Published in final edited form as:

Am J Kidney Dis. 2011 January ; 57(1): 90–100. doi:10.1053/j.ajkd.2010.08.024.

Baseline Characteristics of Participants in the Frequent Hemodialysis Network Daily and Nocturnal Trials

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Abstract

Background—The annual mortality rate for maintenance hemodialysis patients in the United States remains unacceptably high at 15–20%. In 2004, we initiated the Frequent Hemodialysis Network (FHN) clinical trials. This report presents baseline characteristics of FHN trial participants and compares them to hemodialysis patients tracked in USRDS data.

Study design—Two separate randomized clinical trials

Settings and participants—FHN includes 332 patients with chronic kidney disease requiring chronic dialysis therapy enrolled in two separate randomized clinical trials. The FHN Daily Trial (245 randomized subjects) was designed to compare outcomes of six times per week in-center daily hemodialysis (1.5 to 2.75 hours/session) with conventional three times per week in-center hemodialysis. The FHN Nocturnal Trial (87 randomized subjects) was designed to compare outcomes of six times per week nocturnal (6 to 8 hours/session) with conventional three times per week hemodialysis. USRDS data includes 338109 incident and prevalent chronic hemodialysis patients from the calendar year 2007.

Results—Subjects in both trials were, on average, younger than the average hemodialysis patient in the United States (50.4 years; $p < 0.001$ for Daily and 52.8 years; $p < 0.001$ for Nocturnal). Compared to USRDS data, whites were underrepresented in the Daily Trial (36% versus 55%, $p < 0.001$) while Hispanics were underrepresented in the Nocturnal Trial and overrepresented in the Daily Trial (0% versus 28%; $p < 0.001$). In addition, there were more fistulas and fewer catheters in

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Financial Disclosure: The authors declare that they have no relevant financial interests.

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the Daily Trial (61% and 20% respectively, $p < 0.001$ for both) and fewer grafts and more catheters in the Nocturnal Trial (10% and 44% respectively, $p < 0.005$ for both).

Limitations—Clinical trial exclusion criteria and patient willingness to participate limit comparisons with the USRDS.

Conclusions—FHN participants are younger and the racial composition for each study was different than the racial composition of the aggregate US dialysis population. Catheters for vascular access were more common in FHN Nocturnal participants.

Keywords

frequent hemodialysis; daily hemodialysis; nocturnal hemodialysis; left ventricular hypertrophy; physical functioning; randomized clinical trial

Despite the many advances that have occurred since maintenance hemodialysis therapy was first offered in the 1960s, the annual mortality rate for maintenance hemodialysis patients in the United States remains unacceptably high in the range of 15–20%.⁽¹⁾ The National Cooperative Dialysis Study (NCDS) demonstrated that insufficient dialysis dose (measured as the time-averaged urea concentration) can result in increased hospitalization attributable to uremia; ⁽²⁾ however, the HEMO Study primary results indicated that increasing the dose of dialysis (measured as the product of urea clearance and time, normalized to the volume of distribution; ie, Kt/V_{urea}) in a three times per week setting did not improve survival or reduce the rates of cardiovascular or infection-related hospitalizations.⁽³⁾ Moreover, higher Kt/V_{urea} delivered thrice weekly failed to improve physical or mental health, or functional or nutritional status.^(4;5)

Subsequently, investigators have explored the potential role of more frequent hemodialysis in improving outcomes in maintenance hemodialysis patients. A review of published experience with daily hemodialysis indicated that hemodialysis conducted six times per week resulted in improved blood pressure control, and in some cases improved quality of life.⁽⁶⁾ Similarly, a review of nocturnal hemodialysis studies indicated that hemodialysis conducted five to six nights per week led not only to improved blood pressure control but also to a marked increase in the clearance of phosphorus, leading in some cases to the discontinuation of phosphate binders, and in some cases to improved nutritional status and quality of life.⁽⁷⁾ At the time that the Frequent Hemodialysis Network (FHN) studies were conceived, studies in both frequent hemodialysis modalities were generally small, uncontrolled and participants were self-selected and were not randomized to alternative therapies.

Based upon the findings of these small studies, the Frequent Hemodialysis Network (FHN) was conceived, organized, funded and implemented by the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) with the endorsement and support of the Centers for Medicare and Medicaid Service (CMS) and the participation of multiple dialysis provider organizations. The purpose of the FHN was to design and conduct randomized controlled clinical trials in daily and nocturnal hemodialysis conducted six times per week compared to conventional three times per week hemodialysis. In this article, the baseline characteristics of subjects enrolled in both the in-center daily and at home nocturnal trials are presented.

Methods

Study Design

The general design of the FHN Daily and FHN Nocturnal Trials has been previously described in detail. (8) In brief, the FHN Daily Trial is a randomized clinical trial of in-center daily hemodialysis (six times per week, 1.5 to 2.75 hours per session) or conventional in-center hemodialysis three times per week (2.5 to 4.5 hours per session) while the FHN Nocturnal Trial is a randomized clinical trial of six times per week home (6 to 8 hours per session) or conventional hemodialysis three times per week (2.5 to 5 hours per session). Inclusion criteria between the two studies differed only in that patients aged 13 to 17 were permitted to enroll in the FHN Daily Trial but not the FHN Nocturnal Trial and that the exclusion criteria for residual kidney function was a urea clearance of > 3 ml/min/35L urea volume in the Daily Trial and an estimated glomerular filtration rate > 10 ml/min/1.73 m² in the Nocturnal Trial. Upon randomization, each subject was followed for 12 months or until death, kidney transplant, or recovery of kidney function. The two co-primary outcomes for both studies were the change over 12 months in left ventricular mass as measured by cardiac MRI or death and self-reported physical health as measured by the SF-36 RAND Physical Health Composite score (PHC) (9) or death. The LV mass determination did not include the measurement of papillary muscles. The trials were approved at each of the clinical center's local Institutional Review Board. An independent Data Safety Monitoring Board assembled by NIDDK reviewed progress of the trials on a regular basis.

