Family partnership and education interventions to reduce dietary sodium by patients with heart failure differ by family functioning

Sandra B Dunbar, Emory University
Patricia Clark, Emory University
Kelly D. Stamp, Boston College
Carolyn Miller Reilly, Emory University
Rebecca A Gary, Emory University
Melinda K Higgins, Emory University
Nadine Kaslow, Emory University

Journal Title: Heart and Lung
Volume: Volume 45, Number 4
Publisher: Elsevier | 2016-07-01, Pages 311-318
Type of Work: Article | Post-print: After Peer Review
Publisher DOI: 10.1016/j.hrtlng.2016.04.001
Permanent URL: https://pid.emory.edu/ark:/25593/s3r9h

Final published version: http://dx.doi.org/10.1016/j.hrtlng.2016.04.001

Copyright information:
© 2016 Elsevier Inc. All rights reserved.
This is an Open Access work distributed under the terms of the Creative Commons Attribution-NonCommercial-NoDerivatives 4.0 International License (http://creativecommons.org/licenses/by-nc-nd/4.0/).

Accessed December 10, 2018 11:01 PM EST
Family Partnership and Education Interventions to Reduce Dietary Sodium by Patients with Heart Failure Differ by Family Functioning

Sandra B. Dunbar, PhD, RN, FAHA, FAAN\textsuperscript{a} [Charles Howard Candler Professor of Cardiovascular Nursing], Patricia C. Clark, PhD, RN, FAHA, FAAN\textsuperscript{b} [Professor], Kelly D. Stamp, PhD, ANP-C, RN, FAHA\textsuperscript{c,\textsuperscript{*}} [Associate Professor], Carolyn M. Reilly, RN, PhD\textsuperscript{a} [Assistant Professor], Rebecca A. Gary, RN, PhD, FAHA, FAAN\textsuperscript{a} [Associate Professor], Melinda Higgins, PhD\textsuperscript{a} [Associate Research Professor], and Nadine Kaslow, PhD\textsuperscript{d} [Professor]

\textsuperscript{a}Nell Hodgson Woodruff School of Nursing, Emory University, Atlanta, GA
\textsuperscript{b}Georgia State University, Byrdine F. Lewis School of Nursing, Atlanta GA
\textsuperscript{d}School of Medicine, Emory University, Atlanta, GA

Abstract

Objectives—Determine if family functioning influences response to family-focused interventions aimed at reducing dietary sodium by heart failure (HF) patients.

Background—Lowering dietary sodium by HF patients often occurs within the home and family context.

Methods—Secondary analysis of 117 dyads randomized to patient and family education (PFE), family partnership intervention (FPI) or usual care (UC). Dietary sodium measures were obtained from 3-day food record and 24-hour urine samples.

Results—In the poor family functioning groups, FPI and PFE had lower mean urine sodium than UC (p<.05) at 4 months, and FPI remained lower than UC at 8 months (p<.05). For good family functioning groups, FPI and PFE had lower mean sodium levels by 3-day food record at 4 and 8 months.

Conclusion—Optimizing family-focused interventions into HF clinical care maybe indicated.

Keywords

heart failure; family functioning; dietary sodium; adherence; self-care

\textsuperscript{*}Corresponding Author: Boston College, School of Nursing, Chestnut Hill, MA 02467, (617) 552-2119, stampk@bc.edu.

Disclosures: There are no disclosures or conflicts of interests.

Identifier removed: The Emory University Institutional Review Board and all participating sites approved all study protocols and the informed consent.

Publisher’s Disclaimer: This is a PDF file of an unedited manuscript that has been accepted for publication. As a service to our customers we are providing this early version of the manuscript. The manuscript will undergo copyediting, typesetting, and review of the resulting proof before it is published in its final citable form. Please note that during the production process errors may be discovered which could affect the content, and all legal disclaimers that apply to the journal pertain.
Introduction

Promoting heart failure (HF) self-care, especially the reduction of dietary sodium (Na) is challenging for patients and their families. The current clinical guidelines recommend that persons with HF (stage C) consume a low-Na diet consisting of 2–3 gram per day. However, this change in lifestyle is difficult to achieve and maintain, and consequently HF patients revert back to a higher Na diet relatively quickly. HF patients and family members efforts to follow a lower Na diet are difficult due to the amounts of hidden Na in foods, food preferences based on life long patterns, culture, and desire for foods to have a more ‘salty’ taste. The family member frequently is engaged in shopping and food preparation and may not be knowledgeable about low Na strategies. In addition, patients with HF are usually not objectively aware or counting their daily Na intake, therefore they may mistakenly believe that they are following a lower Na diet than what they actually consume.

