



## Group-Based Care in Adults and Adolescents With Hypertension and CKD: A Feasibility Study

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**Rationale & Objective:** Group-based care provides an opportunity to increase patient access to providers without increasing physician time and is effective in the management of chronic diseases in the general population. This model of care has not been investigated in chronic kidney disease (CKD).

**Study Design:** Randomized controlled trial in adults (n = 50); observational study in adolescents (n = 10).

**Setting & Participants:** Adults and adolescents with CKD and hypertension in the Bronx, NY.

**Intervention:** Group-based care (monthly sessions over 6 months) versus usual care in adults. All adolescents received group-based care and were analyzed separately.

**Outcomes:** Participant attendance and satisfaction with group-based care were used to evaluate intervention feasibility. The primary clinical outcome was change in mean 24-hour ambulatory blood pressure. Secondary outcomes included physical activity, medication adherence, quality of life, and sodium intake as assessed by 24-hour urinary sodium excretion and food frequency questionnaires.

**Results:** Among adults randomly assigned to group-based care, attendance was high (77% of

participants attended  $\geq 3$  sessions) and most reported higher satisfaction. Mean 24-hour ambulatory systolic blood pressure decreased by  $-4.2$  (95% CI,  $-13.3$  to  $5.8$ ) mm Hg in group-based care patients compared with usual care at 6 months but this was not statistically significant. Similarly, we did not detect significant differences in health-related behaviors (such as medication adherence, sodium intake, and physical activity) or quality-of-life measures between the 2 groups. Among the adolescents, attendance was very poor; self-reported satisfaction, although high, did not change from baseline compared with the 6-month follow-up.

**Limitations:** Small study size, missing data.

**Conclusions:** Group-based care is feasible and acceptable among adults with hypertension and CKD. However, a larger trial is needed to determine the effect on blood pressure and health-related behaviors. Patient participation may limit the effectiveness of group-based care models in adolescents.

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The burden of chronic kidney disease (CKD) is substantial, affecting 1 in 7 people in the United States.<sup>1</sup> Among children and adults, hypertension is an important cause of CKD and an independent predictor of CKD progression.<sup>2-4</sup> Despite the efforts of health care professionals, studies show that blood pressure (BP) is often poorly controlled and low medication adherence is common in the CKD population.<sup>5-7</sup>

Adherence involves a complex interplay of patient, condition, therapy, provider, and environmental factors.<sup>8</sup> The CKD population is burdened with many socioeconomic and psychosocial stressors (such as limited health literacy, inadequate support or coping skills, low socioeconomic status, inadequate care, or limited access to care) that adversely affect adherence.<sup>9,10</sup> The Information, Motivation and Behavior Skills model<sup>11,12</sup> argues that 3 things are necessary for adequate adherence: (1) information about the condition and management strategies; (2) motivation, which involves assessing patients' attitudes toward adherence and their social support structure (or

network) for adherence; and (3) behavior, which focuses on the skills and strategies to help patients adhere. Interventions based on this model have been effective in influencing adherence across a variety of clinical applications.<sup>12,13</sup>

Group-based care, a newer model of health care delivery, provides an opportunity to increase patient access to providers without increasing physician hours.<sup>14</sup> During a typical group visit, also known as shared medical appointments, individuals with the same disease or condition meet with providers at the same time. The group setting facilitates peer mentoring and support, which may enhance patients' self-care behaviors. This, as well as the added benefit of maximizing provider-patient time, provides a strong rationale for adapting this model of care in the CKD population. This model of health care delivery has been investigated in a number of chronic diseases or conditions (eg, diabetes, hypertension, and pregnancy)<sup>15-18</sup> in adults and children but has not been studied in patients with CKD.

We designed a group-based care education intervention using the principles from the Information, Motivation and Behavior Skills model of adherence that focused on health-related behaviors that improve BP, including medication adherence, healthy diet, and increased physical activity. We then conducted a randomized controlled trial (RCT) in adults and an observational study in adolescents in the Bronx, NY, to evaluate the feasibility and possible effect of our group-based care intervention in a racially and ethnically diverse high-risk patient population with hypertension and CKD. The Bronx is one of the poorest urban counties in the country and the incidence of end-stage kidney disease is one-third higher than the United States average.<sup>19,20</sup>

## METHODS

### Study Design

This study was conducted from August 1, 2014, to August 31, 2017. Adults (aged >21 years) were randomly assigned using a block scheme and stratified by level of estimated glomerular filtration rate (eGFR), 30 to 60 or <30 mL/min/1.73 m<sup>2</sup>, to either group-based or usual care. Adolescents (aged 12-21 years) were recruited for a cohort study of group-based care and analyzed separately. All participants were seen at baseline and 6 months. Patients in group-based care were seen at 1-month intervals for the group sessions.