Vanguard phase

The feasibility of each trial was assessed during a Vanguard phase. In the FHN Daily Trial, 378 subjects were enrolled and 245 were randomized to receive either six times per week in-center hemodialysis (with a target eKt/V_{urea} per session, normalized to body size of 0.9 or more) or three times per week in-center hemodialysis (with a target eKt/V_{urea} of 1.10 per session). In the FHN Nocturnal Trial, predefined recruitment benchmarks were not met during the initial Vanguard phase and the protocol was modified to enhance recruitment and to decrease the expected sample size of the cohort. The original Nocturnal Trial protocol was designed to compare home nocturnal HD six times per week versus *in-center* HD three times per week. The protocol was modified in September 2006 so that the conventional arm was changed to *home* hemodialysis three times per week. This allowed subjects who were motivated to undertake home hemodialysis to participate in the study, knowing that they would dialyze at home, regardless of the group to which they might be assigned.

It was initially proposed that the sample size for the Nocturnal Trial be in the 150 – 200 subject range. After review of the initial protocol by the Data Safety Monitoring Board, the sample size was increased to 250 subjects to be able to detect differences between treatment groups in hospitalizations (which was added as a secondary endpoint). The target sample size of the study was decreased from 250 subjects to 150 subjects in October 2007 and further decreased to 90 subjects in December 2008 because of lower than expected recruitment rates. Indeed, the Vanguard phase of the trial was intended to assess subject recruitment. These decreases in sample size were carried out in conjunction with revised power analyses, taking into account recently published data from a similar trial (10), and approved by the Data Safety Monitoring Board. It is worth noting that for many of the outcomes, the Nocturnal Trial treatment arms have very large expected separations, more than 2-fold those in the Daily Trial. Thus, the effect sizes that can be plausibly hypothesized may be larger in the Nocturnal Trial than in the Daily Trial and the reduction in sample size means that while the “minimum clinically important effect” may not be detectable, there is still power to detect larger effects that remain plausible given the more intensive intervention.

Thirty-two subjects were recruited and 15 were randomized under the original protocol (with in-center hemodialysis three times per week as the control) and 86 subjects were recruited and 72 randomized in the new protocol (with home hemodialysis three times per week as the control), yielding a total of 87 randomized subjects in the Nocturnal Trial.

Power analysis

The minimum detectable effect sizes for the two co-primary composite outcomes were estimated by statistical simulation using a log-rank test with adjustment of the Type 1 error rate using Hochberg's procedure. (11) Using this technique, the threshold used to test the significance of each of the two co-primary composite end points depends on the observed difference in the other outcome. For the FHN Daily Trial, assuming a 20% reduction in mortality and no treatment effect of one on the other co-primary outcome, a sample size of 250 patients has 90% power to detect effects of 4.96 points in the 1-year change in PHC, and 13.0 g in the 1-year change in LVM. For the FHN Nocturnal Trial, assuming a 20% reduction in mortality and no treatment effect of one on the other primary outcome, a sample size of 90 patients has 90% power to detect effects of 8.64 points in the 1-year change in SF-36 PHC score, and 22.7 g in the 1-year change in LVM.

Statistical analysis

The results presented are descriptive and give means and standard deviations for continuous variables and percentages for categorical variables. Comparisons for continuous data were performed using Student's t-tests or Wilcoxon rank-sum tests, as appropriate. Comparisons for binary measures were performed using Chi-square tests and Fisher Exact tests, as appropriate. All *P* values are two-sided without adjustments for multiple comparisons.

Results

FHN Daily Trial

This study was conducted from two clinical core consortiums headquartered at Renal Research Institute in New York City and University of California San Francisco (later transferred to Stanford University). A listing of the ten clinical centers in the United States and Canada that participated in the FHN Daily Trial is elsewhere⁸. During the 32-month enrollment period, informed consent was obtained from 378 patients, of which 245 patients were randomized.

Demographic characteristics of subjects randomized into the FHN Daily Trial are shown in Table 1. The mean ($\pm$ SD) age of participants was 50.4 ± 13.9 years with 38% female and 42% black. Clinical characteristics included a median ESRD vintage (time since initiation of dialysis) of 3.6 (10th–90th percentile, 0.6–14.3) years, and 35% with diabetes mellitus as the primary cause of ESRD. Socioeconomic characteristics of the randomized cohort included an education level of a high school graduate or higher in 79%, 19% with an average annual income in the range of \$15,000 to \$30,000, and 29% who were currently married. Subjects who were recruited into the FHN Daily Trial but were not randomized had an annual income less than \$15,000 ($p = 0.03$ compared to randomized subjects). There was no difference in travel time to the dialysis unit between randomized and non-randomized patients ($p = 0.3$).

Medical comorbidities are shown in Table 2. The most common comorbidities included diabetes mellitus in 40%, history of myocardial infarction in 11%, peripheral arterial disease in 10%, and cerebrovascular disease in 7%. A history of smoking was present in 37%, illicit drug use in 12% and admission to an ICU in the past year in 9% of patients. Compared to subjects who were not randomized, randomized subjects in the FHN Daily cohort were more likely to have a prior kidney transplant ($p = 0.006$) or prior use of peritoneal dialysis as a

modality ($p = 0.02$). The percentage of subjects with an arteriovenous fistula as vascular access was higher (61% for FHN versus 45% for CMS data; $p < 0.001$) and the percentage of patients with either a catheter (18% for FHN versus 29% for CMS data; $p = < 0.001$) or an arteriovenous graft was lower (18% for FHN versus 26% for CMS data; $p = 0.02$) than that seen in the prevalent U.S. hemodialysis population as a whole (Table 3).(12)

Baseline measurements for the two co-primary outcomes and for laboratory data are shown in Table 4. Compared to randomized subjects in the FHN Daily Trial, subjects who were not randomized had a lower physical health composite and mental health composite scores, lower SF-36 subscale scores in physical functioning ($p = 0.03$), role physical ($p = 0.02$), general health ($p = 0.008$), role emotional ($p = 0.02$), and social functioning ($p = 0.003$), a higher Beck Depression Index score ($p = 0.01$) and a lower serum creatinine concentration ($p < 0.001$). Other baseline data are shown in Table 5; there were no other significant differences among subjects who were and were not randomized into the trial.