Due to the chronic nature of HF, family members can provide social support, motivation, and positive communication that are a crucial component to the HF patient performing effective and sustainable self-care. They can provide support through encouragement, empathy, and a sense of choice regarding self-care for the HF patient. Individuals with HF are more likely to perform health behaviors (e.g. low-Na diet), or change unhealthy behaviors when they feel a sense of autonomy, competence and support by family members.

The purpose of this study was to conduct a secondary analysis of a previously reported family education and partnership intervention to examine: 1) the relationship between family functioning and dietary Na intake in persons with HF at baseline and 2) the effect of family context (family functioning) on the response to two types of patient and family interventions. The interventions that were tested against a usual care group included patient and family education and a family partnership intervention. The interventions and the clinical trial testing the effect of the interventions on self-care behaviors are reported elsewhere and identify the positive role of patient and family educational and support interventions on dietary Na intake.

Methods

Study Population and Design

This was a secondary analysis of the data from a 3-group randomized control trial of usual care (UC), patient-family education (PFE), and family-partnership intervention (FPI). HF patients and one family member (n=117) were randomized as dyads with data collection occurring at baseline, 4 and 8 months. The study was based on the model of heart failure self-care, which depicts the influence of individual patient antecedents (including demographic, clinical, behavioral factors), on self-care management and outcomes in heart failure within the influence of a family context. Greater details of study methods, interventions and consort flow chart have been described elsewhere; however, a brief description has been provided below. The Emory University Institutional Review Board and all participating sites approved all study protocols and the informed consent.
The (n=117) dyads were recruited from 3 large academic medical centers in the southeastern U.S. that were affiliated with HF outpatient clinics. Inclusion criteria for the HF patients were: (1) diagnosis of HF confirmed in the medical record, NYHA class II–III, (2) age 30–79 years, (3) ability to read, write and speak English, (4) telephone access, (5) on medication that included ACE-inhibitors or angiotension II receptor blockade, beta-blocker and diuretics unless contraindicated (6) ambulatory, (7) glomerular filtration rate > 30 ml/min and (8) availability of a participating family member who assisted with HF self-care. Exclusion criteria for patients with HF: (1) myocardial infarction within the last 6 months, (2) unstable angina, (3) renal failure, (4) impaired cognition, (5) psychiatric diagnosis of schizophrenia, dementia or any other mental health condition that would impair their ability to participate, (6) HF secondary to a treatable medical condition, (7) planned cardiac surgery or (8) uncorrected visual or hearing problems. Exclusion criteria for the family member was age less than 19 years, non-agreement to participate, or a cognitive impairment or psychiatric diagnosis that would affect their ability to participate and follow the intervention.

### Intervention Groups

**Usual Care (UC)**—UC group received usual care from their providers and was provided with educational pamphlets that were created by the Heart Failure Society of America (HFSA), which focused on HF self-care, dietary Na and medication adherence.

**Patient Family Education (PFE)**—The dyads assigned to the PFE group received UC as described above, the HFSA pamphlets, and an initial 1-hour education session delivered by a trained research nurse. Participants received written and DVD educational content, which included additional general information about HF symptoms and self-care. The dyads attended a second, 2-hour, group session led by a trained research nurse and registered dietician to reinforce education on diet adherence, label reading and Na alternatives. HF participants received feedback about their usual Na intake (see outcome measures; dietary sodium intake) and after 4-months, they received a telephone education booster session. In addition, newsletters were mailed to participants detailing strategies for maintaining a low-Na diet.