The study was approved by our Institutional Review Board (2014-3117). Written informed consent was obtained from all participants before inclusion (Item S1 depicts all inclusion and exclusion criteria). The trial was registered on ClinicalTrials.gov: NCT02467894.

### Study Setting and Participants

We recruited adults and adolescents from the nephrology clinics at Montefiore Medical Center in the Bronx with hypertension and CKD from November 2014 to February 2017. The medical center serves a predominately urban African American/black and Hispanic population.

### Description of Intervention

Patients randomly assigned to group-based care were asked to attend 6 monthly clinic visits as part of a group of 5 to 10 patients. Adolescents met in smaller groups (2-5) and separately from the adults. A Spanish interpreter was available for those who preferred to communicate in Spanish but all participants were either English-dominant speakers or bilingual. All sessions started with self-care activities, including BP measurements and other vitals (including weight). At each session, a specific topic was discussed (Table S1) and the content was sourced from existing educational materials from the National Kidney Disease Education Program (<https://www.niddk.nih.gov/health-information/professionals/clinical-tools-patient-education-outreach>).<sup>21</sup> These materials have been

associated with increased kidney disease knowledge among patients with CKD.<sup>22</sup> Topics for discussion were led by a nephrologist or kidney dietitian (Table S1). Neither person received any special educational training to prepare for the group visits but the kidney dietitian had more than 10 years of experience in providing dietary counseling to patients with CKD.

Health-related behaviors such as medication adherence, reducing sodium intake, and increasing physical activity were reinforced at every meeting. Participants were encouraged to share successful adherent behaviors and strategized with the provider and other participants for implementing healthful habits. They were also encouraged to bring family members or caregivers to the group sessions. Participants randomly assigned to group-based care continued to see their private nephrologist. However, the intervention was separate from their regular nephrology care and group visit data were not shared with their nephrologists. Participants were given the opportunity to address individual concerns, such as medication tailoring and prescriptions, and were encouraged to share these concerns with their private nephrologist.

### Control Group

Participants randomly assigned to usual care received printed health education materials from the National Kidney Disease Education Program. They continued to see their nephrologist as needed but were scheduled on a different day of the week from the group visits to avoid contact with the treatment group.

### Data Collection

Data were collected at enrollment, group, and 6-month follow-up visits. Blood and urine tests were obtained at the enrollment (baseline) and 6-month follow-up visits. Sociodemographic, psychosocial, and medical data were collected using self-report questionnaires at enrollment. We used creatinine-based equations to calculate eGFR, including CKD Epidemiology Collaboration (CKD-EPI) for participants 18 years or older<sup>23</sup> and bedside Schwartz for participants aged 12 to 17 years.<sup>24</sup> Sodium intake was assessed at baseline and 6 months using a 24-hour urine collection and block dialysis food frequency questionnaire (FFQ) from Nutrition Quest.<sup>25</sup> In adolescents, we used neighborhood zipcode data to estimate mean neighborhood income because we did not directly ask for family income. Anthropomorphic data were measured at all visits. Office BPs were measured by taking the average of 3 measurements using the Omron HEM-907XL automated machine after 5 minutes of rest. We used the SpaceLabs 90217 device for 24-hour ambulatory BP monitoring. All BP measurements were taken from the right arm. We used Rapid Estimate of Adult Literacy in Medicine (REALM)<sup>26</sup> and REALM-Teen<sup>27</sup> to assess health literacy skills in adult and adolescent participants, respectively.

## Outcomes

Group session attendance and patient satisfaction were used as the quality metrics to evaluate feasibility. We defined an acceptable threshold for overall participant attendance as  $\geq 67\%$  attendance to 3 or more group sessions. This is similar to the participant attendance acceptability threshold of other group-based care studies.<sup>28,29</sup> To evaluate patient satisfaction, we used a simple paper survey adapted from the Health Resources and Services Administration Health Center Patient Satisfaction Survey.<sup>30</sup>

The primary clinical outcome was change in 24-hour ambulatory BP (SpaceLabs 90217 device) from baseline to 6-month follow-up. Secondary measures included: (1) self-reported medication adherence, (2) dietary sodium adherence as assessed by 24-hour urine sodium and FFQ, (3) physical activity as measured by accelerometer over a 7-day period, and (4) quality-of-life metrics using Pediatric Quality of Life Inventory (PedsQL) in adolescents and 36-Item Short Form Health Survey (SF-36) in adults from baseline to the 6-month follow-up visit. To elicit self-reported medication nonadherence, we asked patients if they had missed any BP medication doses in the past 2 weeks.