FHN Nocturnal Trial

This study was conducted from one clinical core consortium headquartered at Wake Forest University in Winston-Salem, North Carolina. A listing of the nine clinical centers in the United States and Canada that participated in the FHN Nocturnal Trial is provided elsewhere⁸. One hundred twenty subjects were recruited and 87 were randomized.

Demographic characteristics of subjects randomized into the FHN Nocturnal Trial are shown in Table 1. The mean age was 52.8 ± 13.6 years, with 35% female and 26% black. Clinical characteristics included a median ESRD vintage of 1.1 (10th–90th percentile, 0.1–10.7) years, and 35% with diabetes mellitus as the primary cause of ESRD. Socioeconomic characteristics of randomized subjects included an education level of a high school graduate or higher in 85%, an income that was greater than \$30,000 in 49%, and 77% were currently married. Subjects who were enrolled into the FHN Nocturnal Trial but who were not randomized had similar characteristics to randomized patients.

Comorbidities of subjects randomized into the FHN Nocturnal Trial are shown in Table 2. The most common comorbidities included diabetes mellitus in 42%, gout in 19%, peripheral arterial disease in 17%, history of myocardial infarction in 10% and cerebrovascular disease in 2%. A history of smoking was present in 48%, illicit drug use in 2% and admission to an ICU in the past year in 10%. There were no significant differences in medical comorbidities between randomized and non-randomized patients. The functional vascular access for hemodialysis upon enrollment is noted in Table 3. The percentage of subjects randomized to the Nocturnal Trial with catheters (44%) was higher than that seen in the incident U.S. hemodialysis population (64% for FHN versus 45% for the Centers for Medicare and Medicaid (CMS) ESRD Clinical Performance Measures (CPM) data for patients on dialysis less than one year; $p = 0.03$) but not in the prevalent U.S. population (35% for FHN versus 29% for CMS data for patients on dialysis for one or more years; $p = 0.3$). (12)

Baseline measurements for the two co-primary outcomes and for laboratory data are shown in Table 4. Compared to randomized subjects, subjects who were not randomized to the Nocturnal Trial had a lower physical health composite score ($p = 0.03$), lower physical functioning ($p = 0.01$) and energy/fatigue subscores (0.02) and a lower target weight ($p = 0.03$). Other baseline data are shown in Table 5; there were no significant differences among subjects who were and were not randomized into the trial.

Comparison of Randomized Subjects in the FHN Daily and Nocturnal Trials

The demographic characteristics of the subjects in the FHN Daily and Nocturnal Trials were similar in terms of patient age, primary cause of ESRD, comorbidity as measured by the

modified Charlson score (13) and level of education. The most common comorbidities present in either trial included diabetes mellitus, history of myocardial infarction, peripheral arterial disease and gout. Subjects in the Nocturnal Trial, compared to the Daily Trial, were less likely to be African American (26% versus 42%; $p = 0.01$) or Hispanic (0% versus 28%; $p < 0.001$). Nocturnal Trial subjects were also less likely to have hypertensive nephrosclerosis ($p = 0.007$) and were more likely to have glomerulonephritis ($p = 0.002$) as the cause of ESRD. Due to differences in the entry criterion related to residual kidney function (urea clearance of ≤ 3 ml/min/35L urea volume in the Daily Trial and an estimated glomerular filtration rate ≤ 10 ml/min/1.73 m² in the Nocturnal Trial), subjects in the FHN Daily Trial had a longer duration of ESRD than subjects in the FHN Nocturnal Trial ($p < 0.001$). The rationale for different residual function criteria was that as prescribed, nocturnal hemodialysis provided much more solute clearance per session than daily hemodialysis, thereby widening intergroup separation. Subjects in the FHN Nocturnal Trial were much more likely to have a catheter for hemodialysis access than subjects in the FHN Daily Trial ($p < 0.001$) and were less likely to be on the cadaveric transplant waiting list ($p = 0.01$). Both patient target weight and treatment time were higher in the Nocturnal Trial subjects than in the Daily Trial subjects ($p = 0.02$ and < 0.001 respectively) while the mean serum creatinine level was lower in Nocturnal Trial subjects ($p < 0.001$). There were no significant differences in either the medical comorbidities or the SF-36 summary or subscores between subjects in the two trials. Nocturnal subjects reported a longer duration of sleep each night compared to Daily Trial subjects ($p = 0.02$). Finally, subjects enrolled (and randomized) in the FHN Nocturnal Trial were much more likely to have a longer travel time to an outpatient dialysis unit ($p < 0.001$) and to be married compared to patients in the FHN Daily Trial ($p < 0.001$) and to have an annual income of greater than \$30,000 ($p = 0.02$).

Comparison of FHN trial subjects with other hemodialysis study subjects

A comparison of the FHN randomized subjects with other hemodialysis study subjects is depicted in Table 6. The average age in both FHN trials was younger than that reported by the USRDS cohort. (1) Compared to USRDS data, females were underrepresented in the FHN Daily Trial and overrepresented in both the HEMO Study and Alberta study. In addition blacks were overrepresented in the HEMO Study and whites were underrepresented in the FHN Daily Trial and overrepresented in the Alberta study. Finally, Hispanics were overrepresented in the FHN Daily Trial and underrepresented in the FHN Nocturnal Trial.

The dialysis vintage was lower in the FHN Nocturnal Trial compared to the HEMO Study. Compared to USRDS data, subjects with diabetic nephropathy were underrepresented in the FHN Daily Trial; those with hypertensive nephrosclerosis were underrepresented in both FHN trials and glomerulonephritis was overrepresented in both FHN trials. Baseline hemoglobin levels in both FHN trials were higher than that reported in the CMS ESRD CPM report from 2007 (12). In addition, fistulas were more common in FHN Daily and Alberta study participants and less common in HEMO Study participants, grafts were more common in HEMO Study participants and less common in participants in both FHN trials, while catheters were less common in FHN Daily Trial and HEMO Study participants and more common in FHN Nocturnal Trial participants. Mean values on the physical and mental composite scores were similar among all four study cohorts.

