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Isolating the Benefits of Fluid Restriction in Patients with Heart Failure: A Pilot Study

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Central to the treatment of heart failure (HF) is the management of volume status.¹ This principal treatment strategy includes medical therapy in the form of diuretics, lifestyle management in the form of sodium restriction, and a blending of the two in patient-titrated diuresis based upon daily weights and symptoms. Restriction of daily fluid intake is a lifestyle modification that was common prior to the advent of modern-day medications, and is still commonly prescribed, with reports of 37–89% of patients reporting prescription by their practitioners.^{2–4} Yet research on the validity of this intervention and specifically the patients' ability to adhere with a fluid restriction (FR) have been called in to question with recent guidelines only recommending FR in HF patients with persistent recurrent fluid retention despite sodium restriction and high-dose diuretic,¹ or for patients with severe hyponatremia or continued fluid congestion despite high diuretic dosage and dietary sodium restriction.^{5, 6}

To better understand the ability of people with HF to adhere with a prescribed FR and determine if patient reported outcomes and physiological measures could be influenced by adherence with the FR, a pilot study was developed around an intensive nurse-lead educational and behavioral intervention (EBI). We hypothesized that HF patients randomized to the EBI designed to promote self-regulation of FR and manage thirst would have greater adherence to a prescribed FR. Further, we postulated that in the context of appropriate and usual medical management of diuretics, patients adhering to a FR would experience less fluid congestion, symptom distress, and greater health related quality of life

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(HRQL) than those patients who were not adhering to a FR. Secondary aims were to describe the relationships between self-reported and objectively measured determinants of fluid status, symptoms, psychometric properties of the instruments piloted, and determine the effect sizes for measures demonstrating significant differences between groups for use in planning a subsequent study.

Background

The evidence for FRs in randomized clinical trials is conflicting. Four studies have inferred clinical benefit in their randomized samples of 46 to 410 persons with HF assigned to varying restricted sodium diets, restricted fluid intakes, and varying dosages of diuretics. Noted outcomes include improved NYHA class and leg edema,^{7, 8} reduced readmissions,⁹ reduced BNP,⁹ reduced aldosterone,⁹ reduced plasma renin activity,⁹ lower kilocalories,⁸ lower macronutrients,⁸ lower fluid intake,⁸ lower urinary excretion of sodium,⁸ less fatigue,⁹ improved physical activity and functional class,⁸ and better HRQL.^{8, 10}

Alternatively, no clinical benefit was found in a Brazilian study of 75 patients hospitalized for acute HF randomized to 800 ml/d fluid and 800mg sodium restricted diet. This study found no effect in weight loss or clinical stability at 3 days and no difference in readmission at 30 days.¹¹ Similarly, a Swedish study utilizing a cross-over design in 74 stable, HF outpatients followed for 16 weeks found no significant differences in HRQL, physical capacity, morbidity, or mortality between those ingesting 1.5 liters per day or a patient specific 35ml/kg.^{12, 13} Of note, both of these studies reported that patients randomized in the tighter FR reported a greater sense of thirst and more difficulties in adherence to the fluid prescription.

Thirst and Adherence

Thirst may influence the ability of patients to adhere with a prescribed FR. While there are recommendations for fluid requirements in a day (2730 ml/day for healthy sedentary women, and 3750 ml/day for healthy sedentary men), most healthy people meet their daily hydration needs by letting thirst guide their intake.¹⁴ Adherence with a prescribed FR has been described as causing profound thirst, “which is one of the most agonizing and troublesome symptoms experienced by patients with moderate to severe HF”.¹² Thirst has been described as a subjective symptom or sensation of dryness in the mouth and throat with an associated desire for fluids.^{15, 16} Beyond the subjective sensations, thirst has a physiological etiology in the HF patient. Due to low cardiac output, the renin-angiotensin-aldosterone axis is activated triggering the thirst center in the hypothalamus.¹⁷ Compounding this is the sensation of dry mouth due to lack of saliva, or xerostomia, that is induced by diuretics.¹⁸