## Statistical Analysis and Power Considerations

Descriptive statistics were computed for all participant baseline characteristics. To examine within-group differences at baseline compared with 6 months, we used paired *t* tests and Wilcoxon signed rank tests for normally and non-normally distributed data, respectively. To assess between-group differences at 6 months (ie, intervention vs usual care) and determine an effect size for the clinical outcomes, we used analysis of covariance or logistic regression models adjusted for the baseline outcome measurements. Accelerometer data were analyzed as steps per hour and considered valid (ie, included in our analyses) only if participants wore their accelerometer for at least 10 hours on 2 separate days. We also performed a number of sensitivity analyses for the BP outcome, including: (1) limiting our models to participants who attended 3 or more group sessions, (2) evaluating change in office BP, and (3) limiting our analysis to participants with 24-hour ambulatory systolic BP (SBP)  $\geq 140$  mm Hg. All analyses were based on the intention-to-treat principle in which any participant randomly assigned to a treatment remains in it regardless of adherence to or completion of treatment. For the adolescent cohort, we performed only descriptive statistics, and comparisons of outcomes measures at baseline and 6 months were qualitative due to the small sample size.

Our sample size was not large because this was a pilot feasibility study. If group-based care is found to be feasible, the pilot data clinical results will be used to determine the effect and sample size for a future larger study. All statistical analyses were done using Stata statistical software MP version 15.1 (StataCorp).

## RESULTS

### Participant Flow

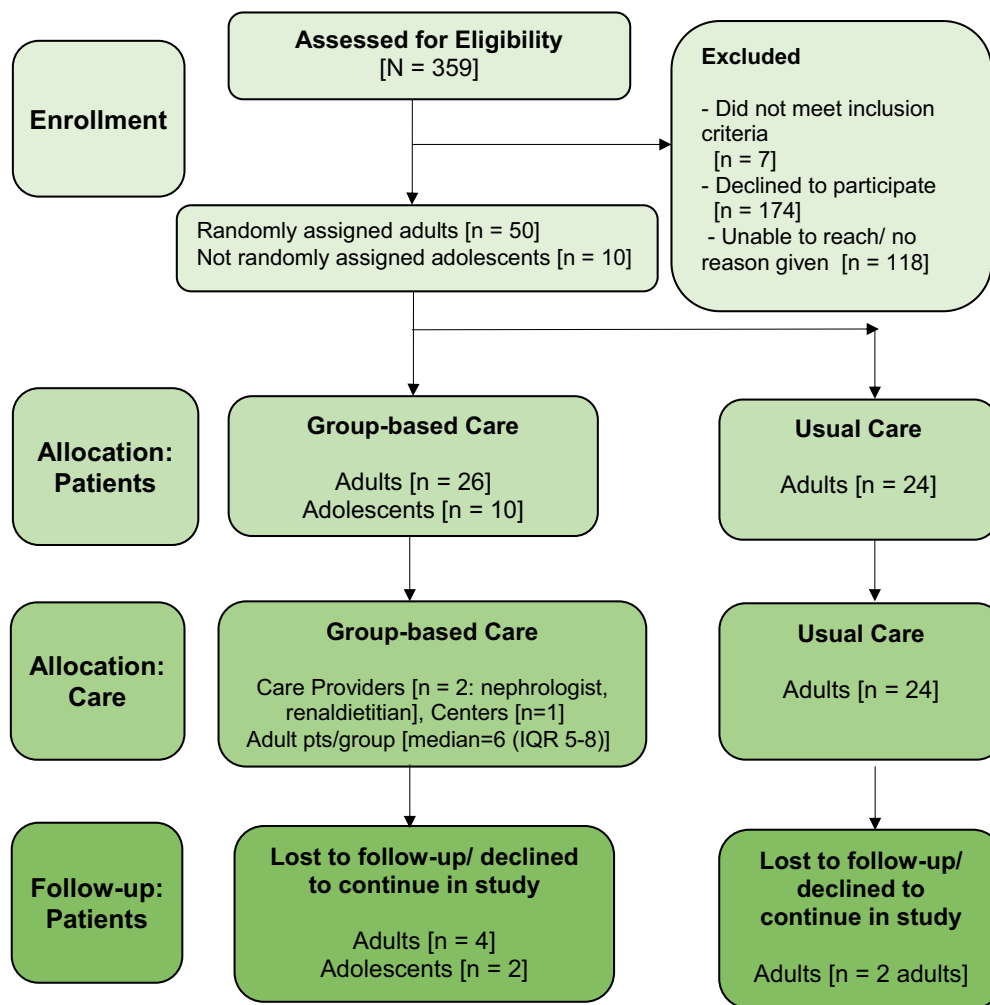
Of the 359 individuals (aged  $\geq 12$  years) screened and contacted for study participation, 60 were eligible and provided the necessary informed consent. The most common reason for individuals not participating was not interested/did not return telephone calls (71%). Of the adult participants ( $n = 50$ ) included in the study, 26 were allocated to group-based care, and 24, to usual care only. All adolescents ( $n = 10$ ) were allocated to group-based care and analyzed separately. [Figure 1](#) depicts participant flow through the study.