**Family Partnership Intervention (FPI)**—Dyads received the same education and counseling as described in the UC and PFE groups plus 2-additional 2-hour group sessions that focused on teaching the dyads how to give support, communication, empathy, and autonomy support for one another’s roles. The family member was counseled on how to decrease criticism and give autonomy support to the HF patient through motivating messages, increase family-problem solving, give choices to support the patient to have more control concerning their self-care, and to promote patient confidence. In addition to the written and DVD education described above, the dyads received written information about family partnership and autonomy support.
Demographic and Clinical Variables

Baseline demographic and clinical characteristics were collected by self-report and from the medical record for each HF participant. The Charlson Comorbidity Index was used to determine other chronic conditions. Additionally, type and dose of diuretics were collected and furosemide equivalents were calculated to account for residual effects of loop diuretics on Na excretion. Characteristics of age, sex, relationship to HF participant and education level were obtained via self-report from the family member.

Family functioning

The Family Assessment Device Questionnaire (FAD) measures family functioning via a 53-item scale that was derived from the McMaster Model of Family Functioning. The FAD is used to describe the overall health and dynamics of the family group and the patterns of communication among family members. In this study we focused on the 12-item global family function (GFF) subscale, which assesses the participant’s perception of the overall family health. Types of questions on the FAD that measured GFF were ‘planning family activities is difficult because we misunderstand each other,’ or ‘there are lots of bad feelings in the family.’ For each question the HF patient would choose from 1 (strongly disagree) to 4 (strongly agree). The GFF ranges from 1–4 (healthy to unhealthy family functioning). Cronbach alpha for the GFF in this study was 0.90. The standard cut score for the GFF was (2.0). The cut score was used to determine the percentage in the highest and lowest category for GFF, with score (>2) indicating poor GFF and lower scores (≤2) indicating better GFF. FAD-GFF was measured at baseline prior to randomization and interventions.

Depressive Symptoms

Depressive symptoms can be associated with adherence and was included as a covariate in the primary analysis testing the interventions. The well-established 21-item Beck Depression Inventory II (BDI-II) was used to measure patient depressive symptoms. The BDI-II assesses feelings of sadness, guilt, self-criticism, tearfulness, and feelings of cynicism or negativity. The items are on a scale from 0–3, representing the degree in which the symptoms were experienced in the past 2 weeks. The total scores range from 0–63, with scores ≥14 representing the presence of depressive symptoms. Cronbach alpha for this study was 0.90.

Outcome Measures of Dietary Sodium

Dietary Na was the main outcome and was measured in 2 ways: (1) 3-day food record and 24-hour urine analyzed for Na, creatinine, and urea. At baseline, 4 and 8 months HF participants were asked to complete a 3-day food record. The 3-day food record was then reviewed for completeness, accuracy and portions of foods consumed and then analyzed by a registered dietician. The registered dietician was blinded to the group assignment and used a software program – Food Processor SQL (version 10.2; ESHA Research), which is well validated in obtaining a mean daily Na intake. The 24-hour urine analysis was completed because 95% of ingested Na is excreted in the urine in the presence of normal kidney function therefore the urinary Na value serves as an objective measure of Na consumption. Participants were asked to collect their urine for 24 hours on the third day of completing...
their food record. Written instructions and supplies were provided to each participant for collecting their urine over a 24-hour period. Each participant received a reminder and education call concerning the procedures for collecting the urine the day before their scheduled collection of 24-hour urine. In this paper we will report the results of dietary Na intake via both the 24-hour urine and 3-day food record Na values.3

