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Family Consultation to Reduce Early Hospital Readmissions among Patients with End Stage Kidney Disease

A Randomized Controlled Trial

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Abstract

Background and objectives The US Centers for Medicare and Medicaid Services have mandated reducing early (30-day) hospital readmissions to improve patient care and reduce costs. Patients with ESKD have elevated early readmission rates, due in part to complex medical regimens but also cognitive impairment, literacy difficulties, low social support, and mood problems. We developed a brief family consultation intervention to address these risk factors and tested whether it would reduce early readmissions.

Design, setting, participants, & measurements One hundred twenty hospitalized adults with ESKD (mean age=58 years; 50% men; 86% black, 14% white) were recruited from an urban, inpatient nephrology unit. Patients were randomized to the family consultation (n=60) or treatment-as-usual control (n=60) condition. Family consultations, conducted before discharge at bedside or *via* telephone, educated the family about the patient's cognitive and behavioral risk factors for readmission, particularly cognitive impairment, and how to compensate for them. Blinded medical record reviews were conducted 30 days later to determine readmission status (primary outcome) and any hospital return visit (readmission, emergency department, or observation; secondary outcome). Logistic regressions tested the effects of the consultation versus control on these outcomes.

Results Primary analyses were intent-to-treat. The risk of a 30-day readmission after family consultation (n=12, 20%) was 0.54 compared with treatment-as-usual controls (n=19, 32%), although this effect was not statistically significant (odds ratio, 0.54; 95% confidence interval, 0.23 to 1.24; P=0.15). A similar magnitude, nonsignificant result was observed for any 30-day hospital return visit: family consultation (n=19, 32%) versus controls (n=28, 47%; odds ratio, 0.53; 95% confidence interval, 0.25 to 1.1; P=0.09). Per protocol analyses (excluding three patients who did not receive the assigned consultation) revealed similar results.

Conclusions A brief consultation with family members about the patient's cognitive and psychosocial risk factors had no significant effect on 30-day hospital readmission in patients with ESKD.

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Introduction

The pursuit of "high value" health care, defined as the best possible outcomes at lowest possible costs (1), is one goal of the US Patient Protection and Affordable Care Act. One specific mechanism to achieve this goal has been the reduction of avoidable early hospital readmissions for discharged inpatients (2). Early readmissions—admissions within 30 days of discharge—reflect recurrent medical crises of sufficient severity to warrant a hospitalization, although less acute medical crises are also of concern and are often managed in the emergency department or observation units (3).

Patients with ESKD have the highest 30-day readmission rates of all patients in the US Medicare/Medicaid population, averaging >30% across hospitals nationwide (2,3). Such readmissions are likely related to a high disease burden and driven by patient nonadherence (4); many patients with ESKD do not adhere to diet, fluid-intake, and medication regimens (5). Yet, uncoordinated or inadequate advanced care or discharge planning also contributes to early readmissions (6,7).

Behavioral factors driving readmission have rarely been examined (8), although research suggests that cognitive impairment, identified by clinical bedside examination, predicts early readmissions (9,10). In fact, cognitive impairment has been found to prospectively predict hospital admission and mortality in chronically ill patients (9,11–13), a result even more likely to occur when attending physicians are unaware of the patient's cognitive limitations (14). Indeed, medical providers and family members are poor at recognizing cognitive impairment among patients,

particularly when only mild or moderate in severity (15–17). Additional factors that likely contribute to early readmission are low health literacy, poor patient-physician relationships, psychiatric and substance abuse history, and limited social support (5). Together, these risk factors likely cause individuals to flounder with the complexities of their self-care at home, especially in the absence of compensatory assistance (4,18,19).

Involving family members or support people in the care of chronically ill patients is generally beneficial and is associated with better adherence (20–24). We anticipated that an intervention to educate family members about the patient's risk factors and to mobilize reliable social support would reduce some of the risk of cognitive impairment, literacy problems, and mood disturbances, thereby reducing early readmissions in patients with ESKD (10,25–27). In another pilot study, we found that a brief family consultation was associated with a reduction in readmissions among patients with congestive heart failure (26).