### RCT in Adults

Mean age was 62 (standard deviation [SD], 11) years; 94% were Hispanic or African American, 54% were female ([Table 1](#)), and 36% had a REALM score  $< 61$ , corresponding to less than high school literacy. There were more people with diabetes mellitus and congestive heart failure in the control than the intervention group ( $P = 0.05$ ). BP medication use was similar between the 2 groups and  $> 50\%$  of participants were using 3 or more BP medications at baseline. Mean eGFR was 35.4 (SD, 13.2) mL/min/1.73 m<sup>2</sup>, median 24-hour sodium excretion was 2,622 (interquartile range [IQR], 1,840–3,910) mg, and mean 24-hour ambulatory SBP and diastolic BP (DBP) were 137 (SD, 20) and 77 (SD, 11) mm Hg, respectively ([Table 1](#)). At baseline, 32% of all participants reported missing doses of their BP medication(s) within the past 2 weeks, and the proportion of patients reporting medication nonadherence was similar between the intervention and usual-care groups ([Table 1](#)).

Attendance was high, with 77% ( $n = 20/26$ ) of participants attending 3 or more group sessions. Two (8%) participants attended all 6 visits and 4 (15%) attended none of the visits. Patient satisfaction with the intervention was high, with 70% of group-based participants rating their experience as “5 = great” or “4 = good” after the intervention. This was a significant improvement compared with their baseline assessment, in which only 58% rated their satisfaction with their health care favorably ( $P < 0.001$ ). Furthermore, 88% of participants in group-based care reported that they would recommend it for friends or relatives. Participants who dropped out or did not complete the survey ( $n = 4$ ) were considered to have an unfavorable response to the intervention. Patient satisfaction also improved in the control group at the 6-month follow-up visit compared with baseline (75% vs 54%). During the 6-month follow-up, participants in group-based care had a median of 1 (IQR, 0–2) visit to their outpatient nephrologists. In the usual-care group, the median was also 1 (IQR, 0–2.3) outpatient visit during the 6 months.

There was a non-statistically significant decrease in mean 24-hour ambulatory SBP,  $-4.2$  (95% confidence



**Figure 1.** Study flow chart. Abbreviations: IQR, interquartile range; pts, patients.

interval [CI],  $-13.3$  to  $5.8$ ) mm Hg, and 24-hour ambulatory DBP,  $-0.5$  (95% CI,  $-6.4$  to  $5.7$ ) mm Hg, in the intervention group compared with usual care after 6 months (Table 2). Limiting our analyses to adults who attended 3 or more group visits did not change the interpretation of our results. Using office BP, which had fewer missing data compared with 24-hour ambulatory BP measurements, also did not change the interpretation of our results. Limiting our analysis to participants with 24-hour ambulatory SBP  $> 140$  mm Hg at baseline changed our point estimate for the effect of the intervention from  $-4.2$  to  $-7.1$  (95% CI,  $-21.5$  to  $7.2$ ) mm Hg.

There was no significant difference between groups at baseline or 6 months in the proportion reporting medication nonadherence (Table 2). From the FFQ estimates of dietary sodium intake (86% completed an assessment at baseline and the 6-month follow-up), we estimated that the intervention resulted in a decrease in sodium intake,  $-133$  (85% CI,  $-1,045$  to  $780$ ) mg/d, but this was not statistically significant. Patients in the intervention group took more steps per hour at baseline and 6 months

compared with the usual-care group, and we estimated that the effect of intervention on steps was positive,  $9.3$  (95% CI,  $-50$  to  $69$ ) after adjusting for baseline steps. Very few adults ( $<30\%$ ) completed a 24-hour urine sodium excretion at baseline and 6 months, but among those with complete data, there was a modest decrease in sodium excretion in both groups. The intervention was also associated with improved SF-36 mental composite scores,  $3.1$  (95% CI,  $-1.2$  to  $7.5$ ), but this was not statistically significant (Table 2).