Data Analysis

Data were analyzed with SPSS v.22, included initial review for completeness (including assumptions for missing completely at random (MCAR), covariate-dependent MCA (CD-MCAR), or missing at random (MAR)18 and assessment of distributional assumptions. Due to incomplete urine collections for only 8.1% of the participants enrolled at each time point, the urine Na data were imputed using unbiased multivariate regression imputation based on BMI and urinary volume. Remaining missing data were due to attrition (which was 27.4% and even across the 3 groups with no significant differences at 4 or 8 months 3 and were missing at random. Intervention (group), time and group-by-time effects for 24-hour urinary Na values and 3-day food record were analyzed using multi-level modeling (MLM) treating group and time as factors adjusted for the covariates of gender and depressive symptoms (BDI-II). MLM was used instead of repeated measures ANOVA since it adjusts appropriately for missingness due to attrition over time.18 Furosemide equivalents were included as a covariate to adjust the 24-hour urinary Na levels relative to fluid variations. Depression (BDI-II) was also included as a covariate since participants who were missing at 8 months had higher baseline depressive symptoms (p=.06)3 Gender was also designated apriori as a covariate related to the outcomes. Post hoc pairwise comparisons were conducted (Sidak multiple comparisons error rate adjustment), which included contrasts for the hypothesized initiation phase (BL to 4 months) and maintenance phase (4 to 8 months), with p values of < .05 considered significant. In this study, adherence and clinical relevance of changes in dietary Na was reflected by 24-hour urine Na was assessed using the categories of adherent (urine Na levels ≤ 2500 mg/day) or non-adherent (> 2500 mg/day) to compare adherence proportions over time using Generalized MLM (GzMLM) for a binary outcome with a logit-link function for group, time and group-by-time effects adjusting for the covariates. Both the MLM for the urinary and food diary Na levels and GzMLM for the proportion adherent were stratified by family functioning as measured by the FAD from the patient’s perspective. The strata were: good family functioning defined as FAD-GFF scores ≤2 and poor family functioning defined as FAD-GFF > 2.

Results

Sample Characteristics

The CONSORT chart and detailed demographic and clinical characteristics were reported in Dunbar, et al 2013.3 Baseline data collection was completed by 117 dyads, and there were no significant differences among the 3 study groups in demographic or clinical characteristics.3 At baseline there were a total of n=37 in the UC; n=41 in the PFE; n=37 in the FPI groups. In the UC group, n=15 had poor family functioning and n=22 had good family functioning; PFE group, n=12 had poor family functioning and n=27 had good family functioning; and FPI, n=19 had poor family functioning and n=18 had good family
functioning. Of the 117 participants enrolled at baseline, 27.4% did not complete the study due to death, withdrawal or were lost to follow-up and there were no significant differences in attrition rates between the 3 groups.\textsuperscript{3}

The HF patients ranged in age from 28 to 78 years with a mean of 56 years; slightly more than a third were women; and more than 50% were African American. The participants were fairly well educated group with nearly half (47%) having a college or advanced degree education. Nearly two-thirds of HF participants were NYHA Class II, tended to be slightly overweight, and 36% having BDI-II scores indicating mild to moderate depressive symptoms. Half of the participating family members were spouses with another quarter of the family members being an adult child. Family member ages ranged from 19 to 78 years averaging 52.3 years of age and were primarily women (83%), African American (59%), and well educated (48% had college degrees).

### Dietary Sodium - Comparison of Groups at Initiation and Maintenance Phases

Table 1 presents the unadjusted means and standard deviations of the ingested Na from 24-hour urine and Table 2 presents the unadjusted means and standard deviations of the 3-day food diary for all participants in each group and split by good and poor family functioning. These levels of dietary Na are similar to reports in other HF studies.\textsuperscript{7,9} As previously reported \textsuperscript{3} when not adjusted for family functioning, for 24-hour urine Na there were significant group differences (p=.01) and close to significant changes over time (p=.06) with post hoc tests indicating that at 8 months the FPI group had significantly lower urine Na than UC (mean difference 1241.038, SE=449.427, p=.018), moderate-to-large effect size Cohen’s d=0.54\textsuperscript{19} whereas neither UC nor PFE achieved adjusted mean reductions more than 500 mg/day from baseline. When considering family functioning (Table 1), participants with poor family functioning tended to have higher Na levels at baseline. However, there was no significant association between family functioning scores and Na levels (r=0.074, p=.435) and, there were no significant differences in overall baseline Na levels between good and poor family functioning strata (t=−1.133, df=111, p=.260).