While behavioral studies to improve adherence to a prescribed FR have been undertaken in the renal population,^{19, 20} few approaches have proven effective. In persons with HF, both a recent pilot intervention study (n=30)²¹ and a subsequent larger study of 97 patients⁷ demonstrated positive results in helping patients better adhere to a FR through individualized patient counseling and education.²¹ In another study of persons with HF and hyponatremia (n=46) randomized to an aggressive 1000ml FR or usual care, a trend toward

improved adherence with fluid restricting behaviors ($p=.11$) was found in the intervention group receiving education on quenching thirst without increasing fluid intake, measuring fluid intake, and determining fluid sources. Actual measurement of fluid intake in this study was not undertaken, but patients rated their ability to manage fluid intake and adherence. An additional finding was no difference between groups in the sensation of thirst as measured by a 100mm VAS scale.

In summary, the literature is sparse and conflicting on the patient reported outcomes and physiological measures influenced by a prescribed FR. While some clinical benefits have been observed including decreased hospitalizations, questions remain about the ability of the patient to adhere with the prescription and manage adverse sensations such as thirst. The two recent studies demonstrate promise for improving adherence with FR through meaningful education and counseling of patients which may translate into improved clinical and patient reported outcomes. However, none of the studies to date have isolated the effect of a measurable FR over other self-care interventions and evaluated a comprehensive set of outcomes including adherence, physiologic measures of clinical stability, and patient reported outcomes.

Methods

As part of a larger study evaluating FR adherence and outcomes in HF patients with an intrathoracic impedance measurement (IIM) device, a randomized controlled approach with longitudinal follow up was used to ascertain if the EBI improved adherence with a prescribed FR in comparison to an attention control (AC) group. A comprehensive set of outcomes were examined for trends in effects and to determine effect size for use in planning a future study including adherence with FR (three day food record), physiologic measures of fluid congestion (daily weights, BNP, and the congestion score), patient reported symptom distress (heart failure symptoms and thirst) and HRQL at baseline, 3 and 6 months.

Setting and Sample

Institutional Review Board approval including HIPAA waiver for eligibility screening, was granted for the screening, consent, and enrollment of eligible participants from a large Center for Heart Failure Therapy in the Southeast US. All aspects of this investigation conformed with the principles outlined in the Declaration of Helsinki.²² NYHA class II to IV outpatients were recruited who met the additional inclusion criteria of: presence of an intrathoracic impedance monitoring device (IIM), hospitalization for HF exacerbation within the previous six months; ability to read, write, and speak English; appropriate medical management with prescribed daily diuretics, angiotensin converting enzyme inhibitors or angiotensin II receptor blockers, and beta-blockers (or documented contraindication);¹ prescribed FR of 1.5 to 2 liters per day; and telephone access. Exclusion criteria included residence over 100 miles from the enrolling center; physical or mental impairments that would limit ability to comply with study procedures; medical condition which could cause HF exacerbations such as renal failure defined as serum creatinine greater than 2.0mg/dl, anemia defined as a hemoglobin less than 10gm/dl, or documented, uncontrolled

hypothyroidism. While inclusion criteria required the presence of an IIM device, the impedance values were not collected by the researcher until study conclusion and thus did not influence the intervention. Further, while the IIM readings were noted by the clinical providers, the values were being evaluated for their clinical utility and care was primarily influenced by traditional provider physical assessment. Thus, patients with an IIM device in this study received care comparable to patients without the IIM device.

Data Collection

Within 2 weeks of enrollment, a home visit by the research nurse was conducted during which biologic samples and completed questionnaires were collected, and the education session detailed below was provided. A second home visit with the same data collection was completed at 3 months, and at 6 months, patients completed and mailed back only the self-reported measures.

An hour long education session was provided to all participants concerning usual information about HF, prescribed medications, need for daily weights, signs and symptoms of HF exacerbation which require medical attention, and 2000mg per day sodium restriction. Both groups were provided the education via a calendar/ educational booklet which included a daily log requiring daily journaling of weight, perception of health, and in the EBI group, the amount of daily fluid intake.

