tr>
<td>Risk factors</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Current smoker</td>
<td>12.6 (76)</td>
<td>12.9 (27)</td>
<td>11.5 (23)</td>
<td>13.5 (26)</td>
<td>.83</td>
</tr>
<tr>
<td>High Cholesterol</td>
<td>67.1 (404)</td>
<td>68.9 (144)</td>
<td>67.0 (134)</td>
<td>65.3 (126)</td>
<td>.74</td>
</tr>
<tr>
<td>High blood pressure</td>
<td>80.9 (487)</td>
<td>85.6 (179)</td>
<td>73.0 (146)</td>
<td>83.9 (162)</td>
<td>.002</td>
</tr>
<tr>
<td>Sedentary</td>
<td>48.6 (292)</td>
<td>52.9 (110)</td>
<td>48.0 (96)</td>
<td>44.6 (86)</td>
<td>.24</td>
</tr>
<tr>
<td>BMI &gt; 25</td>
<td>74.5 (446)</td>
<td>73.1 (152)</td>
<td>76.8 (152)</td>
<td>73.6 (142)</td>
<td>.66</td>
</tr>
<tr>
<td>Cardiac history</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Angina</td>
<td>46.2 (278)</td>
<td>50.2 (105)</td>
<td>44.5 (89)</td>
<td>43.5 (84)</td>
<td>.34</td>
</tr>
<tr>
<td>Acute myocardial infarction</td>
<td>50.3 (303)</td>
<td>50.7 (106)</td>
<td>55.5 (111)</td>
<td>44.6 (86)</td>
<td>.09</td>
</tr>
<tr>
<td>Angioplasty</td>
<td>34.4 (207)</td>
<td>37.8 (79)</td>
<td>31.5 (63)</td>
<td>33.7 (65)</td>
<td>.39</td>
</tr>
<tr>
<td>Coronary artery bypass graft</td>
<td>31.2 (188)</td>
<td>30.6 (64)</td>
<td>31.5 (63)</td>
<td>31.6 (61)</td>
<td>.97</td>
</tr>
</tbody>
</table>
Heart value surgery  10.8 (65) 10.0 (21) 13.0 (26) 9.3 (18) .46
Cardiac Function
Cause of heart failure  .68
  Ischemic/MI/CAD  47.7 (286) 50.0 (104) 49.7 (99) 43.0 (83)
  Hypertension  24.3 (146) 24.0 (50) 23.6 (47) 25.4 (49)
  Cardiomyopathy  18.2 (109) 15.4 (32) 17.6 (35) 21.8 (42)
  Idiopathic /Viral/ Other  9.8 (59) 10.6 (22) 9.0 (18) 9.8 (19)
Ejection Fraction  .73
NYHA  .41
  I  10.6 (64) 8.2 (17) 12.0 (24) 11.9 (23)
  II  54.1 (325) 55.3 (115) 51.0 (102) 56.0 (108)
  III  31.1 (187) 30.3 (63) 35.0 (70) 28.0 (54)
  IV  4.2 (25) 6.3 (13) 2.0 (4) 4.1 (8)
Cardiac medications
Diuretic  84.2 (506) 87.1 (182) 84.9 (169) 80.3 (155) .17
Digitalis  22.7 (136) 21.5 (45) 26.8 (53) 19.7 (38) .22
ACE inhibitor  56.4 (337) 52.2 (108) 58.6 (116) 58.5 (113) .33
Beta Blocker  80.0 (481) 78.0 (163) 77.9 (155) 84.5 (163) .18
Anticoagulant  79.4 (477) 82.3 (172) 77.4 (154) 78.2 (151) .42
Angiotensin II receptor blockers  19.0 (114) 22.5 (47) 16.1 (32) 18.1 (35) .24
Aldosterone inhibitors  23.2 (139) 27.4 (57) 20.6 (41) 21.2 (41) .19

Table 2. Total self-care scores at each visit by group.

<table>
<thead>
<tr>
<th>Visit</th>
<th>Group</th>
<th>Control (n=209)</th>
<th>Fluid Watchers LITE (n=200)</th>
<th>Fluid Watchers PLUS (n=193)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Mean</td>
<td>Std. Error</td>
<td>Mean</td>
<td>Std. Error</td>
</tr>
<tr>
<td>Baseline</td>
<td>24.61</td>
<td>0.54</td>
<td>25.15</td>
<td>0.55</td>
</tr>
<tr>
<td>3 Months</td>
<td>23.32</td>
<td>0.48</td>
<td>21.18</td>
<td>0.50</td>
</tr>
<tr>
<td>12 Months</td>
<td>23.41</td>
<td>0.52</td>
<td>21.49</td>
<td>0.53</td>
</tr>
<tr>
<td>24 Months</td>
<td>23.15</td>
<td>0.54</td>
<td>21.92</td>
<td>0.56</td>
</tr>
</tbody>
</table>
Table 3. Comparison of clinical outcomes by treatment group (N=602)