Figure 1 shows the adjusted mean 24-hour urine Na across time by study groups (with 95% confidence intervals) from the MLM ANCOVA adjusting for the covariates of gender, BDI-II scores, and furosemide equivalents stratified by good and poor family functioning. For the good family functioning strata none of the effects were significant (group, time, group-by-time) and none of the covariates. For the poor family functioning strata, however, all 3 covariates were significant: gender (p=.001) (women participants had lower Na levels than male participants), BDI-II (p=.006) (participants with higher depressive symptoms had higher Na levels) and furosemide equivalents (p=.010) (participants with higher furosemide equivalents had higher Na levels). After adjusting for these covariates, for the poor family functioning strata, the group effect was significant (p=.012) with post hoc tests yielding significant differences with FPI having lower urine Na than UC at 4 months (p=.024) and 8 months (p=.018).

Figure 2 shows the adjusted mean of the Na recorded by the 3-day food record across time by study groups (with 95% confidence intervals) from the MLM ANCOVA adjusting for the covariates of gender and BDI-II scores, stratified by good and poor family functioning. For
the good family functioning strata the time effect was significant (p=.024) with the covariate gender significant (p=.017) (women participants had lower Na levels than male participants). After adjusting for these covariates, for the good family functioning strata, the post hoc test revealed that there were significant decreases in dietary Na from baseline to 4 months for both the PFE (p=.052) and FPI (p=.028) groups. Also, in Figure 2, the 95% confidence intervals for the 3-day food record Na levels were completely below 2500 mg/day at both 4 and 8 months indicating the PFE group was significantly adherent after baseline. For the poor family functioning strata, however, none of the effects were significant. It is also worth noting that overall the Na levels for the 3-day food record are much lower than those from the 24-hour urinary Na (comparing levels in Figures 1 and 2) indicative of common under-reporting and under-estimating Na consumed.

Figure 3 shows the percentage of participants meeting recommended Na adherence levels (≤2500 mg/day) by group over time stratified by good and poor family functioning. Using Generalized Multilevel Models (binary response logit-link function) for these proportions of participants meeting the recommended ≤2500 mg/day Na levels: for the good family functioning strata, PFE showed significant change from baseline to 8 months (p=.024); for the poor family functioning strata, at 8 months the proportion of the FPI group meeting the ≤2500 mg/day Na was significantly higher than UC (p=.011) and greater proportion of the PFE group was adherent at 8 months than UC but this was not significant (p=.133). The covariates of gender (p=.01) and depression BDI-II (p=.05) were significant for only the poor family functioning strata.

Discussion

Our first aim was to determine the effect of family context at baseline on dietary Na intake in persons with HF. Once grouped by family context (i.e. good and poor family functioning scores) we found that participants with poor family functioning had higher levels of Na intake at baseline than those with good family functioning. Although this difference was not statistically different, the levels of difference are clinically relevant and reflect that family context may have an effect on HF patients’ ability to adhere to a lower Na diet. Prior literature supports this trend by showing the positive effects that good family functioning can have on patient’s ability to adhere to their chronic illness regimen.\textsuperscript{2,7,20,21}

Our second aim was to examine the effects of family context (e.g. family functioning) on response to two types of patient and family interventions. Because good family functioning has been linked to better patient outcomes,\textsuperscript{15} we were interested to know if adding more information, communication support and problem solving was useful for those experiencing better and worse family contexts. When examining the response (per the 24-hour urine sodium results) to the two types of patient and family interventions compared with UC by good and poor family functioning scores, we found that those HF patients with poor family functioning scores benefited from the more intense family focused intervention than those with reported good family functioning scores. This finding is important and is congruent with prior studies showing that a family’s influence on health can be quite powerful on a patient’s emotional and physical state – ultimately affecting their ability to perform recommended self-care.\textsuperscript{22} As we know, HF requires a tiresome and at times complex
regimen (i.e. low Na diet) that requires major changes in the family lifestyle, ways of role functioning and autonomy of family members and/or the patient. Families can either ‘reorganize’ and adapt to the new regimen with the HF patient or undermine the disease management recommendations thereby affecting self-care. When dyads start with poor family dynamics, non-supportive behavior could simply be due to lack of knowledge about HF itself and/or poor communication habits. An intense intervention such as the FPI presented in this study provides more opportunity and time for behavior change within the family leading to better family communication and patient outcomes.