Intervention

Following recruitment and prior to the home visit, patients were randomized to either the AC or the EBI group using computer generated randomization schema for a 1:1 group allocation. The EBI was developed from a self-care framework^{23, 24} which postulates that fostering knowledge and skills will improve patient self-care behaviors, in turn improve outcomes.²⁵ Strategies to promote knowledge including the rationale for FR, and skills to implement FR were adapted from research in the renal population^{19, 20} such as conveying information related to the importance of the FR, goal setting, and self-monitoring using a daily log. The key elements and differences provided by group are listed in Table 1. Of note, daily logging of fluid intake has previously been demonstrated to assist in maintaining adherence to a FR,^{26, 27} thus, recording was used as a motivational means in the EBI group only and not for data collection purposes. Intentionally, persons assigned to the AC group were instructed to track only their weights and perception of health status daily.

The second component of the intervention provided to EBI group centered on providing feedback to the patient regarding the physiologic parameters measured during the baseline session, providing support, and encouraging adherence to the FR. This was accomplished with three scripted telephone calls to the patient, placed every other week starting two weeks from the baseline session. Importantly, autonomy supportive practices (discussing alternatives, minimizing pressure and criticism, and acknowledge the individual's feelings and perspectives) were employed while reviewing patient reported daily journaling of weight and fluid intake. AC group participants received calls to review weight logs only.

Variables and Measures

Several measures utilized in this study are well known having demonstrated accuracy or sound psychometric properties in this population including **Brain Natriuretic Peptide (BNP)**, a 32-amino acid peptide secreted predominantly from the ventricles in response to ventricular dilation,²⁸ and recognized as a ‘measure’ of congestion,²⁹ and the **EuroQOL (EQ5D)** a self-administered, validated, multi-attribute, preference-based measure of health status.³⁰ The remaining variables and measures are defined grouped below according to the domains assessed.

Self-Care Behaviors—While adherence with the prescribed FR was the self-care behavior of interest in this pilot, sodium ingestion needed to be accounted for given its physiologic relationship with water and possible contribution to excess fluid intake and possible thirst distress. Thus both fluid and dietary sodium were assessed with a **Three Day Food and Fluid Diary (3DFR)**. Following review by a research dietician blinded to group assignment, and prompting of participants for greater details on food preparation, portions, and discretionary salt use, the diet record information was analyzed with a computerized food composition software program (Nutritionist V®, First Databank, San Bruno, CA). Fluid intake reported in this study was determined from the 3DFR, and not the daily log previously described and used as a motivational tool only.

As a secondary means of validating sodium ingestion, **24-hour Urine Collection (24h Urine)** were collected at baseline and 3 month visits with patients in “steady state” (on stable medication regimen for at least 14 days), providing total volume, urinary sodium, urea and creatinine to determine completeness of collections based on standard formulas correcting for gender and age. More than 95% of ingested sodium is excreted in the urine,³¹ a measure validated in compensated HF patients.³² Calculated sodium ingestion was then evaluated for contribution to excess fluid intake and measures of thirst distress.

Physiologic Measures of Fluid Congestion—In addition to BNP, fluid congestion was determined with the **Congestion Score (CS)** by assigning a value of 1 for the presence of typical HF signs of orthopnea, jugular venous distention, peripheral edema, increase in weight, and/or the need to adjust diuretic doses. Scores were summed for a total possible score of 0–5 quantifying the degree of fluid retention.^{29, 33} The CS has previously been associated with two-year survival²⁹ and guided the clinical assessment of HF patients randomized to treatment based upon pulmonary artery catheter (PAC) values or clinical assessment.^{34, 35}

Patient Reported Symptom Distress—Patient reported symptoms were measured with the **Heart Failure Symptom Survey (HFSS)** and **Thirst Distress Scale (TDS)** at baseline, 3 and 6 months. The **HFSS** consists of 12 physical symptoms (e.g.: shortness of breath at rest, irregular heart beat) and two psychological symptoms (i.e.: depression and cognitive impairment),³⁶ for which participants rate the symptom severity, frequency, interference with physical activity and enjoyment of life during the past seven days on a scale of 0 (no symptom/ interference) to 10 (very frequent or severe/ great deal of interference). Items are summed along the four subscales with higher results indicating worse symptom experience

and interference. Psychometric evaluation reveals excellent content validity index coefficients ranging from 0.90 to 1.00³⁶ and good internal consistency across the four symptom dimensions with Cronbach alpha coefficients of .80, .87, .88 and .88 when tested with 138 HF subjects.³⁷ Originally developed to assess the thirst in patients requiring hemodialysis, thirst was assessed using the 6-item *TDS* for which participants rated items using a 5-point scale from 1 (strongly disagree) to 5 (strongly agree).³⁸ In the renal patients, inter-item correlations of the six items was found to range between .43 and .68, with Cronbach's alpha of .78,³⁸ a goodness-of-fit index of .94, and a relative chi-square of 4.52 representing good data-model fit.³⁹