In the current trial, we refined the family consultation developed and piloted earlier (26) and tested it in a randomized, controlled trial among patients with ESKD. Our prespecified primary outcome and endpoint was the presence or absence of a hospital readmission within 30 days of discharge. We also analyzed the presence of any unplanned early hospital return visit, including not only readmissions but also observation status and emergency department visits; although the latter two are not yet targeted by the Affordable Care Act, they represent the larger set of clinically relevant negative outcomes. We tested the hypothesis that the family consultation would reduce 30-day readmissions (primary outcome) and unplanned early hospital visits (secondary outcome), compared with treatment as usual (*i.e.*, no added family consultation). We also included a secondary endpoint (6-month follow-up) to determine the duration of any effects of the family consultation.

Methods

Participants and Recruitment

Participants were adult patients (aged 18 or older) diagnosed with ESKD who were hospitalized on the nephrology unit at Henry Ford Hospital in Detroit, Michigan. Inclusion criteria were a current admission to the unit and willingness to contact a family member or friend, who was expected to be available and willing to meet with the consultant if the patient was randomized into the experimental condition. To maximize generalizability, exclusion criteria were few: delirium, inability to speak English, and unavailability or discharge before recruitment and informed consent. We included not only patients with cognitive impairment, but also those with no evidence of cognitive impairment, because the latter often have other risk factors for readmission (*e.g.*, low support, literacy problems) and remain at risk for future cognitive impairment.

Procedure

This trial was registered at clinicaltrials.gov (NCT02504021) before recruitment, which occurred from July of 2015 to March of 2016, with primary (30-day) outcome assessment completed in May of 2016, and secondary (6-month) outcome assessment completed in October of 2016. The study protocol was approved by the hospital's institutional review board and adhered to the ethical principles in the Declaration of Helsinki. The randomization scheme was created before recruitment began by an independent research assistant using a computer program (randomization.com). Randomization in a 1:1 allocation ratio was stratified by patient sex (male or female) and conducted in randomized blocks of six or eight; assignments were placed in sealed, opaque envelopes. Figure 1 presents the flow of patients through the trial.

Patients were approached at bedside on the nephrology unit. Those who met study criteria were informed about the trial, and written consent was obtained. Patients then completed several questionnaires, which informed the subsequent family consultation (if assigned). Given concerns about literacy in this population, questionnaire items were read aloud by the researcher to assure the patient's understanding. After the assessment, the researcher unsealed the envelope to determine the assigned condition; patients and researcher were blind to condition assignment before this point. Patients were remunerated for participating in the initial assessment.

Patient Descriptive Measures

Cognitive impairment and educational attainment were assessed with the Montreal Cognitive Assessment (28), which is a brief (approximately 10-minute), easily administered and scored screening instrument to detect signs of cognitive impairment among patients in medical settings. The measure assesses executive function, immediate memory, language, abstraction, short-term memory, and orientation, with a correction for education level. Scores <23 are considered in the cognitively impaired range.

Health literacy was assessed with the Rapid Estimate of Health Literacy in Medicine-Short Form (REALM-SF) (29), which is a brief (approximately 2-minute) screening instrument for use in medical settings to assess patients' reading level. A score <7 represents reading ability below the ninth grade level.

Social support was assessed with three items from the Diabetes Social Support Questionnaire–Family Version (30), and two items from the Modified Scale of Social Support–5 (31).

Treatment adherence was assessed with the four-item Immunosuppressant Therapy Adherence Scale, with wording changed to refer to patients with ESKD (32). A fifth item "How often did you miss your planned dialysis sessions?" was added.

Depression was assessed using the Patient Health Questionnaire–8 (33).

Anxiety was assessed using the Generalized Anxiety Disorder 7-Item Scale (34).