Furthermore, providing chronic care interventions is resource intensive especially when patients do not follow provider recommendations. The findings from this study provide knowledge and understanding of the risk factors/characteristics (e.g. poor family functioning) of those HF patients that could benefit from a more intense family partnership intervention. This secondary analysis sheds light on the possibility that not all patients need the same type of intervention and level of intensity, which can increase precision in nursing and education interventions, clinician efficiency and healthcare costs while improving patient outcomes.

Lastly, based on the model we were interested in the influence of family functioning on HF patients’ adherence to a low Na diet when controlling for gender, depressive symptoms, and furosemide levels. For the good family functioning strata, none of the covariates were significant. However, our findings indicated that for the poor family functioning group, when controlling for gender (women had lower Na levels than men), those with higher depressive symptoms had higher Na levels and those taking greater doses of furosemide-like diuretics, which controls for effects on sodium excretion and reflects higher severity of HF, had higher Na levels at 4 and 8 months. It is not surprising that higher depressive symptoms were associated with lower adherence to a low Na diet, as prior studies have shown poor self-care adherence in those with higher depressive symptoms. This was specifically demonstrated in the poor family functioning strata, and likely reflects the increased vulnerability for poor dietary adherence that depressive symptoms add when the family context is not ideal. Likewise, research has shown that in general women with HF tend to be more adherent to a lower Na diet than do men. However, in the presence of poor family functioning we continued to see lower Na levels with the greatest and most sustained change in those exposed to the FPI when measuring Na via 24-hour urine at 4 and 8 months. We did not see significant effects in those with poor family functioning when measuring Na via the 3-day food record. As stated before, this could be due to underreporting and underestimating Na intake by the patient with HF. Prior literature supports that family and patient educational sessions improves patient’s attitudes, feeling of control over their condition, depressive symptoms, medication adherence and health outcomes. However, the finding that gender differed only in relation to following a low Na diet in one strata (poor family functioning) was unexpected. This may be explained in that poor family functioning is indicative of less family member knowledge about the importance of adhering to a low Na diet and the family member not providing support in terms of encouragement, assistance when shopping for low Na foods and preparing meals, however women with good family functioning and poor family functioning tend to have a greater resiliency to succumbing to a higher Na diet. A possible explanation could be that women tend to be the food preparers of...
the household and have more general knowledge about how to actualize a lower Na diet, therefore, poor family functioning may not have as negative effects on their dietary restrictions as do men who may not have as much knowledge about food shopping and preparation and may not be in charge of preparing their own meals. As explained above, those in the FPI group received intensive education and counseling for both the HF patient and family member overtime regarding the importance of maintaining a low Na diet. This type of reinforcement may have helped family members and HF patients with poor family functioning improve their communication, which promoted the HF patient’s adherence to their diet and treatment regimen. When family function is poor, the ability of the family to adapt, manage conflict and problem solve is in jeopardy. It is possible that the intervention focusing on communication and problem solving for the benefit of the HF patients may have helped reduce the overall impact of the poor family function.

Limitations

There are limitations to this study. First, we used an existing data set and researchers had access to only the data collected in the original study. Second, as stated in the original research paper both intervention groups received objective feedback about their Na levels, which could have introduced bias regarding the outcome of the study. Third, dietary Na measures can be inexact and affected by inaccurate or incomplete urine collection, inaccurate or incomplete 3-day food record or prescribed medications such as diuretics and may not necessarily reflect everyday behavior. Furosemide equivalents were used to counteract the effect of loop diuretics, however, this may be an approximate measure as well. Finally, dividing the groups in to the good and poor strata resulted in small participant numbers for the final analysis, which reduces the generalizability. Nevertheless the concordance with the literature increases our confidence in the findings.

Conclusions

Overall our findings indicated that the FPI, which incorporated teaching family members supportive communication using autonomy support, demonstrated a greater maintenance effect for those with poor family functioning than the PFE intervention, which provided information alone. It is an important finding and worth repeating that those with good family functioning benefited from patient and family education alone, which may indicate that HF patients with good family functioning can thrive with a less intense intervention. Likewise, clinical indications for those with poor family functioning at baseline could be placed in a more intense family focused intervention like the FPI. In addition, clinically meaningful approaches to assess and incorporate family functioning into HF clinical care also need more investigation.