Discussion

The FHN trials of in-center “daily” (actually six times per week) hemodialysis and at home nocturnal hemodialysis are the largest randomized trials of frequent hemodialysis to have been conducted to date. We are unaware of other randomized trials conducted that have compared in-center daily hemodialysis with conventional (2.5 to 5.0 hours) hemodialysis three times per week. The only other randomized trial of nocturnal hemodialysis was

conducted in Alberta, Canada by Culleton et al. who reported on 51 patients who were randomized to receive either six times per week nocturnal hemodialysis or three times per week conventional hemodialysis for six months, instead of one year as in the FHN Nocturnal Trial. (10)

There are differences in the enrollment characteristics among these recent randomized trials in hemodialysis and in comparison to USRDS data. Subjects in both trials were, on average, younger than the average hemodialysis patient in the United States (50.4 vs. 60.2 years, $p < 0.001$ for the Daily Trial and 52.8 vs. 60.2, $p < 0.001$ for the Nocturnal Trial) and were diverse in terms of educational background and income. In the Daily Trial, the mix of vascular access types was similar to that reported in national surveys (12) while in the Nocturnal Trial, a larger fraction of patients had a catheter as their hemodialysis access, possibly due to issues regarding self-cannulation. In both studies, about one-third of subjects had diabetic nephropathy as the primary cause of ESRD. Otherwise, a larger fraction of subjects in the FHN Nocturnal Trial had glomerulonephritis as a primary cause of ESRD ($p = 0.002$). Both trials included subjects with a broad range of comorbid medical conditions.

With regard to socioeconomic status, the key differences compared with the general hemodialysis population (documented by USRDS) was the much higher percentage of subjects randomized to the Nocturnal Trial who were married (77% vs. 55%), $p < 0.001$ (14) and who predominantly spoke Spanish (0% vs. 7%, $p = 0.01$), (15) this latter point reflecting the geography of the study sites. These findings were not surprising due to 1) the requirement that a participant in the Nocturnal Trial have a partner present whenever hemodialysis was performed in the home and 2) the need for regular communication with home dialysis training personnel, the vast majority of whom spoke English only. Detailed information on the recruitment and training of participants for home hemodialysis are provided in a separate publication. (16) Baseline data on physical performance, health and functioning of the FHN Trial participants have been described previously. (17) Finally, a lower percentage of subjects randomized to the FHN Daily Trial were married compared to the general hemodialysis population (29% vs. 55%, $p < 0.001$) (14).

The FHN Daily Trial concluded recruitment in March 2009 and the FHN Nocturnal Trial concluded recruitment in May 2009. Follow-up in each of the trials ended 12 months after the last subject was recruited. In addition, a longer term observational (after the 12 month interventional phase) follow-up study of participants in both FHN trials is currently underway with an expected completion date in early 2011. In this follow-up study, one additional clinic visit will be scheduled to ascertain the two co-primary endpoints as well as many of the secondary endpoints of the main trials.

Acknowledgments

The members of the FHN Trial Group are A. Klinger, P. Eggers, A. Narva, R. Star, B. Augustine, P. Mohr, G. Beck, Z. Fu, J. Gassman, T. Greene, J. Daugirdas, L. Hunsicker, B. Larive, J. MacKrell, K. Wiggins, S. Sherer, B. Weiss, S. Rajagopalan, J. Sanz, S. Dellagotto, M. Kariisa, M. Unruh, C. Chan, R. Frome, H. Higgins, S. Ke, C. Snell, G. Eknoyan, L. Appel, A. Cheung, A. Derse, C. Kramer, N. Geller, R. Grimm, L. Henderson, S. Prichard, E. Roecker, G. Chertow, M. Kurella, C. McCulloch, P. Painter, I. Gorodetskaya, M. Tichy, T. Depner, G. Kaysen, M. Suter, G. Ting, J. Moran, B. Moran, N. Coplon, S. Doss, J. Rogers, A. Dominguez, J. Atwal, A. Nissenson, W. Goodman, I. Salusky, S. Schweitzer, M. Rivas, M. Smith, P. Gayda, R. Mehta, J. Pepas, B. Bharti, J. Ayus, S. Achinger, M. Gutierrez, N. Levin, M. Carter, O. Sergeyeva, M. Kuhlmann, G. Handelsman, F. Gotch, F. Finkelstein, P. Kimmel, E. Lacson, D. Ornt, P. Kotanko, A. Kaufman, J. Winchester, I. Meisels, J. Chang, Y. Fofie, R. Ramos, R. Suri, A. Garg, R. Lindsay, R. Bullas, M. Rocco, T. Kaufman, G. Schulman, S. McLeroy, M. Sika, E. Leavell, B. Miller, J. Riley, R. Schuessler, R. Lockridge, M. Pipkin, C. Peterson, C. Hoy, A. Fensterer, J. Stokes, D. Somers, A. Hilkin, K. Lilli, W. Wallace, M. McGrath-Chong, M. Copland, A. Levin, L. Sioson, E. Cabezon, S. Kwan, J. Champagne, J. Burkart, A. Pierratos, W. Chan. A list of participating centers may be found elsewhere⁸.

The authors thank Ms. Laura Harvey for her excellent secretarial support.

Support: The funds for these trials were received from NIDDK, Centers for Medicare and Medicaid Services, the NIH Research Foundation, Fresenius Medical Care, the Renal Research Institute, and Satellite Health Care. These trials were supported by NIDDK grants U01DK066597 (DCC), 2U01DK066579 (Dr Levin), 3U01DK066481 (Dr Chertow), and 3U01DK066480 (Dr Rocco).