### Cohort Study in Adolescents

In the adolescent cohort, median age was 18 (IQR, 15-21) years; there were 8 males and 2 females, and 6 self-identified as Hispanic and the other 4 as African American (Table 3). Based on the REALM-Teen, 80% had a literacy level that correlated to an educational level of 10th grade or higher. The burden of comorbid conditions was minimal; 50% had body mass index  $\geq 30$  kg/m<sup>2</sup> but only 2 patients reported a diagnosis of diabetes mellitus (type 1 in 1 patient, type 2 in another). Seven adolescents reported

**Table 1.** Baseline Characteristics of Adult Participants

Characteristic	All Participants (N = 50)	Group-Based Care (n = 26)	Usual Care (n = 24)
Age, y	62 ± 11	63 ± 11	60 ± 10
Female sex	27 (54%)	12 (46%)	15 (62%)
Race/ethnicity			
Non-Hispanic black	24 (48%)	14 (54%)	10 (42%)
Non-Hispanic white	2 (4%)	0 (0%)	2 (8%)
Hispanic	23 (46%)	11 (42%)	12 (50%)
Other	1 (2%)	1 (4%)	0 (0%)
High school graduate	31 (62%)	18 (69%)	13 (54%)
Income < \$15,000 per y	20 (40%)	11 (42%)	9 (37%)
REALM score <sup>a</sup>	65 [54-66]	65 [58-66]	64 [53-65]
REALM score < 61 <sup>a</sup>	17 (36%)	8 (32%)	9 (41%)
Comorbid conditions			
Diabetes mellitus	26 (52%)	10 (38%)	16 (66%)
Coronary artery disease	14 (28%)	7 (27%)	7 (29%)
Congestive heart failure	9 (18%)	2 (8%)	7 (29%)
Peripheral vascular disease	13 (26%)	6 (23%)	7 (29%)
Cerebrovascular disease	13 (26%)	6 (23%)	7 (29%)
ACE inhibitor or ARB use	27 (54%)	16 (61%)	11 (46%)
Diuretic use	24 (48%)	13 (50%)	11 (46%)
β-Blocker use	28 (56%)	15 (58%)	13 (54%)
Calcium channel blocker use	33 (66%)	17 (65%)	16 (67%)
≥3 antihypertensives	27 (54%)	16 (61%)	11 (46%)
Medication nonadherence	16 (32%)	10 (38%)	6 (25%)
Weight, kg	95 [76-104]	95 [80-107]	92 [73-102]
BMI ≥ 30 kg/m <sup>2</sup>	34 (68%)	18 (69%)	16 (67%)
Current smoker	2 (4%)	1 (4%)	1 (4%)
24-h SBP, mm Hg <sup>b</sup>	137 ± 20	137 ± 18	137 ± 23
24-h DBP, mm Hg <sup>b</sup>	77 ± 11	76 ± 10	78 ± 12
24-h SBP ≥ 140 mm Hg <sup>b</sup>	19 (42%)	10 (42%)	9 (43%)
Office SBP, mm Hg	139 ± 19	141 ± 20	136 ± 17
Office DBP, mm Hg	76 ± 11	76 ± 11	75 ± 12
Office SBP ≥ 140 mm Hg	24 (48%)	11 (42%)	13 (54%)
eGFR, <sup>c</sup> mL/min/1.73 m <sup>2</sup>	35.4 ± 13.2	37.1 ± 12.9	33.6 ± 13.5
24-h sodium excretion, mg <sup>d</sup>	2,622 [1,840-3,910]	2,599 [2,392-3,381]	3,381 [1,840-4,416]

Note: Values for categorical variables are given as count (proportion); values for continuous variables are given as mean ± standard deviation for normally distributed variables or median [interquartile range] for skewed variables. There were no significant differences ( $P > 0.05$ ) between the groups for all measured baseline characteristics.

Abbreviations: ACE, angiotensin-converting enzyme; ARB, angiotensin II type 1 receptor antagonist; BMI, body mass index; DBP, diastolic blood pressure; eGFR, estimated glomerular filtration rate; REALM, Rapid Estimate of Adult Literacy in Medicine; SBP, systolic blood pressure.

<sup>a</sup>Three patients (1 from group-based care and 2 from usual care) were unable to perform a REALM score assessment because they were legally blind. REALM score < 61 corresponds to less than high school literacy.

<sup>b</sup>Data available for 24 (92%) group-based care patients and 21 (87%) usual-care patients.

<sup>c</sup>eGFR was calculated using Chronic Kidney Disease Epidemiology Collaboration equation.