Acknowledgments

This study was supported by (1) A Family Partnership Intervention for Heart Failure”, (RO1 R08800) National Institute of Nursing Research, NIH 07/01/04-11/30/09, PI: S. Dunbar and in part by PHS Grant M01 RR0039 from the General Clinical Research Center program, National Institutes of Health, National Center for Research Resources and PHS Grant UL1 RR025008 from the Clinical and Translational Science Award program, National Institutes of Health, National Center for Research Resources, and the Atlanta Veterans Administration Medical
Center. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health.

We acknowledge Judy Robinson, RN, MSN, Kendaly Meadows, RN, MA, Bridget Fielder, RN, MSN and Christina Quinn, RN, PhD for their outstanding contributions to this project.

References


Figure 1. 24-Hour Urinary Sodium (mg/day) Over Time By Group Stratified by Good and Poor Family Functioning (GFF)

24-Hour Urinary Sodium (mg/day) Over Time By Group Stratified by good and poor Family Functioning (GFF) Markers indicate means adjusted for covariates (gender, BDI and furosemide equivalents). Error Bars indicate 95% confidence intervals. For Poor GFF, there were significant overall group differences (p=.012). Sidak adjusted post hoc tests yielded significant group differences between UC and FPI at 4m (p=.024) and 8m (p=.018).

Covariates were significant for the Poor FF strata: gender (p=.001) (women had lower sodium levels), BDI-II (p=.006) (subjects with higher depression had higher sodium levels) and furosemide equivalents (p=.010) (subjects with higher furosemide equivalents had higher sodium levels).
Figure 2. Three Day Food Record Dietary Sodium (mg/day) Over Time By Group Stratified by FAD-GFF

Three Day Food Record (3-DFR) Dietary Sodium Stratified by Good and Poor GFF (patient perspective). Markers indicate means adjusted for covariates (gender and BDI-II). Error Bars indicate 95% confidence intervals. For Good GFF, there were significant overall time differences (p=.024). Sidak adjusted post hoc tests yielded significant time differences between baseline and 4 months for the PFE group (p=.052) and FPI group (p=.028). The only significant covariate for the Good GFF strata was gender (p=.017) (women had lower sodium levels).
Figure 3. Percentage of Participants Adherent to \( \leq 2500 \) mg/day Sodium Over Time By Group Stratified by FAD-GFF

Using Generalized Multilevel Models (binary response logit-link function) for the percentage of subjects meeting the recommended \( \leq 2500 \) mg/day sodium levels (percentages adjusted for covariates: gender, BDI and furosemide equivalents). For Good GFF PFE showed significant change from baseline to 8m (\( p=0.024 \)) and for Poor GFF at 8m the FPI group was significantly higher than UC (\( p=0.011 \)). For Poor GFF strata: gender (\( p=0.010 \)) and depression BDI (\( p=0.052 \)) were significant covariates.
Table 1
Unadjusted Means for Dietary Sodium from 24-Hour Urine (mg/day) by family functioning (GFF) and study randomization groups