Analysis

All data analyses were completed with SPSS statistical software version 21. Descriptive statistics were assessed for all measures (Table 2), and group means and standard deviations of outcomes were examined across time (Tables 3 and 4) as well as frequencies and percentages for dichotomized measures. All data collection was complete except for a few instances where BNP levels were unable to be ascertained because venipuncture was unsuccessful; as the missing values were equally represented in both groups, no substitutions were made and analysis was conducted with only values obtained.

All measures were assessed for skewness and outliers prior to analysis. Differences between groups at baseline were assessed using t-tests or Mann Whitney tests, chi-square tests and Fisher's exact tests as appropriate. BNP and congestion scores were right skewed so Mann Whitney non-parametric tests were performed to test for differences between the groups at baseline. For the outcomes measured only twice at baseline and 3 months [fluid, sodium (assessed via the 24 hour urine collection and 3DFR) BNP and congestion scores], change scores were calculated (3 months – baseline) and independent group t-tests run to test for difference between the groups for these change scores. While BNP and congestion scores were skewed at each time point, their difference scores were normally distributed. For the TDS and EQ5D-VAS outcomes measured at 3 time points, repeated measures analysis of variance (RM-ANOVA) was used to test for between group effects, within subject changes over time, and group by time interaction (intervention effects over time). Since HFSS Frequency and Severity scores were right skewed and slightly bimodal, they were dichotomized into “high scores” (>20) and “low scores” (≤ 20) based on their medians at baseline (baseline HFSS Frequency median=19, HFSS Severity median=20; 20 was chosen to be consistent for both scales). Given these two dichotomized outcomes, generalized multilevel linear models (GLMM; SPSS GENLINMIXED procedure) (using binary logistic function) were run to assess group, time and group-x-time effects.

For both the RM-ANOVA and GLMM approaches, when significance was found for model effects, post hoc tests for the multiple pairwise time comparisons were run using Sidak error rate adjustments. For significant results, Cohen's d effect sizes were calculated and reported. For all models, demographic variables (age, gender, race) and clinical measures (BMI, NYHA class and diuretic equivalents) were investigated as potential covariates. Only NYHA class found to be significant for the *Thirst Distress Scale* and was included as a

covariate in the RM-ANOVA. Significance for any statistical test was determined as $p < .05$, with all results and effect sizes reported when $p < .10$.

Results

A total of 244 patients followed by the HF clinic with systolic HF were screened for inclusion in this study with 27 consented, 25 completing the baseline assessment, 23 completing the three month, and 21 completing the six month assessments (Figure 1). Demographics of the 25 NYHA Class II–IV persons completing the baseline assessment are presented in Table 2. There were no significant differences between groups in baseline characteristics in this mostly Caucasian, male sample that ranged from 44–83 years of age. However, males had significantly higher NYHA class than females (NYHA class III/IV: males 10 [71.4%] versus females 3 [27.3%]; $\chi^2 = 4.812$, $p < .05$). A majority (60%) of the study sample had lived with HF for greater than 5 years, and mean EF was $23.0 \pm 11.7\%$. Attrition was equivalent between groups in both percent of group and time frame of study departure.

Concerns that several of the measures could be directly influenced by the amount of daily diuretics were evaluated using a standard formula to calculate furosemide equivalents such that 1 equivalent is equal to 1 mg bumetanide, 20 mg torsemide, 40 mg furosemide, or 50 mg ethacrynic acid.⁴⁰ Nearly all of the subjects completing the study were taking daily diuretics with no differences between groups observed in the amount of furosemide equivalents (AC mean 1.83 ± 1.78 ; EBI mean 0.96 ± 0.95 ; Mann Whitney $Z = -1.617$, $p = 0.11$).