<sup>d</sup>Data available for 17 (65%) group-based care patients and 15 (62%) usual-care patients.

taking a BP medication (5 were taking an angiotensin-converting enzyme inhibitor or angiotensin receptor blocker, and 1 each was taking a diuretic or calcium channel blocker). None were using more than 1 antihypertensive medication. At baseline, eGFR was 91.2 (SD, 25.6) mL/min/1.73 m<sup>2</sup>, median 24-hour sodium excretion was 3,701 [IQR, 2,713-6,092] mg, and mean 24-hour ambulatory SBP and DBP were 133 (SD, 4) and 75 (SD, 5) mm Hg, respectively (Table 3). Mean office SBP and DBP were lower; 127 (SD, 8) and 76 (SD, 10) mm Hg, respectively, but still above the recommended BP (<120/80 mm Hg) for children 13 years and older.<sup>31</sup>

Attendance was suboptimal, with only 40% of participants attending 3 or more sessions. Reported satisfaction with the group sessions was high and largely unchanged from baseline and follow-up, with 90% rating their satisfaction positively at baseline versus 100% at 6 months. During the 6-month follow-up, they saw their outpatient nephrologist for median of 1 (IQR, 1-2.5) visit.

Only 1 participant completed the 24-hour ambulatory BP monitoring at both time points. Six adolescents had an office BP measured at baseline and 6 months, and mean office SBP was similar at both time points, 127 (SD, 8) versus 125 (SD, 10) mm Hg (Table 4). Self-reported

**Table 2.** Intention-to-Treat Analysis of Clinical Outcomes in Adults

Outcome	Group-Based Care		Usual Care		Effect of Intervention Adjusted for Baseline (95% CI)
	Baseline	6 mo	Baseline	6 mo	
Blood pressure					
24-h SBP, mm Hg <sup>a</sup>	139 ± 4.5	139 ± 3.1	139 ± 4.9	144 ± 4.0	-4.2 (-13.8 to 5.3)
24-h DBP, mm Hg <sup>a</sup>	75 ± 2.9	75 ± 2.1	78 ± 2.6	78 ± 3.0	-0.5 (-6.6 to 5.7)
Medication nonadherence <sup>b,c</sup>	8 (38%)	10 (43%)	6 (30%)	8 (40%)	1.11 (0.3 to 3.9)
Sodium intake					
24-h sodium excretion, mg <sup>d,e</sup>	2,852 ± 851	2,553 ± 483	2,783 ± 552	2,461 ± 598	NE
FFQ, mg/d <sup>f</sup>	2,844 ± 344	2,600 ± 347	2,312 ± 365	2,383 ± 401	-133 (-1,045 to 780)
Physical activity					
Mean steps/h <sup>g</sup>	314 ± 75	306 ± 59	223 ± 33	224 ± 40	9.3 (-50 to 69)
Quality of life (SF-36) <sup>h</sup>					
Composite physical score	39 ± 1.8	36 ± 1.6	37 ± 2.0	36 ± 2.2	-0.7 (-4.1 to 2.6)
Composite mental score	45 ± 2.1	47 ± 2.0	49 ± 2.3	47 ± 2.6	3.1 (-1.2 to 7.5)

Note: Values are given as mean ± standard error of the mean for continuous variables; number and proportion (percent) for binary outcome.

Abbreviations: CI, confidence interval; DBP, diastolic blood pressure; FFQ, food frequency questionnaire; NE, not estimated; SBP, systolic blood pressure; SF-36, 36-Item Short Form Health Survey.

<sup>a</sup>A total of 28 participants completed a 24-hour SBP and 24-hour DBP at baseline and 6 months.

<sup>b</sup>A total of 43 participants completed a medication adherence assessment at baseline and 6 months.

<sup>c</sup>Odds ratio for reporting nonadherence.

<sup>d</sup>A total of 13 participants completed a 24-hour collection for urinary sodium excretion at baseline and 6 months.

<sup>e</sup>Effect not estimated due to small number of participants with 24-hour urine collection at baseline and 6 months.

<sup>f</sup>A total of 43 participants completed FFQs at baseline and 6 months.

<sup>g</sup>A total of 33 participants completed accelerometer testing at baseline and 6 months.

<sup>h</sup>A total of 43 participants completed the SF-36 at baseline and 6 months.

medication nonadherence decreased from 57% to 40% and estimated sodium intake from the FFQ also decreased by ~800 mg/d at 6 months (Table 4). There was an increase in median steps per hour from 499 (IQR, 111-712) to 688 (IQR, 302-1,107) at 6 months; however, this is still well below the pediatric hypertension guidelines recommendation of 12,000 to 15,000 steps per day (860-1,070 steps per waking hour) for male and female children/adolescents, respectively.<sup>32</sup> Sodium intake as measured by 24-hour urinary excretion and pediatric quality-of-life metrics was largely unchanged at 6 months compared with baseline (Table 4).