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Table 1

FHN subject demographics and socioeconomics at enrollment

	Daily Trial		Nocturnal Trial	
Variable	Randomized (n=245)	Excluded (n=133) ¹	Randomized (n=87)	Excluded (n=31) ²
Age (years)	50.4 ± 13.9	53.3 ± 13.8	52.8 ± 13.6	49.7 ± 13.1
Female	94 (38%)	58 (44%)	30 (35%)	15 (48%)
Race				
Native American, Aboriginal Canadian or Alaskan Native, First Nation	8 (3%)	2 (1%)	3 (3%)	3 (10%)
Asian	16 (7%)	9 (7%)	12 (14%)	5 (16%)
Native Hawaiian or Other Pacific Islander	4 (2%)	1 (1%)	0	0
Black or African American	102 (42%)	58 (44%)	23 (26%)	8 (26%)
White	89 (36%)	55 (41%)	48 (55%)	15 (48%)
More than one race (multiracial)	4 (2%)	2 (2%)	0	0
Unknown or not reported	22 (9%)	6 (5%)	1 (1%)	0
Hispanic or Latino Ethnicity	69 (28%)	34 (26%)	0	2 (7%)
Primary Language				
English	196 (80%)	112 (84%)	77 (89%)	26 (84%)
Spanish	41 (17%)	17 (13%)	0	1 (3%)
Other	8 (3%)	4 (3%)	10 (11%)	4 (13%)
Weight (kg)	77.5 (66.8, 95.2)	76.6 (64.8, 105)	88.4 (67.5, 103)	72.1 (60.1, 89.2)
Height (cm)	168 ± 10.6	169 ± 10.6	171 ± 9.98	168 ± 9.82
BMI (kg/m ²)	27.4 ± 6.76	28.5 ± 8.81	29.0 ± 8.03	26.5 ± 7.82
Years since 1st ESRD	3.64 [0.63, 14.3]	3.84 [0.44, 10.3]	1.08 [0.10, 10.7]	0.91 [0.09, 11.5]
24 hour urine output (ml)	0 [0, 550]	0 [0, 600]	538 [0, 1255]	401 [0, 1325]
Primary Reason Kidneys Failed				
Diabetic nephropathy	84 (35%)	21 (37%)	30 (35%)	6 (43%)
Hypertensive nephrosclerosis	51 (21%)	15 (26%)	7 (8%)	2 (14%)
Glomerulonephritis	47 (19%)	10 (17%)	31 (36%)	3 (21%)
Polycystic kidney disease	10 (4%)	3 (5%)	3 (3%)	1 (7%)
Analgesic nephropathy	1 (1%)	0	0	0
Obstructive uropathy	6 (2%)	0	1 (1%)	0
Other	28 (11%)	4 (7%)	12 (14%)	1 (7%)
Unknown	18 (7%)	4 (7%)	3 (3%)	1 (7%)
Travel Time to Unit (min)	26.8 ± 18.2	25.5 ± 20.2	38.1 ± 30.1	29.6 ± 24.3
Education				
Not High School Graduate	51 (21%)	11 (18%)	13 (15%)	1 (7%)
High School Graduate	58 (24%)	13 (21%)	21 (24%)	4 (27%)
Vocational School or Some college	82 (34%)	24 (39%)	29 (33%)	5 (33%)

	Daily Trial		Nocturnal Trial	
Variable	Randomized (n=245)	Excluded (n=133) ¹	Randomized (n=87)	Excluded (n=31) ²
Associate or Bachelor Degree	42 (17%)	8 (13%)	18 (21%)	4 (27%)
Master or Doctoral Degree	9 (4%)	4 (7%)	5 (6%)	1 (7%)
Unknown	3 (1%)	1 (2%)	1 (1%)	0
Current Employment Status				
Not currently Employed	202 (83%)	52 (87%)	61 (70%)	8 (53%)
Currently employed part time	26 (11%)	3 (5%)	10 (11%)	4 (27%)
Currently employed full time	16 (7%)	5 (8%)	16 (18%)	3 (20%)
Current Household Gross Annual Income				
< \$15,000	87 (36%)	31 (51%)	15 (17%)	2 (13%)
\$15,000 – \$30,000	47 (19%)	6 (10%)	20 (23%)	4 (27%)
> \$30,000	46 (19%)	8 (13%)	43 (49%)	7 (47%)
Unknown or refused	65 (26%)	16 (26%)	9 (10%)	2 (13%)
Currently Married	70 (29%)	15 (25%)	67 (77%)	8 (53%)
Living Status				
Lives with Family	168 (69%)	38 (62%)	81 (93%)	13 (87%)
Lives Alone	51 (21%)	15 (25%)	3 (3%)	2 (13%)
Lives with Others	25 (10%)	7 (11%)	3 (3%)	0
Homeless	1 (1%)	0	0	0

¹Data missing on 76 subjects for primary reasons kidneys failed.

²Data missing on 17 subjects for primary reasons kidneys failed.

Values shown are number (percentage), mean $\pm$ standard deviation, median (25th, 75th percentile), or median [10th, 90th percentile].

Randomized refers to participants who were randomized; excluded refers to participants who were enrolled but not randomized. The latter did not complete a run-in period (for in-center dialysis six times per week for the Daily Trial or for home dialysis training for the Nocturnal Trial), or were unable to complete the cardiac MRI.