Experimental Conditions

Family Consultation Condition

The model underlying the intervention posits that it is beneficial to provide patients and their families with plain language, nonthreatening information about the patient's unique psychosocial risk factors for health problems and to

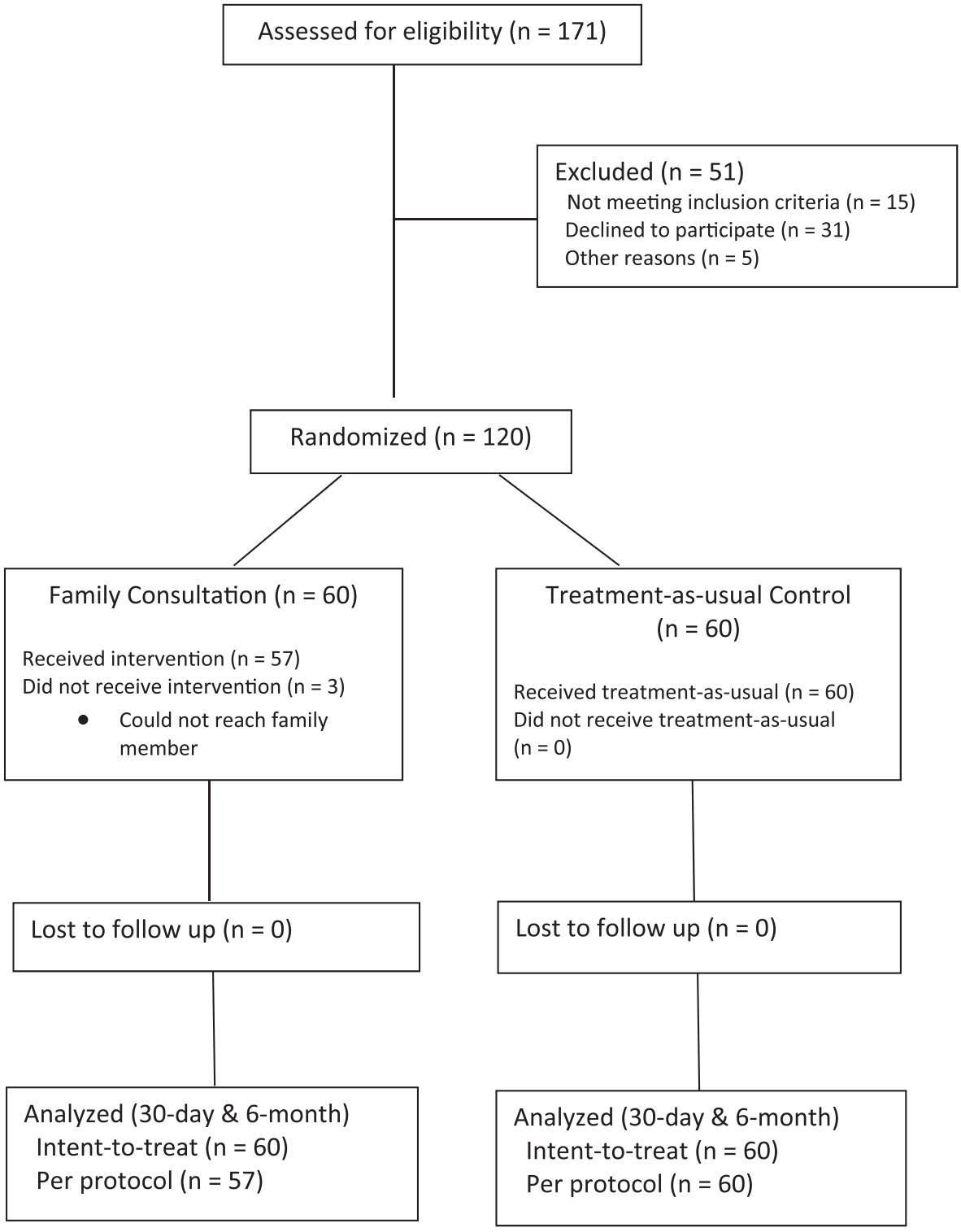

Figure 1. | **Consolidated standards of reporting trials (CONSORT) flowchart displaying recruitment, randomization, and participation.**

encourage the family to support the patient's adaptive health behaviors. The consultation consisted of one relatively brief session conducted by a male clinical psychology predoctoral intern, supervised by a doctoral psychologist. To maintain trial integrity, the consultant worked independently from the rest of the health care team on the unit. The family consultation was conducted while the patient was in hospital, as soon as possible after the background assessment and randomization. If the family member or support person selected by the patient was present or could be readily scheduled to come to the hospital, the consultation was conducted at the bedside with both the patient

and family member/support person. However, in-person family meetings were sometimes not feasible, so to maximize participation, some family consultations occurred by telephone. In such cases the consultation was conducted with the family member over the phone, and patients were subsequently briefed about the content of the discussion.