<table>
<thead>
<tr>
<th>Group</th>
<th>Baseline</th>
<th>4 M N</th>
<th>8 M N</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>M ± SD (mg) (Min–Max)</td>
<td>M ± SD (mg) (Min–Max)</td>
<td>M ± SD (mg) (Min–Max)</td>
</tr>
<tr>
<td>Participants Enrolled [UC, PFE, FPI]</td>
<td>117 [38, 42, 37]</td>
<td>96c [31, 33, 32]</td>
<td>85 [29, 30, 26]</td>
</tr>
<tr>
<td>UC Overall</td>
<td>423 ± 2044 (1656–9757)</td>
<td>3714 ± 1912 (1196–8947)</td>
<td>3879 ± 2138 (870–9591)</td>
</tr>
<tr>
<td>Good GFF</td>
<td>22 3975 ± 1691 (1656–7429)</td>
<td>3002 ± 1488 (1196–6411)</td>
<td>3382 ± 2030 (870–9591)</td>
</tr>
<tr>
<td>Poor GFF</td>
<td>15 4622 ± 2487 (2076–9757)</td>
<td>4945 ± 1995 (1656–8947)</td>
<td>4824 ± 2114 (1702–8211)</td>
</tr>
<tr>
<td>PFE Overalla</td>
<td>41 3657 ± 1604 (1219–7498)</td>
<td>3101 ± 1536 (851–6371)</td>
<td>3224 ± 2349 (506–8694)</td>
</tr>
<tr>
<td>Good GFF</td>
<td>27 3586 ± 1494 (1219–7051)</td>
<td>3114 ± 1633 (851–6371)</td>
<td>3015 ± 2243 (506–8418)</td>
</tr>
<tr>
<td>Poor GFF</td>
<td>12 3350 ± 1529 (1380–6555)</td>
<td>3235 ± 1341 (1440–5093)</td>
<td>3715 ± 2895 (1127–8694)</td>
</tr>
<tr>
<td>FPI Overall</td>
<td>37 3610 ± 1765 (736–9269)</td>
<td>2933 ± 1904 (322–7061)</td>
<td>2717 ± 1621 (1035–6578)</td>
</tr>
<tr>
<td>Good GFF</td>
<td>18 3253 ± 1682 (736–7544)</td>
<td>2691 ± 1704 (322–5980)</td>
<td>2654 ± 1433 (1081–6118)</td>
</tr>
<tr>
<td>Poor GFF</td>
<td>19 3948 ± 1819 (2047–9269)</td>
<td>3146 ± 2093 (598–7061)</td>
<td>2792 ± 1880 (1034–6578)</td>
</tr>
</tbody>
</table>

aTwo PFE subjects with 24 Hour Urinary Sodium were missing FAD-GFF
bExact sample sizes (N) are reported at each time point relative to attrition over time.
cOne subject at 4 months was missing 24-hour urinary NA

Good GFF (FAD-GFF ≤ 2); Poor GFF (FAD-GFF > 2)
Table 2
Unadjusted Means for Dietary Sodium from Three Day food Record (3-DFR) (mg/day) by family functioning (GFF) and study randomization groups

<table>
<thead>
<tr>
<th>Group</th>
<th>Baseline N(b)</th>
<th>4 M N</th>
<th>8 M N</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>(M ± SD) (mg) (Min–Max)</td>
<td>(M ± SD) (mg) (Min–Max)</td>
<td>(M ± SD) (mg) (Min–Max)</td>
</tr>
<tr>
<td>Participants Enrolled</td>
<td>117 [38, 42, 37]</td>
<td>96c [31, 33, 32]</td>
<td>85 [29, 30, 26]</td>
</tr>
<tr>
<td>UC Overall</td>
<td>38</td>
<td>30</td>
<td>29</td>
</tr>
<tr>
<td>Good GFF</td>
<td>23</td>
<td>18</td>
<td>19</td>
</tr>
<tr>
<td>Poor GFF</td>
<td>15</td>
<td>12</td>
<td>10</td>
</tr>
<tr>
<td>PFE Overalla</td>
<td>40</td>
<td>33</td>
<td>29</td>
</tr>
<tr>
<td>Good GFF</td>
<td>27</td>
<td>23</td>
<td>21</td>
</tr>
<tr>
<td>Poor GFF</td>
<td>12</td>
<td>9</td>
<td>7</td>
</tr>
<tr>
<td>FPI Overall</td>
<td>37</td>
<td>32</td>
<td>25</td>
</tr>
<tr>
<td>Good GFF</td>
<td>18</td>
<td>15</td>
<td>13</td>
</tr>
<tr>
<td>Poor GFF</td>
<td>19</td>
<td>17</td>
<td>12</td>
</tr>
</tbody>
</table>

a One PFE subject with 3-DFR Dietary Sodium was missing FAD-GFF
b Exact sample sizes (N) are reported at each time point relative to attrition over time.
c One subject at 4 months was missing 24-hour urinary NA

Good GFF (FAD-GFF ≤ 2); Poor GFF (FAD-GFF > 2)