Abbreviations: FHN, Frequent Hemodialysis Network; ESRD, end-stage renal disease; BMI, body mass index

Table 2

FHN subject comorbidities present at enrollment

	Daily Trial		Nocturnal Trial	
Medical Comorbidity	Randomized (n=245)	Excluded (n=133) ¹	Randomized (n=87)	Excluded (n=31) ²
Modified Charlson Comorbidity score	1 (0, 2)	2 (0, 4)	1 (0, 2)	1 (0, 4)
0	101 (41%)	19 (33%)	34 (39%)	6 (43%)
1	43 (18%)	8 (14%)	19 (22%)	3 (21%)
2	42 (17%)	7 (12%)	16 (18%)	1 (7%)
3	29 (12%)	8 (14%)	8 (9%)	0
4	15 (6%)	7 (12%)	8 (9%)	1 (7%)
5–6	13 (5%)	5 (9%)	1 (1%)	1 (7%)
7–12	2 (1%)	3 (5%)	1 (1%)	2 (14%)
Myocardial infarction*	27 (11%)	11 (19%)	9 (10%)	4 (29%)
>1 hospital admission in past year for CHF/ fluid overload	3 (1%)	0 (0%)	1 (1%)	0
Connective Tissue Disease	15 (6%)	4 (7%)	0	0
PVD (includes aortic aneurysm > 6 cm)	25 (10%)	7 (12%)	15 (17%)	3 (21%)
History of AAA repair or bypass grafting	5 (2%)	1 (2%)	7 (8%)	0
Current infection ulceration or gangrene of a digit or limb	5 (2%)	2 (3%)	2 (2%)	0
Cerebrovascular disease	18 (7%)	5 (9%)	2 (2%)	1 (7%)
Hemiplegia	3 (1%)	0	0	0
Dementia	1 (1%)	0	0	0
Chronic pulmonary disease	11 (4%)	6 (10%)	4 (5%)	1 (7%)
Rheumatologic condition	8 (3%)	2 (3%)	2 (2%)	0
Ulcer disease	7 (3%)	2 (3%)	2 (2%)	2 (14%)
Diabetes without end-organ damage	16 (6%)	4 (7%)	7 (8%)	1 (7%)
Diabetes with end-organ damage	84 (34%)	23 (40%)	30 (34%)	6 (43%)
Moderate or Severe Liver Disease**	2 (1%)	0	1 (1%)	0
Gout	17 (7%)	4 (7%)	17 (19%)	0
Human immunodeficiency virus	17 (7%)	4 (7%)	0	1 (7%)
Uses nasal CPAP at night	8 (3%)	1 (2%)	14 (16%)	0 (0.0%)
History of cigarette smoking	91 (37%)	25 (44%)	42 (48%)	6 (43%)
History of excess alcohol use	26 (11%)	11 (19%)	9 (10%)	1 (7%)
History of illicit drug use	30 (12%)	7 (12%)	2 (2%)	1 (7%)
Admitted to an ICU at least once during past year	21 (9%)	9 (16%)	9 (10%)	3 (21%)
Currently on cadaveric transplant waiting list	88 (36%)	18 (32%)	16 (18%)	1 (7%)
Has had a previous kidney transplant	44 (18%)	2 (3%)	13 (15%)	5 (36%)
Has previously received PD	37 (15%)	2 (3%)	7 (8%)	4 (29%)
Legally blind	4 (2%)	1 (2%)	1 (1%)	0 (0%)

¹Data missing on 76 subjects.

²Data missing on 17 subjects.

* By history, not just by EKG changes.

** such as portal hypertension or jaundice

Values shown are number (percentage). Randomized refers to participants who were randomized; excluded refers to participants who were enrolled but not randomized. The latter did not complete a run-in period (for in-center dialysis six times per week for the Daily Trial or for home dialysis training for the Nocturnal Trial), or were unable to complete the cardiac MRI.

Abbreviations: AAA, abdominal aortic aneurysm; PVD, peripheral vascular disease; ICU, intensive care unit; CHF, congestive heart failure; CPAP, continuous positive airway pressure; PD, peritoneal dialysis; FHN, Frequent Hemodialysis Network;

Table 3

Vascular Access characteristics for FHN subjects at enrollment

	Daily Trial		Nocturnal Trial	
Current Type of Vascular Access	Randomized (n = 245)	Excluded (n = 133) ¹	Randomized (n=87)	Excluded (n=31) ²
AVG -forearm	16 (6%)	6 (7%)	4 (5%)	1 (6%)
AVG -upper arm	30 (12%)	15 (19%)	5 (6%)	1 (6%)
AVF -forearm	74 (30%)	19 (24%)	25 (29%)	5 (31%)
AVF -upper arm	75 (31%)	21 (26%)	15 (17%)	5 (31%)
Catheter	45 (18%)	18 (22%)	38 (44%)	4 (25%)
Femoral	5 (2%)	1 (1%)	0	0

¹Data missing on 53 subjects.²Data missing on 15 subjects.

Abbreviations: AVF, arteriovenous fistula; AVG, arteriovenous graft; FHN, Frequent Hemodialysis Network

Table 4

Other measures for FHN subjects at enrollment (1)

Outcomes	Daily Trial				Nocturnal Trial			
	Randomized (n=245)		Excluded (n=133)		Randomized (n=87)		Excluded (n=31)	
	No. Missing	Value	No. Missing	Value	No. Missing	Value	No. Missing	Value
LV Mass (g)	0	140.3 ± 54.5	115	153.6 ± 59.4	0	137.1 ± 45.7	22	152.3 ± 55.7
SF-36 Scales¹								
PHC	1	38.1 ± 10.5	70	34.0 ± 10.3	1	37.8 ± 9.0	13	32.7 ± 9.8
MHC	2	45.2 ± 11.7	71	41.3 ± 11.9	1	45.8 ± 11.5	13	41.7 ± 10.5
Physical Functioning	0	57.9 ± 27.1	70	49.7 ± 28.4	0	61.4 ± 22.0	13	45.8 ± 25.8
Physical Health Problems	0	49.0 ± 41.0	70	35.7 ± 35.3	0	41.3 ± 37.5	13	27.8 ± 35.2
Pain	0	64.6 ± 26.8	70	58.4 ± 28.5	0	69.2 ± 25.1	13	61.4 ± 24.5
General Health Perceptions	0	45.3 ± 22.1	70	37.5 ± 20.6	0	43.9 ± 20.6	13	34.4 ± 24.7
Emotional Well-being	0	75.4 ± 19.7	70	71.6 ± 20.6	0	76.4 ± 19.8	13	71.5 ± 17.7
Emotional Health Problem	0	76.1 ± 36.6	70	63.2 ± 42.7	0	82.4 ± 32.9	13	74.1 ± 38.9
Social Functioning	0	71.7 ± 26.9	70	60.1 ± 25.1	0	74.3 ± 25.3	13	72.9 ± 25.5
Energy/Fatigue	0	49.6 ± 23.5	70	44.2 ± 24.3	0	50.2 ± 22.3	13	36.2 ± 23.9
Lab Measure/Treatment Factor								
Target (Dry) Weight (kg)	0	73.5 (63.0, 92.0)	53	73.1 (61.8, 99.5)	0	85.0 (65.0, 99.5)	17	70.2 (57.3, 84.8)
Prescribed Treatment Time (min)	0	217 ± 27	53	209 ± 29	0	235 ± 23	17	234 ± 12
Pre-dialysis SUN (mg/dL)	0	58.5 ± 16.0	53	58.1 ± 18.2	0	54.5 ± 15.6	17	64.3 ± 20.6
Pre-dialysis SCr (mg/dL)	0	10.5 ± 2.7	53	8.6 ± 3.8	0	8.7 ± 3.0	17	8.4 ± 2.9
Pre-dialysis Serum Phosphate (mg/dL)	0	5.8 ± 1.6	53	5.7 ± 1.9	0	5.8 ± 1.6	17	6.2 ± 2.3
Pre-dialysis Albumin (g/dL)	0	3.9 ± 0.4	53	3.9 ± 0.4	0	3.9 ± 0.5	17	3.8 ± 0.5