The family consultation had several components. The consultant: (*1*) introduced himself and informed the family member and patient that the health care team was working to improve postdischarge care by communicating better with the patient's support people; (*2*) built rapport by providing empathy regarding the burden of managing ESKD; (*3*) reviewed patient and family understanding of events that caused the hospital admission; (*4*) explained cognitive impairment (as "forgetfulness") and educated the patient and family about of the level of cognitive impairment that the patient was experiencing by discussing the results of the initial cognitive assessment; (*5*) discussed ways for the support person to assist the patient with his or her medication adherence, even when the patient displayed no overt signs of cognitive impairment; (*6*) tailored the consultation to each patient by including information about other risk factors identified in the initial assessment (*i.e.,* health literacy, social support, and adherence); and (*7*) used motivational interviewing techniques, as indicated, such as asking permission to make recommendations, and reflecting ambivalence (35) over patient-reported treatment adherence.

Control Condition

After the initial assessment, control patients engaged only in their medical treatment as usual. No family consultations were conducted.

Outcome Measures: Early Readmissions and Hospital Visits

Two outcome variables were extracted from the electronic medical record of each patient. The prespecified primary outcome and endpoint was whether a patient was readmitted as an inpatient within 30 days of discharge from the index admission. This is the narrowly defined Affordable Care Act metric with financial penalties, which is used by hospitals nationwide. This metric, however, misses several additional problematic outcomes that fall short of full readmission, which we observed early in the trial. Thus, before outcome data collection, we defined a secondary outcome: whether a patient had any unplanned return hospital visit, defined as an observation unit visit, an emergency department visit, or an inpatient readmission within 30 days of discharge. All outcome data were initially retrieved by the consultant, and then independently retrieved by a senior staff member blinded to experimental condition. Complete agreement between the two coders was >98%; the few differences were resolved by consensus. After 6 months, a blinded reviewer again classified patients as to whether they had had a readmission or any unplanned return hospital visit during the prior 6 months.

Statistical Analyses

An initial power analysis, conducted with G*Power 3.1.9.2, yielded the sample size needed to obtain power of 0.80, given an estimated medium effect size (w=0.3) difference between the two conditions on the primary outcome (presence or absence of an early readmission), in a 2×2 contingency table with α=0.05. A minimum of 88 patients was indicated; however, we recruited beyond that number to increase our power. Analyses of the effects of the family consultation versus control on the primary and secondary outcomes at the 30-day and 6-month endpoints were conducted with logistic regressions. Primary analyses were conducted on the full, intent-to-treat sample; secondary "per protocol" analyses excluded three patients who did not receive the assigned family consultation (described below). All analyses were conducted two-tailed using an α of 0.05. Primary analyses were conducted with no covariates, although we ran a sensitivity analysis, adjusting the logistic model for variables that seemed to be imbalanced at baseline. For effect sizes, we calculated the odds ratio (OR; <1.0 indicates reduced readmissions/unplanned return visits for family consultation relative to controls) and 95% confidence interval (95% CI). For significant effects, we also calculated the number needed to treat; that is, the number of patients who would need the family consultation to prevent one negative outcome (an early readmission or unplanned hospital visit).

Results

Sample Descriptives

As shown in Figure 1, we screened 171 patients, and 156 (92%) were eligible for inclusion. Of these, 120 (77%) were randomized. Sociodemographic and medical history data for the full sample and each condition separately are presented in Table 1. The overall sample was half men and half women, had a mean age of 58 years (SD=14; range= 24–88), was predominantly black (86%), and less than half (43%) had education beyond high school. Patient literacy averaged between the seventh and eighth grade level. In addition to ESKD, most patients had multiple medical comorbidities.