Fluid restriction adherence

As presented in Table 3, patients tended to ingest about 2000ml fluid per day despite group assignment and provision of education and behavioral strategies. While a modest decrease was noted over time in the EBI group, this decrease by an average of 257 ml/day only trended toward significance ($p = .08$). Further, when considering the EBI subjects only, a paired t-test of fluid intake reduction from baseline to 3 months was significant ($t_{(11)} = 2.243$, $p < .05$), producing a moderate-to-large effect size,⁴¹ Cohen's $d = 0.65$. It should be noted that for only 21 EBI subjects this effect size would yield 80% power or better in a future study.

Group difference in dietary sodium was also examined due to its contribution to thirst and fluid intake. As previously described, both groups received counseling to reduce sodium consumption to less than 2000mg per day with specific education regarding label reading, meal planning, and strategies to handle difficult situations such as holiday eating and ordering in restaurants. No significant differences were observed in sodium intake between groups or over time, and both groups consumed less sodium at 3 months ($M = 3262\text{mg/day}$, $SD = 1900$) compared to baseline ($M = 3662\text{mg/day}$, $SD = 1977$) as measured by the 24 hour urine collection. Similar decreases were observed in the calculated sodium ingestion from analysis of the patient's *Three Day Food Record*. Our calculated sodium ingestion from the 24 hour urine and the *Three Day Food Record* were well correlated ($r = .536$, $p < .01$), reflecting stability of the measures.

Fluid congestion

To determine if objective measures of fluid congestion would differ between groups, BNP levels and the *Congestion Score* were analyzed. The covariates of gender, BMI and NYHA were investigated for the change scores of BNP; none were significantly associated with the BNP change scores. It should be noted, however, that while BMI was not significantly associated with BNP in this sample, Gender and NYHA were both significantly associated with BNP and with each other (71.4% of the men were NYHA Class III/IV compared to only 27.3% of the women, chi-square=4.812, df=1, p=.03). BNP for women was significantly lower than men at baseline (Mann Whitney Z=-2.481, p=.01). None of the covariates were significant for the congestion change scores (Table 3). There were no significant differences between the groups for their BNP and congestion change scores.

The *Congestion Score* demonstrated concurrent validity by a moderate-to-large correlation with BNP (Spearman's rho 0.401, p=.058). Pooling of patient reported daily measures of weights revealed very little variability and no differences between groups.

Patient reported symptoms

Symptom distress was measured by the *Heart Failure Symptom Survey* and the *Thirst Distress Scale*. As seen in Table 4, participants in the EBI did report a trend in less frequency (p=.13) and severity of symptoms (p=.06) when analyzed by dichotomizing on the median split of greater than and less than scores of 20. Because the group effect for HFSS Severity (>20) was close to significant (p=.06, Table 4), post hoc were performed confirming that the EBI group trended toward lower HFSS Severity scores than AC at 3mo (p=.06) and at 6mo (p=.09) with moderate effect sizes (Table 4 footnote 5). *Thirst Distress Scale* scores increased (worsened) significantly from 3 months to 6 months in the EBI group by an average of 4.70 points (p<.01, large effect size d=1.23) after adjusting for NYHA class (Figure 3). Cronbach α at baseline for the *Heart Failure Symptom Survey* was measured at .90 for each of the two subscales of frequency and severity, and the *Thirst Distress Scale* Cronbach α was .94 which while demonstrating strong internal consistency reliability of these scales, may indicate redundancy in concept measurement and an opportunity to decrease the number of items in future assessments.

Health related quality of life—As measured by the generic and utility generating EQ5D, participants in the EBI group had no significant change over time in their reported measures of HRQL. However, there was a significant increase in EQ-VAS scores for the AC group from baseline to 3 months (p=.01, large effect size d=1.08) and from baseline to 6 months (p=.01, large effect size d=1.05) (Table 4). Cronbach α at baseline was measured at .71 for the EQ5D.

There was a significant inverse relationship between the changes in *Thirst Distress Scale* and HRQL (EQ-VAS) from baseline to 6 months. Regardless of group, for subjects whose *Thirst Distress Scale* scores increased, a corresponding decrease in their EQ-VAS scores was observed. Simple linear regression revealed that for every 1 unit increase in *Thirst Distress Scale* score, subjects experienced an average decrease of 0.84 points in their EQ-VAS scores (significant moderate-to-large correlation $r=-0.46$, p=.04).