¹ SF-36 subscales range from 0 to 100 with 100 being more favorable. PHC & MHC are normalized to have an average score of 50 with a standard deviation of 10.

Values shown are Mean ± standard deviation or median (25th, 75th percentile).

PHC, Physical Health Composite; MHC, Mental Health Composite; SCr, serum creatinine; SUN, serum urea nitrogen; SF-36, 36-Item Short Form Health Survey; LV, left ventricular.

Conversion factors for units: serum creatinine in mg/dL to micromol/L, x88.4; SUN in mg/dL to mmol/L, x0.357.

Table 5

Other measures for FHN subjects at enrollment (2)

Scores	Daily Trial				Nocturnal Trial			
	Randomized (n=245)		Excluded (n=133)		Randomized (n=87)		Excluded (n=31)	
	No. Missing	Mean ± SD	No. Missing	Mean ± SD	No. Missing	Mean ± SD	No. Missing	Mean ± SD
Beck Depression Inventory ¹ .	4	13.2 ± 9.3	78	16.7 ± 10.7	4	12.1 ± 8.7	14	12.1 ± 6.9
Trail Making B (sec) ² .	1	234 ± 205	86	295 ± 240	1	200 ± 207	18	213 ± 224
Trail Making B (sec) ³ .	1	166 ± 95.6	86	184 ± 108	1	141 ± 94.8	18	143 ± 97.7
Modified Mini-Mental Status ⁴ .	0	87.1 ± 9.5	82	85.4 ± 12.5	0	90.3 ± 7.2	18	89.5 ± 8.5
Sleep Problems Index II ⁵ .	0	35.8 ± 21.1	70	42.1 ± 20.4	0	32.3 ± 18.0	13	39.7 ± 16.1
Hours Slept Each Night	0	5.98 ± 1.70	70	5.75 ± 1.79	0	6.45 ± 1.51	13	5.76 ± 1.64
Cousineau Caregiver Burden Score ⁶ .	122	37.4 ± 25.4	99	42.4 ± 21.5	22	32.4 ± 18.9	17	43.7 ± 24.4
Feeling Thermometer Score ⁷ .	0	72.6 ± 17.7	80	65.7 ± 22.4	0	74.5 ± 14.8	18	75.1 ± 15.4
Short Physical Performance Battery Score ⁸ .	1	8.31 ± 2.72	88	7.8 ± 3.38	2	8.86 ± 2.34	18	8.38 ± 3.59
HUI-3 Multi-attribute Utility Scale ⁹ .	0	0.54 ± 0.38	70	0.43 ± 0.36	0	0.59 ± 0.33	13	0.49 ± 0.34

¹ Beck Depression Inventory ranges from 0 to 63; higher values represent greater depression.

² Trial Making B (10 minute limit) ranges from 0 to 600 seconds; less time represents better executive control and less cognitive impairment.

³ Trial Making B (5 minute limit) ranges from 0 to 300 seconds; less time represents better executive control and less cognitive impairment.

⁴ Modified Mini-Mental State Exam ranges from 0 to 100; higher values represent better cognitive function.

⁵ MOS Sleep scales which range from 0 to 100; higher values represent more problems.

⁶ The Cousineau Self-Perceived Caregiver Burden ranges from 0 to 100; higher scores represent greater anxiety. Scores were only calculated for subjects with unpaid caregivers.

⁷ Feeling Thermometer Scores range from 0 to 100 with 100 representing best imaginable health state.

⁸ Short Physical Performance Battery ranges from 1 to 12; higher values represent better physical function.

⁹ HUI-3 scores range from 0 to 1; higher scores represent better health.

Table 6
Selected comparisons of characteristics of FHN participants and other hemodialysis populations¹