The family consultation was conducted as planned for 57 of the 60 patients randomized to the consultation condition; family consultations did not occur for three patients for whom the consultant was unable to reach any support person, even after three attempted telephone calls. The 57 consultations were relatively brief, averaging about 8 minutes (SD=5.0 minutes, range: 2–30 minutes); 23 consultations (40%) were conducted with the family at bedside, and the rest (60%) were conducted over the telephone. Consultations involved a variety of different support people: 17 (30%) spouses, 12 (21%) children, ten (16%) parents, six (11%) siblings, six (11%) multiple people, and six (11%) nonrelatives.

Testing the Superiority of Family Consultation to Treatment as Usual

As shown in the top half of Table 2, under intent-to-treat analyses, the two conditions did not differ significantly (P=0.15) on the prevalence of early readmission; the rate of readmission in the consultation (n=12, 20%) was numerically lower than in the control condition (n=19, 32%), and the risk or odds of early readmission after consultation compared with control was 0.54 (95% CI, 0.23 to 1.24). A similar magnitude, nonsignificant result was seen for the

Table 1. Baseline characteristics of participants randomly assigned to family consultation or treatment as usual in a clinical trial of patients with ESKD discharged from an urban hospital

Variable	Total Sample *n*=120	Family Consultation *n*=60	Treatment as Usual *n*=60
Demographics			
Age (M, SD)	58 (14)	58 (14)	57 (15)
Sex (male)	60 (50%)	30 (50%)	30 (50%)
Sex (female)	60 (50%)	30 (50%)	30 (50%)
Race (black)	103 (86%)	51 (83%)	52 (86%)
Race (white)	17 (14%)	9 (15%)	8 (13%)
Education>12th grade	51 (42%)	24 (40%)	27 (45%)
Medical risk factors			
Congestive heart failure	58 (48%)	28 (46%)	30 (50%)
Smoking	71 (59%)	35 (58%)	36 (60%)
Diabetes	74 (61%)	42 (70%)	32 (53%)
Hypertension	118 (98%)	59 (99%)	59 (99%)
COPD	22 (18%)	10 (16%)	12 (20%)
BUN (M, SD)	41 (23)	38 (19)	43 (26)
Serum creatinine (M, SD)	7.4 (3.7)	7.0 (3.3)	7.7 (3.9)
Phosphorous (M, SD)	4.4 (1.7)	4.1 (1.5)	4.6 (1.9)
Number of medications (M, SD)	14.4 (5.9)	15.1 (5.9)	13.7 (5.9)
On hemodialysis	113 (94%)	57 (95%)	56 (93%)
Type of vascular access[a]			
AVF	45 (38%)	25 (42%)	20 (33%)
AVG	19 (16%)	7 (12%)	12 (20%)
Catheter	47 (39%)	24 (40%)	23 (38%)
Charlson Comorbidity (M, SD)	7.5 (3.1)	7.6 (3.0)	7.3 (3.3)
Behavioral risk factors			
Psychiatric diagnosis	35 (29%)	17 (28%)	18 (30%)
Psychiatric medication	30 (25%)	14 (23%)	16 (26%)
Substance use history	31 (25%)	11 (18%)	20 (33%)
Positive toxicology screen	11 (9%)	4 (6%)	7 (11%)
Cognitive risk factors			
Delirium	37 (30%)	17 (28%)	20 (33%)
Positive head imaging	61 (50%)	29 (48%)	32 (53%)
History of seizures	14 (11%)	6 (10%)	8 (13%)
History of hypoxia	19 (15%)	6 (10%)	13 (21%)
Dementia	5 (4%)	2 (3%)	3 (5%)
Stroke history	10 (8%)	4 (6%)	6 (10%)
Cognitive impairment (M, SD)	20. 5 (4.5)	20. 5 (4.8)	20. 4 (4.2)
Initial assessment (M, SD)			
Health literacy	5.5 (2.1)	5.1 (2.0)	5.4 (2.2)
Social support	2.9 (1.0)	2.9 (1.0)	2.9 (1.1)
Adherence	2.4 (0.6)	2.4 (0.6)	2.4 (0.6)
Depression	6.8 (4.6)	6.9 (4.3)	6.7 (4.9)
Anxiety	5.3 (4.6)	5.2 (4.1)	5.2 (5.0)

Data are presented as *n* (%) and mean (M) standard deviation (SD) where applicable. COPD, chronic obstructive pulmonary disease; AVF, arteriovenous fistula; AVG, arteriovenous graft; tox, toxicology.
[a]This information was missing from 11 patients.

occurrence of any early hospital return visit: family consultation condition (*n*=19, 32%), control condition (*n*=28, 47%; OR, 0.53; 95% CI, 0.25 to 1.11; *P*=0.09). At 6 months, condition differences were much smaller, and family consultation did not differ significantly from control on either the prevalence of readmission or any hospital return visit.