## DISCUSSION

In this RCT of adults with hypertension and CKD, we found that group-based care was feasible and acceptable based on attendance to group visits and higher patient satisfaction during follow-up. Our study also suggests that an educational group-based care intervention could have a positive effect on BP if sufficiently powered. Using an estimated effect size of 5-mm Hg difference in SBP between the intervention and control, SD of 20, 80% power, and alpha = 0.05, we determined that we would need to recruit 506 adults (253 in each group) for a sufficiently powered trial to evaluate effects of our group-based care intervention on BP. Our small sample size also limited the detection of significant differences in other clinical outcomes (ie, medication adherence, sodium intake, physical activity, and quality of life).

Although our pilot study sample size limited detection of significant differences in our clinical outcomes, other

studies of group-based care models in the non-CKD population have shown benefit. Edelman et al<sup>18</sup> randomly assigned 239 adults from the Veterans Administration population with hypertension and diabetes to a group-based care intervention versus usual care and found that SBP decreased by 13.7 mm Hg in the intervention group versus 6.4 mm Hg in the usual-care group. There were a number of notable differences between their study and ours, which could account for the larger effect size observed in their study. They excluded participants with SBP < 140 mm Hg (mean SBP was ~150 mm Hg) and therefore patients had more room for improvement as compared with our study, in which mean SBP was much lower (137 mm Hg).<sup>18</sup> Their intervention also included a medication intensification strategy led by their group visit physicians and pharmacists, which has been shown to have a greater effect than education interventions alone on change in BP.<sup>33</sup> In Edelman et al's<sup>18</sup> study, as was the case in ours, self-reported medication adherence was similar in both groups at the end of the study, which suggests that adherence as captured by self-report may not have been a major mediating factor. However, participants in their group-based care intervention had increased self-efficacy scores, another potential mediating factor, which was not assessed in our study. In contrast, other studies have shown a positive effect of group-based care interventions on medication adherence. In a study of adult patients initiating treatment for chronic hepatitis C, patients who received group-based care had lower rates of treatment discontinuation compared with those who received usual care.<sup>34</sup>

**Table 3.** Baseline Characteristics of Adolescent Participants

Patient Characteristics	All Participants (N = 10)
Mean age, y	18 [16-19]
Male sex	8 (80%)
Race/ethnicity	
Non-Hispanic black	4 (40%)
Hispanic	6 (60%)
Mean neighborhood income	\$35,217
REALM score <sup>a,b</sup>	64 [64-66]
Comorbid conditions	
Diabetes	2 (20%)
ACE inhibitor or ARB use	5 (50%)
Diuretic use	1 (10%)
Calcium channel blocker use	1 (10%)
β-Blocker use	0 (0%)
Receiving >1 antihypertensives	0 (0%)
Weight, kg	84 [74-112]
eGFR, <sup>c</sup> mL/min/1.73 m <sup>2</sup>	91.2 ± 25.6
BMI ≥ 30 kg/m <sup>2</sup>	5 (50%)
24-h SBP, mm Hg <sup>d</sup>	133 ± 4
24-hour DBP, mm Hg <sup>d</sup>	75 ± 5
Office SBP, mm Hg	127 ± 8
Office DBP, mm Hg	76 ± 10
24-h sodium excretion, mg <sup>e</sup>	3,701 [2,713-6,092]

Note: Values for categorical variables are given as count (proportion); values for continuous variables are given as mean ± standard deviation for normally distributed variables or median [interquartile range] for skewed variables.

Abbreviations: ACE, angiotensin-converting enzyme; ARB, angiotensin II type 1 receptor antagonist; BMI, body mass index; DBP, diastolic blood pressure; eGFR, estimated glomerular filtration rate; REALM, Rapid Estimate of Adult Literacy in Medicine; SBP, systolic blood pressure.

<sup>a</sup>Seven individuals were age appropriate for the REALM tool.

<sup>b</sup>REALM scores normalized to general population.

<sup>c</sup>eGFR was calculated using the Chronic Kidney Disease Epidemiology Collaboration equation for adolescents aged 18 to 21 years and the bedside Schwartz equation for adolescents aged 12 to 17 years.

Complete data available except for the following variables: <sup>d</sup>6 individuals had mean 24-hour ambulatory SBP and DBP at baseline and <sup>e</sup>6 individuals had urine sodium values at baseline.