Variable	FHN Daily Trial (Randomized; n=245)	FHN Nocturnal Trial (Randomized; n=87)	HEMO Baseline Characteristics (N = 1846)	Alberta Nocturnal HD Study Baseline Characteristics (N = 51) ²	USRDS 2010 data on HD Patients (N = 338109)
Age (years)	50.4 ± 13.9	52.8 ± 13.6	57.6 ± 14.0 ^{*o}	54.1 [*]	61.3 ± 15.0 ^{*o}
Female	94 (38%)	30 (35%)	1038 (56%) ^{*o}	32 (63%) ^{**}	151994 (45%) [*]
Race					
Native American, Aboriginal Canadian or Alaskan Native, First Nation	8 (3%)	3 (3%)	11 (1%) ^{*o}	N/A	5005 (1%)
Asian	16 (7%)	12 (14%)	54 (3%) ^{*o}	N/A	15421 (5%) ^o
Native Hawaiian or Other Pacific Islander	4 (2%)	0	0 [*]	N/A	N/A
Black or African American	102 (42%)	23 (26%)	1157 (63%) ^{*o}	N/A	128707 (38%)
White	89 (36%)	48 (55%)	624 (34%) ^o	44 (86%) ^{*o}	185561 (55%) [*]
More than one race (multiracial)	4 (2%)	0	N/A	N/A	N/A
Unknown or not reported	22 (9%)	1 (1%)	0	N/A	3415 (1%)
Hispanic or Latino Ethnicity	69 (28%)	0	N/A	N/A	53703 (16%) ^{*o}
Years since 1st ESRD ³	3.64 [0.63, 14.3] ^{***}	1.08 [0.10, 10.7] ^{***}	3.7 ± 4.4 [*]	5.2	2.5
Primary Reason Kidneys Failed					
Diabetic nephropathy	84 (35%)	30 (35%)	686 (37%)	15 (29%)	150254 (44%) [*]
Hypertensive nephrosclerosis	51 (21%)	7 (8%)	582 (31%) ^{*o}	4 (8%)	96003 (28%) ^{*o}
Glomerulonephritis	47 (19%)	31 (36%)	257 (14%) ^o	13 (25%)	33777 (10%) ^{*o}
Cystic kidney diseases	10 (4%)	3 (3%)	62 (3%)	4 (8%)	8299 (2%)
Analgesic nephropathy	1 (1%)	0	N/A	N/A	N/A
Obstructive uropathy/other urologic	6 (2%)	1 (1%)	N/A	6 (12%) ^{*o}	6709 (2%)
Other	28 (11%)	12 (14%)	259 (14%)	9 (18%)	29777 (9%)
Unknown	18 (7%)	3 (3%)	N/A	N/A	13290 (4%)
Education ⁴					

Variable	FHN Daily Trial (Randomized; n=245)	FHN Nocturnal Trial (Randomized; n=87)	HEMO Baseline Characteristics (N = 1846)	Alberta Nocturnal HD Study Baseline Characteristics (N = 51) ²	USRDS 2010 data on HD Patients (N = 338109)
Not High School Graduate	51 (21%)	13 (15%)	700 (38.0%) ^{*o}	N/A	20%
High School Graduate	58 (24%)	21 (24%)	565 (30.7%)	N/A	30%
Vocational School or Some college	82 (34%)	29 (33%)	355 (19.3%) ^{*o}	N/A	N/A
Associate or Bachelor Degree	42 (17%)	18 (21%)	160 (8.7%) ^{*o}	N/A	39% ^{*o}
Master or Doctoral Degree	9 (4%)	5 (6%)	63 (3.4%)	N/A	N/A
Unknown	3 (1%)	1 (1%)	3 (0.2%)	N/A	12%
Laboratory values⁵					
Serum albumin (g/dL)	3.9 ± 0.4	3.9 ± 0.5	3.6 ± 0.4	3.6	3.9 ± 0.5
Hemoglobin (g/dL)	11.9 ± 1.3	11.8 ± 1.1	N/A	11.8	11.5 ± 1.6 ^{*o}
Phosphorus (mg/dL)	5.8 ± 1.6	5.8 ± 1.6	5.8 ± 1.9	5.2	N/A
LV mass (g)⁶	140.9 ± 54.1	136.7 ± 45.7	N/A	179.5	N/A
Blood pressure (mm Hg)					
Predialysis SBP	146.7 ± 17.9	149.0 ± 18.5	151.8 ± 22.1 [*]	132	N/A
Predialysis DBP	79.7 ± 11.5	81.3 ± 12.1	81.4 ± 12.9	76	N/A
Vascular access⁵					
AV fistula	149 (61%)	40 (46%)	620 (31%) [*]	29 (57%) [*]	3933 (45%) [*]
AV graft	46 (19%)	9 (10%)	1204 (61%) ^{*o}	9 (18%)	2272 (26%)
Tunneled catheter	50 (20%)	38 (44%)	150 (8%) ^{*o}	13 (25%)	2535 (29%) ^{*o}
SF-36 health scales⁷					
PHC score	38.1 ± 10.5	37.8 ± 9.0	36.4 ± 9.6	32.2	N/A
MHC score	45.2 ± 11.7	45.8 ± 11.5	43.3 ± 11.2	46.1	N/A

¹ All data expressed as either no. (%) or mean ± standard deviation (SD) unless otherwise indicated. Comparisons made using chi-square and Fisher's exact tests for categorical data and Student's *t* tests based on comparative means and standard deviations for continuous data.

^{*} Statistically significant difference at the *p* < 0.01 level with FHN Daily Trial.

^o Statistically significant difference at the *p* < 0.01 level with FHN Nocturnal Trial.

*** Median [10th, 90th percentile]

- ² SD for this cohort unavailable, thus unable to make comparison to FHN cohorts for data presented as mean $\pm$ SD
 - ³ Values could only be compared using Student's *t* tests despite skewed distribution of data since individual data are not available for Alberta study.
 - ⁴ Education data for USRDS column based on the Comprehensive Dialysis Study, a sample of 1,646 U.S. incident dialysis patients during 2005–2007 (15).
 - ⁵ USRDS Data through 12/31/2007. Serum albumin, hemoglobin and vascular access data for USRDS column from CMS ESRD CPM project for 2007 for prevalent patients. Serum albumin data using bromocresol green methodology only.
 - ⁶ LV mass not directly comparable between the FHN and Alberta studies as the measurement of LV mass excluded papillary muscle in the FHN studies but included papillary muscle in the Alberta study.
 - ⁷ HEMO Study data converted from PCS and MCS scores respectively to PHC and MHC scores to allow for comparison with FHN data.
- Abbreviations: SBP, systolic blood pressure; DBP, diastolic blood pressure; N/A, _____; USRDS, US Renal Data System; PHC, Physical Health Composite; MHC, Mental Health Composite; SF-36, 36-Item Short Form Health Survey; LV, left ventricular; AV, arteriovenous; ESRD, end-stage renal disease; HD, hemodialysis; HEMO, Hemodialysis Study; FHN, Frequent Hemodialysis Network.