Two of the three patients who did not get the family consultation as assigned had an early readmission, and all three of these patients had an early return visit. Per protocol analyses that excluded these three patients revealed nonsignificant condition differences that were slightly larger than noted under intent-to-treat analyses. As shown in the bottom half of Table 2, the prevalence of early readmission did not differ significantly between the family consultation condition (*n*=10, 18%) and the control condition (*n*=19, 32%; OR, 0.46; 95% CI, 0.19 to 1.10; *P*=0.08). Finally, the family consultation condition had a significantly lower prevalence of any unplanned early hospital return visit (*n*=16, 28%) than did the controls (*n*=28, 47%); the odds of any return visit after family consultation compared with control were 0.45 (95% CI, 0.21 to 0.96; *P*=0.04; number needed to treat=6). Again, at 6 months, the condition differences were negligible, and neither readmissions nor unplanned return visits differed significantly between conditions.

Finally, we ran a sensitivity analysis on our primary outcome to test the effects of a possible imbalance between the two conditions in several background factors: history of diabetes, hypoxia, substance use history, and a positive toxicology screen. Adjusting the logistic model simultaneously for these covariates indicated that the risk of early

Table 2. Outcomes of a clinical trial comparing family consultation to treatment as usual among patients with ESKD discharged from an urban hospital

Variable	Family Consultation	Treatment as Usual	OR	95% CI	*P*
Intent-to-treat analyses	(*n*=60)	(*n*=60)			
30-d readmission[a]			0.54	0.23 to 1.24	0.15
Yes	12 (20.0%)	19 (31.7%)			
No	48 (80.0%)	41 (68.3%)			
30-d any return visit			0.53	0.25 to 1.11	0.09
Yes	19 (31.7%)	28 (46.7%)			
No	41 (68.3%)	32 (53.3%)			
6-mo readmission			0.93	0.44 to 1.96	0.85
Yes	38 (63.3%)	39 (65.0%)			
No	22 (36.7%)	21 (35.0%)			
6-mo any return visit			0.75	0.32 to 1.77	0.51
Yes	45 (75.0%)	48 (80.0%)			
No	15 (25.0%)	12 (20.0%)			
Per-protocol analyses	(*n*=57)	(*n*=60)			
30-d readmission			0.46	0.19 to 1.10	0.08
Yes	10 (17.5%)	19 (31.7%)			
No	47 (82.5%)	41 (68.3%)			
30-d any return visit			0.45	0.21 to 0.96	0.04
Yes	16 (28.1%)	28 (46.7%)			
No	41 (71.9%)	32 (53.3%)			
6-mo readmission			0.86	0.40 to 1.82	0.69
Yes	35 (61.4%)	39 (65.0%)			
No	22 (38.6%)	21 (35.0%)			
6-mo any return visit			0.70	0.30 to 1.66	0.42
Yes	42 (73.7%)	48 (80.0%)			
No	15 (25.0%)	12 (20.0%)			

Data are presented as *n* (%). OR, odds ratio; 95% CI, 95% confidence interval.
[a]Prespecified primary study outcome at the primary endpoint (30 d) in primary analyses (intent-to-treat). All other outcomes, endpoint, and analyses are secondary.

readmission after consultation compared with control was largely unchanged from the unadjusted model presented above: the OR changed only from 0.54 to 0.55 (95% CI, 0.23 to 1.32), and the condition effect remained nonsignificant (*P*=0.18).