The positive effects of group-based care on patient satisfaction and quality of life in adults are better established.<sup>35</sup> A meta-analysis by Jaber et al<sup>35</sup> suggests that group-based care is effective in improving patient and physician satisfaction, quality of care, and quality of life and decreasing emergency department and specialist visits. In our study, both the intervention and usual-care groups reported higher patient satisfaction during follow-up. We surmise that our study design fostered increased patient engagement, which has been associated with higher patient satisfaction.<sup>36</sup>

In our study, the average sodium intake far exceeded the recommendation of 1,500 mg/d for patients with CKD.<sup>37</sup> Low physical activity was also common among our participants, consistent with other studies in the CKD population.<sup>38-40</sup> There have been very few published studies evaluating the effect of group-based interventions on health-related behaviors such as diet or exercise. Studies of peer-delivered interventions to increase physical activity, some of which were delivered in a clinic setting, have shown mixed results.<sup>41</sup> The results from 2 of the larger

**Table 4.** Clinical Outcomes for the Adolescents Cohort

Outcome	Group-Based Care	
	Baseline	6 mo
Blood pressure		
Office SBP, mm Hg <sup>a</sup>	127 ± 8	125 ± 10
Office DBP, mm Hg <sup>a</sup>	76 ± 10	78 ± 8
Medication nonadherence <sup>b</sup>	4 (57%)	2 (40%)
Sodium intake		
24-hr sodium excretion, mg <sup>c</sup>	3,701 [2,713-6,092]	3,816 [3,724-4,345]
FFQ, mg/d <sup>d</sup>	3,878 ± 1,760	3075 ± 2,303
Physical activity		
Mean steps/h <sup>e</sup>	499 [111-712]	688 [302-1,107]
Psychosocial (PedsQL) <sup>f</sup>		
Physical functioning	94 ± 8.5	93 ± 6.4
Emotional functioning	84 ± 15.9	93 ± 7.6
Social functioning	100 ± 0	100 ± 0
School functioning	81 ± 15.6	80 ± 8.7

Note: Values for continuous variables are given as mean ± standard deviation for normally distributed variables and median [interquartile range] for non-normally distributed variables.

Abbreviations: DBP, diastolic blood pressure; FFQ, food frequency questionnaire; PedsQL, Pediatric Quality of Life Inventory; SBP, systolic blood pressure.

<sup>a</sup>A total of 6 participants had an office SBP and DBP at baseline and 6 months.

<sup>b</sup>A total of 5 participants completed the nonadherence question at baseline and 6 months.

<sup>c</sup>A total of 3 participants completed 24-hour urinary sodium excretion at baseline and 6 months.

<sup>d</sup>A total of 5 participants completed the FFQ at baseline and 6 months.

<sup>e</sup>A total of 5 participants completed the accelerometer testing at baseline and 6 months.

<sup>f</sup>A total of 3 participants completed the PedsQL scale at baseline and 6 months.

RCTs (each with >200 participants) on self-reported physical activity were discordant; 1 showed no benefit of the group intervention and the other showed an improvement in a number of health-related behaviors, including increased physical activity.<sup>42,43</sup>

In the adolescent cohort study, we found that attendance at the group sessions was poor, though self-reported satisfaction scores were high. There have been fewer studies evaluating group-based interventions in children or adolescents compared with adults. The small studies in diabetes mellitus and obesity management in children or adolescents have shown little to no effect on diabetes control or weight reduction.<sup>44-46</sup> However, 1 study showed a significant improvement in self-reported physical health and school functioning, 2 subscales of the PedsQL, among adolescents enrolled in a group-based care intervention for obesity management compared with routine individual care.<sup>46</sup>

Our study has a number of limitations. First, our sample size was small and therefore underpowered to detect differences in BP and health-related behaviors. The significant proportion of missing data and lack of participation, specifically for adolescents, also limited our analyses. Furthermore, the duration of our study or number of group visits (6 sessions) also may not have been adequate to significantly change health-related behaviors. We also

tested group-based care as an adjunct to usual nephrology care in our study. Future studies can test group-based care as a replacement of usual nephrology care.

Withstanding these limitations, to our knowledge, this is the first study assessing the feasibility and possible effect of a group-based care intervention on BP and health-related behaviors in both adults and adolescents with CKD. The paucity of data for interventions in adolescents with CKD underscores the need for more studies in this group. By targeting a low-income vulnerable ethnic minority population that is disproportionately susceptible to CKD and its consequences, we also aimed to address a major health disparity.

In summary, our study findings indicate that group-based care is feasible and may be a promising alternative to usual nephrology care alone in adult patients with CKD. However, larger studies are needed to determine its effect on BP management and health-related behaviors. In adolescents with CKD, patient participation may limit the feasibility and effectiveness of group-based care. Potential future directions could include assessment of barriers to participants, school-based interventions, and technology/electronic applications to facilitate group-based care in adolescents.

## SUPPLEMENTARY MATERIAL

### Supplementary File (PDF)

**Item S1:** Inclusion and Exclusion Criteria

**Table S1:** Description of specific topics discussed at each session

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