Discussion

While adherence to a FR could theoretically positively influence clinical outcomes, symptom burden, quality of life, health resource utilization and costs, research to date has been limited and inconclusive. Few studies have isolated the effect of FR from other self-care strategies such as sodium restriction and monitoring of symptoms and daily weights. This pilot study demonstrated that adherence with a prescribed FR remained difficult for patients even when provided with in-depth education and behavioral strategies. In this sample of NYHA class II–IV patients, those receiving the intervention consumed less fluid, but the amount did not reach statistical significance ($p = .08$).

No differences in clinical measures of congestion were observed. This may be explained in part by close self- and physician- monitoring resulting in diuretic titration. While no differences in baseline furosemide equivalents were noted between groups, diuretic dosage was adjusted throughout the study by the patient's medical provider.

Trending toward significance, the EBI group did report fewer typical HF symptoms and less severity of these symptoms. Unfortunately, they also had greater thirst distress as was observed in the Holst study which also isolated the effects of a FR as compared to other self-care strategies.¹³ Thirst is not a symptom that HF patients are routinely questioned about and it may be that the discussion of strategies to combat thirst distress may have primed EBI participants to be more sensitive to this symptom. The AC group did not receive any discussion regarding the symptom of thirst, how to assess this symptom, or strategies to manage.

Interestingly, HRQL significantly improved in the AC group over the course of the study as measured by the EQ5D visual acuity scale but remained stable in the EBI group. This finding was not expected nor is readily understood except that it may be attributed to the attention received in the study without the increased demands of adhering with a FR. Of note, a direct relationship between the adverse symptom of thirst and worse HRQL was observed through post-hoc linear regression. It may be that while other HF symptoms improved as a result of less fluid congestion secondary to better adherence with the FR, the symptom of thirst adversely affected HRQL such that no overall improvement was perceived by the participants receiving the FR intervention. Importantly, HRQL was not reduced overall in this EBI group.

Unlike earlier studies of FR,^{7–9, 11} this was the first study to isolate the contribution of FR alone in a normonatremic HF population as part of a self-management strategy, with direct measurement of fluid intake and measured clinical outcomes. The standardized education delivered to both groups included critical elements of self-care for persons with HF including a sodium restricted diet, monitoring of daily weight and symptoms, adherence with medications, and regular clinical appointments. Effectiveness of this intensive education session is evidenced through the noted decrease in sodium consumption over time in both groups. In other studies evaluating FR, part of their protocol included sodium restriction education in the intervention group, whereas in our study, sodium restriction was standard for both groups as our goal was to isolate the contribution of FR alone. Thus

patients receiving the prescribed FR as an element of patient self-care were found to decrease the number and severity of typical HF symptoms, experience greater thirst distress, and experience stable HRQL.

Importantly, this study demonstrated that no harm was experienced by patients who did not receive the intervention or chose not to comply with the FR. Despite the small sample size, there were significant results with large effect sizes for elements of thirst distress and reported HRQL by group assignment and over time. Further, the reliability of the measures for use in subsequent studies in this population was demonstrated. These data can be used to inform future work on FR and symptom distress, specifically thirst, and HRQL in HF patients. Further data are needed on whether FR of various levels can contribute to better clinical outcomes, and reduce health care utilization and costs. Finally, interventions to address thirst need further investigation in this population already burdened by disabling symptoms.

Limitations

The very small sample size limits generalizability and determination of significant differences between groups. During the planning phase of this study, a potential sample pool of approximately 275 patients seen in the HF clinic having an intrathoracic impedance measurement (IIM) device and meeting the inclusion criteria were identified. While this IIM device was a necessary component of the larger study, the requirement of this device limited the possible patient pool for recruitment. Whereas it was hoped that 25% would be eligible and agree to participate in the research, only 11% of the 244 assessed for inclusion were enrolled as detailed in the consort flow-chart (Figure 1).

One of the more challenging aspects of this research was the high rate of appointment nonadherence demonstrated by the frequency of appointment changes, cancellations, and “no-shows” encountered in the clinic when attempting to approach patients for inclusion.