<table>
<thead>
<tr>
<th>Event</th>
<th>Control (n=209)</th>
<th>Fluid Watchers LITE (n=200)</th>
<th>Fluid Watchers PLUS (n=193)</th>
<th>Significance</th>
</tr>
</thead>
<tbody>
<tr>
<td>HF hospital admission or cardiac death</td>
<td>79 (37.8)</td>
<td>57 (28.5)</td>
<td>75 (38.9)</td>
<td>.058</td>
</tr>
<tr>
<td>HF hospital admission</td>
<td>64 (30.6)</td>
<td>53 (26.5)</td>
<td>63 (32.6)</td>
<td>.397</td>
</tr>
<tr>
<td>Cardiac death+</td>
<td>37 (17.7)</td>
<td>15 (7.5)</td>
<td>23 (11.9)</td>
<td>.008</td>
</tr>
<tr>
<td>Death from any cause</td>
<td>52 (24.9)</td>
<td>36 (18.0)</td>
<td>37 (19.2)</td>
<td>.185</td>
</tr>
<tr>
<td>Physician office visits for HF^</td>
<td>27 (12.9)</td>
<td>23 (11.5)</td>
<td>46 (23.8)</td>
<td>.001</td>
</tr>
</tbody>
</table>

+Control vs LITE p=0.003, Control vs PLUS p=0.123, LITE vs PLUS p=0.172
^ Control vs LITE p=0.388, Control vs PLUS p=0.006, LITE vs PLUS p=0.001

Figure Legends:

Figure 1. Flow of participants through the trial.

Figure 2. Comparison of three treatment groups over time on cardiac death or HF-related hospital admission.

Figure 3. Comparison of three treatment groups over time on survival from cardiac death. LITE compared to usual care p=0.005; LITE compared to PLUS p=0.191; PLUS compared to usual care p=0.112.
Figure 1

Enrollment

Assessed for eligibility (n=636)

Failed inclusion criteria (n=12)
Refused to participate (n=10)

Randomized (n=614)

Allocated to LITE Group (n=203)
Received LITE (n=202), 1 Deceased

Lost-to-followup: 39
- Reasons
  - Unable to contact (n=8)
  - Moved out of area (n=4)
  - Health problems, dialysis, cancer (n=11)
  - Family health or family request (n=1)
  - Per physician (n=2)
  - Hospice, nursing home, cardiac rehab (n=3)
  - Patient decision (unstated reason) (n=5)
  - Inconvenience, too busy (n=3)
  - Homeless (n=2)

No primary end-point data (n=3)
- Reason
  - Failure to complete follow-up after 3-months

Primary outcome analysis (n=200)

Allocated to PLUS Group (n=198)

Lost-to-followup: 29
- Reasons
  - Unable to contact (n=11)
  - Moved out of area (n=1)
  - Health problems, dialysis, cancer (n=8)
  - Family health or family request (n=4)
  - Patient decision (unstated reason) (n=1)
  - Inconvenience, too busy (n=3)
  - Homeless (n=1)

No primary end-point data (n=5)
- Reason
  - Failure to complete follow-up after 3-months

Primary outcome analysis (n=193)

Allocated to Usual Care Group (n=213)

Lost-to-followup: 29
- Reasons
  - Unable to contact (n=10)
  - Moved out of area (n=4)
  - Health problems, dialysis, cancer (n=5)
  - Per physician (n=1)
  - Joined another HF program (n=1)
  - Hospice, nursing home, cardiac rehab (n=2)
  - Patient decision (unstated reason) (n=2)
  - Inconvenience, too busy (n=4)

No primary end-point data (n=4)
- Reason
  - Failure to complete follow-up after 3-months

Primary outcome analysis (n=209)
Figure 2

Cumulative Survival

Number of Follow-up Days or Days Until Cardiac Death or First Rehospitalization

Lite
Usual Care
Plus

p = 0.167
Figure 3
A Randomized Controlled Trial to Improve Self-Care in Patients with Heart Failure Living in Rural Areas
Kathleen Dracup, Debra K. Moser, Michele M. Pelter, Thomas Nesbitt, Jeffrey Southard, Steven M. Paul, Susan Robinson and Lawton Cooper

Circulation. published online May 9, 2014;
Circulation is published by the American Heart Association, 7272 Greenville Avenue, Dallas, TX 75231
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Print ISSN: 0009-7322. Online ISSN: 1524-4539

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