Discussion

Patients with ESKD are at substantial risk for early readmission, particularly due to cognitive impairment, low health literacy, low social support, and subsequent nonadherence to medications and dialysis (9,10). This randomized controlled trial tested whether a brief behavioral intervention among patients with ESKD—consulting with the patient's family members about the patient's cognitive status and other risk factors and the need for better adherence—could reduce early (30-day) hospital readmissions and, secondarily, any unplanned early return visit, compared with treatment as usual (no family consultation). The consultation yielded a small-to-medium effect that was not statistically significantly different than that observed among controls.

Although our central focus was the effect of family consultation on readmissions and unplanned return visits, it also is important to understand the mechanisms or processes by which the consultation may achieve such benefits. Unfortunately, we were unable to collect reliable data on possible mechanisms after discharge, such as improvements in medication or dialysis adherence, family communication patterns, or reduced stress. Thus, we must rely on our knowledge of the general literature, this population, and some anecdotal observations to speculate about possible mechanisms.

We suspect that any reductions in early readmission or unplanned return visits after a family consultation could result from destigmatized education of the patient and family regarding the complexities of managing ESKD and the challenges that patients experience, particularly the existence of cognitive impairment and its implications for adherence. Many patients and family members in this trial remarked that no one had ever explained to them that cognitive impairment (*i.e.*, "forgetfulness") was common in patients with ESKD, and that such impairment puts them at risk for missing medications and dialysis treatments, resulting in further hospital care. Research has noted problems in medication adherence among cognitively impaired patients with congestive heart failure, and studies in other populations suggest that family interventions can improve adherence (4,24,36). Thus, the most plausible biobehavioral mechanism for explaining why patients get readmitted is that they forget to refill prescriptions and take medications consistently, and/or miss dialysis sessions. Therefore, we speculate that by providing education to patients and families about the risk that cognitive impairment plays in readmissions, one may improve patients' ability and willingness to utilize their family to help with treatment adherence postdischarge.

The nonsignificant differences in 30-day readmissions after family consultation found in this trial were completely eliminated by 6-month follow-up. We think that a single,

brief family consultation is unlikely to improve longer-term outcomes. Families likely need additional consultations or booster sessions to reinforce their motivation and maintain the important behavioral or interpersonal changes they make initially. Home health care may represent a feasible opportunity to deliver these ongoing services.

This trial has several unique strengths. The consultation was designed to maximize feasibility—being conducted at bedside or *via* telephone—and did not rely on special resources or involvement from other providers on the nephrology unit. Also, very few patients were excluded, and over three-quarters of eligible patients were randomized, thereby enhancing sample generalizability. Furthermore, the sample was one that is often viewed as particularly high risk: urban, largely black patients, with multiple social, economic, and behavioral risk factors. Given these challenges, we believe that this intervention can be implemented readily on other nephrology units and perhaps other hospitalized populations with chronic diseases and high risk for readmission.

This trial has several limitations. First, most of the analyses failed to reach statistical significance, likely due to insufficient sample size. Our initial power analysis overestimated the effect size; rather than medium in magnitude, our obtained ORs are closer to a "small" effect (37), indicating the need for a larger sample. Second, our results are limited to a specific population and provider. Future trials should test the consultation in different populations of people with ESKD (including at-risk outpatients on hemodialysis) and with more than a single consultant working independently from the nephrology team. We predict that larger reductions in early readmissions will be found when the family consultant works closely with other providers on the unit. Third, initial diagnoses, plans for follow up, and specific reasons for readmission or return visits are complex and not well delineated in medical records, which could bias the trial in unknown ways. Also, it is possible that some patients were readmitted to other hospitals of which we were unaware. Fourth, as noted above, assessment of possible mechanisms of change, particularly adherence to medications and dialysis as well as family relations or communication, would clarify how such a consultation might reduce early readmissions. Fifth, baseline characteristics of family members (*e.g.*, cognitive status and literacy), which could affect implementation of the intervention, were not assessed. Finally, it is likely that this intervention is most effective with subsets of patients, such as those with a certain degree of cognitive impairment or certain types of family relations, but our sample was not large enough to reliably test such moderators. There is a compelling argument for testing and disseminating interventions that assess cognitive impairment and other risk factors and involve families in the care of patients. The results of this trial, although not reaching statistical significance, do not completely exclude the value of greater involvement of behavioral medicine in treatment and discharge planning.

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Disclosures

None.

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