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FIGURE 1.
CONSORT Flowchart

Table 1

Educational and Behavioral Content by Group Assignment

Timeframe	Both AC and EBI Group Educational Content	EBI Additional Educational and Behavioral Content
Home visit at baseline	<ul style="list-style-type: none"> Heart Failure: background, physiology, signs and symptoms Heart Failure Medications Low Sodium Diet: label reading and helpful strategies Measurement of daily weight and fluid intake Avoidance of harmful substances 	<ul style="list-style-type: none"> Fluid Restriction Education: rationale, physiology of fluid congestion, and strategies for limiting Behavioral: practice measurement, return demonstration Goal setting with patient regarding fluid intake and measurement strategies
Telephone Calls at 2, 4, and 6 weeks	<ul style="list-style-type: none"> Review daily weight log 	<ul style="list-style-type: none"> At 2 week call: Provide results from baseline visit. Illicit possible ways to address issues revealed by these findings; discuss successes of previous 2 weeks; support positive choices. Review Daily Weight and Fluid Log At 4 and 6 week calls: Address patient progress with goals made at baseline session and changes since last call. Support positive choices. Review Daily Weight and Fluid Log

Table 2

Baseline Demographic and Clinical Data (N=25 except where noted)

Variable	Overall			AC			EBI		
	Mean	SD	%	Mean	SD	%	Mean	SD	%
Age (years)	62.96	9.76	56%	64.50	8.66	58%	61.54	10.83	54%
Ejection Fraction	22.96	11.74		22.50	10.55		23.38	13.16	
Furosemide Equivalents (n=21)	1.27	1.48		1.83	1.78		.76	.95	
Variable	n	%		n	%		n	%	
Male Gender	14	56%		7	58%		7	54%	
Marital Status									
Married/Domestic Partner	19	76%		8	67%		11	85%	
Single/Divorced/Separated/Widowed	6	24%		4	33%		2	15%	
Race									
African American	5	20%		3	25%		2	15%	
Caucasian	20	80%		9	75%		11	85%	
Highest Education Completed									
Tech/vocational school, HS or Less	15	60%		8	67%		7	54%	
College or post Graduate	10	40%		4	33%		6	46%	
Length of Time with HF									
< 2 years	5	20%		1	8%		4	30.8%	
2 – 4 years	5	20%		3	25%		2	15.4%	
> 4 years	15	60%		8	67%		7	53.8%	
Type of HF									
Systolic	20	80%		10	83%		10	77%	
Mixed Systolic/ Diastolic	5	20%		2	17%		3	23%	
NYHA Classification									
II	12	48%		6	50%		6	46%	
III or IV	13	52%		6	50%		7	54%	
Attempting to Follow a Fluid Restriction at Baseline	23	92%		12	100%		11	85%	
Attempting to Follow a Sodium Restriction at Baseline	20	80%		11	92%		9	69%	

HS high school; HF Heart Failure; NYHA New York Heart Class

Table 3

Fluid, Sodium, BNP and Congestion Scores: descriptive statistics and group comparisons

Study Collection Time Point										
N Mean SD	Baseline			3 months			Change Scores (3mo-BL) ²			T-test (df)
	AC	EBI	EBI	AC	EBI	EBI	AC	EBI	EBI	
Group Difference @ BL ¹	AC	EBI	EBI	AC	EBI	EBI	AC	EBI	EBI	P
Fluid Intake from 3DFR (ml/ day)	12	13	11	12	11	12	11	12	12	
	2112.56	1971.47	2021.47	1702.63	-78.5	-256.8	178.3			
	906.23	548.69	881.01	432.81	552.8	396.5	199.3			
	t(23)=0.475, p= .639									
										t(21)=0.895 .38
Sodium from 24 hr urine (mg/day)	12	13	11	12	11	12	12	12	12	
	3684.25	3641.08	3115.73	3396.00	-807.3	-90.4	-716.9			
	2129.59	1912.68	1887.15	1985.94	2318.7	2116.0	924.5			
	t(23)=0.053, p= .958									
										t(21)=-0.775 .45
Sodium from 3DFR (mg/day)	12	13	11	12	11	12	12	12	12	
	2398.94	2382.34	2276.81	2558.97	-187.9	202.4	-390.2			
	1137.71	509.87	1076.42	1185.34	772.9	1393.0	476.1			
	t(14.99)=0.048, p= .962									
										t(21)=-0.820 .42
BNP (pg/ml)	12	11	9	11	9	10				
	234.84	201.45	214.57	189.91	37.7	-2.2	39.8			
	200.32	251.25	131.40	251.66	75.9	129.4	49.4			
	MW Z=0.862, p= .389									
										t(17)=-0.806 .43
Congestion Score (range 0-5)	12	13	11	12	11	12	12	12	12	
	1.50	1.46	1.18	1.25	-0.3	-0.3	-0.02			
	1.51	1.33	1.25	1.60	1.0	1.1	0.43			
	MW Z=-0.056, p= .955									
										t(21)=-0.053 .96

Abbreviations: SD standard deviation, AC attention control, EBI educational behavioral intervention

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At Baseline independent t-tests for difference run between groups for water and sodium (3DFR and ingested) and Mann Whitney non-parametric tests run for BNP and Congestion scores (which were skewed).

² Change scores calculated subtracting baseline (BL) values from 3 month values (change score=3mo-BL)

³ All change scores were normally distributed, independent 2-group t-tests runs

At Baseline independent t-tests for difference run between groups for TDS and EQ5D and Mann Whitney non-parametric tests run for HFSS Frequency and Severity scores (which were skewed).

2 NYHA class was a significant covariate for TDS where NYHA class III/IV had significantly higher TDS scores at all 3 time points.

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Study Collection Time Point							
Baseline	3 months		6 months		RM-ANOVA		
					Model Effects	F(df1,df2)	p
N Mean SD							
Group Difference @ BL ¹							
AC	EBI	AC	EBI	AC	EBI		
Thirst Distress Score (range 6–30)							
12	13	10	12	10	11	F(1,17)=5.894	.03
15.50	15.69	13.20	14.50	13.60	18.36	F(1,17)=0.825	.38
8.34	7.34	7.89	6.45	7.63	5.45	F(2,16)=3.617	.05
t(23)=−0.061, p=.952						F(2,34)=2.261	.12
EQ4D Visual Acuity Scale (range 0–100)							
12	13	11	12	10	11	F(1,19)=0.494	.49
58.58	56.77	72.00	59.92	70.50	61.82	F(2,18)=5.256	.02
19.19	21.75	17.66	20.21	18.77	19.27	F(2,38)=2.920	.07
t(23)=0.220, p=.828							
GLMM Binomial Logistic Models							
HFSS Frequency (split)							
12	13	11	12	10	11	F(1,63)=2.389	.13
6	6	8	3	5	2	F(2,63)=0.773	.47
50.0%	46.2%	72.7%	25.0%	50.0%	18.2%	F(2,63)=1.637	.20
$\chi^2(1)=0.037, p=.85$							
HFSS Severity (split)							
12	13	11	12	10	11	F(1,63)=3.651	.06
7	5	7	3	6	2	F(2,63)=0.235	.79
58.3%	38.5%	63.6%	25.0%	60.0%	18.2%	F(2,63)=0.370	.69
$\chi^2(1)=0.987, p=.37$							

- ³ Pillai's trace for Time for TDS overall ($p=.05$); for the EBI group ($F(2,16)=8.052$, $p<.01$) there was a significant increase in TDS scores from 3 months to 6 months (mean increase 4.703, $SE=1.151$, $p<.01$; $ES\ d=1.23$)
- ⁴ EQ-VAS significantly increased for the AC group ($F(2,18)=7.027$, $p<.01$) from baseline to 3 mo (mean increase 12.40, $SE=3.46$, $p<.01$, $ES\ d=1.08$) and from baseline to 6 mo (mean increase 12.20, $SE=3.67$, $p=.01$, $ES\ d=1.05$)
- ⁵ Post Hoc tests (Sidak adjusted) revealed that the EBI group had almost significantly lower HFSS Severity scores than AC at 3mo ($t(63)=-1.935$, $p=.06$, $ES\ d=0.49$) and at 6mo ($t(63)=-1.710$, $p=.09$, $ES\ d=0.43$).