# Impact of Community Health Representative-Led Patient Activation and Engagement on Home-Based Kidney Care

*Vallabh Shah, PhD,[1]; Robert Nelson, MD, PhD, [2,3]; Thomas Faber, MD[4] ; Val Panteah[5]*

[1]University of New Mexico Health Sciences Center, Albuquerque, NM
[2]National Institute of Diabetes and Digestive and Kidney Diseases, Bethesda, MDNIDDK,
[3]National Institute of Health, Bethesda, MD
[4]Zuni IHS, Zuni, NM
[5]Govenor, Zuni Pueblo, Zuni , NM

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## Abstract

**Aim:** To determine the effectiveness of a home-based kidney care (HBKC) model of patient activation with lifestyle intervention compared with usual care (UC) in improving patient activation and to preliminarily evaluate its potential effect on markers of and risk factors for chronic kidney disease (CKD) in rural adult Zuni Indians with the disease.

**Methods:** We screened 315 Zuni Indians who had ≥2 risk factors (family history of diabetes and kidney disease, microalbuminuria, overweight/obesity, and increased $A_{1c}$) for CKD. We randomized 125 participants with CKD to a UC or an HBKC intervention (1:1) group. After initial lifestyle coaching, the intervention group also received reinforcement—about adherence to medications, diet, and exercise; self-monitoring; and coping strategies for living with stress—in the form of continuous engagement with community health representatives and in quarterly group sessions. The primary outcome was change at 12 months in Patient Activation Measure (PAM), which assesses an individual's knowledge, skill, and confidence in managing his or her own health and health care.

**Results:** Of the 125 individuals randomized to the study (**63 to the HBKC intervention** and **62 to the UC control**), 98 (49 in each treatment group) completed the 1-year study, and no individuals crossed over from 1 treatment group to the other. Among those who completed the study, we observed improvements in our primary outcome measure of PAM. The HBKC group increased its PAM total score by 8.6 points (95% CI, 1.2-16.0) more than those in the UC group ($p$ = 0.023). Of those with valid 12-month PAM scores, 34 in the HBKC group and 39 in the UC group were in the PAM-activated group (PAM level >3) at baseline. At study completion, a significantly higher percentage of those from the HBKC group moved into the PAM activated group (12 of 14, 85.7%) than into the UC group (2 of 9, 22.2%), and a lower percentage of patients left the PAM-activated HBKC group during treatment (4 of 34, 11.8%) than the UC group (8 of 39, 20.5%; $p$ = 0.002). Of the 27 secondary outcomes, the HBKC group improved more than the UC group for BMI, $A_{1c}$, High Sensitivity C-Reactive Protein (hsCRP), and mental subscale of the SF-12 questionnaire. HBKC had no effect on medication or dietary adherence. In particular, we observed a decrease in BMI of 1.05 kg/m$^2$ (95% CI, 0.3-1.8) more in the HBKC

group than in the UC group ($p$ = 0.007), a decrease in $A_{1c}$ levels of 0.92% (95% CI, 0.86-0.99) more in the HBKC compared with the UC group ($p$ = 0.022), and a decrease in hsCRP levels by 5.6 mg/L (SD = 9.08) in the HBKC group compared with an increase of 5.7 mg/L (SD = 13.1) in the UC group ($p$ < 0.001). The HBKC group increased its SF-12 mental subscale score by 3.5 points (95% CI, 0.4-6.7) more than the UC group ($p$ = 0.028). There were no significant differences between the 2 groups in the SF-12 physical health, burden of kidney disease, effects of kidney disease, and symptoms and problems of Kidney Disease Quality of Life scales. The study did not find significant differences between the 2 groups in adherence to prescribed medications or dietary guidelines.

**Conclusion:** A HBKC intervention of continuous patient engagement improved participants' activation in their health and health care, as measured by the PAM instrument, and reduced markers of and risk factors for CKD. This randomized controlled trial proves that the HBKC intervention can have positive effects in patients with CKD among rural and disadvantaged populations.

**Limitations:** (1) The statistically significant difference in primary outcome had wide CIs, reflecting our small sample size; and (2) our study did not assess the contribution of the individual components of the HBKC intervention program to improved activation.

## Background

Chronic kidney disease (CKD)—defined by an estimated Glomerular filtration rate (GFR) of 15 to 59 ml/min/1.73m$^2$ or a urine albumin to creatinine ratio ≥30 mg/g—affects nearly 30 million adults in the United States[1] and is associated with increased morbidity and mortality.[2-4] The burden of CKD is greater in ethnic and racial minorities and in persons living in rural communities, where access to care is limited.[5] More than 17% of American Indians in the southwestern United States have CKD,[6] and many of them live in remote locations. Appropriated Indian Health Service funds cover only 55% of the cost of care for American Indians,[7] so effective and low-cost approaches are needed to manage CKD in these disadvantaged populations.

The Zuni Pueblo is experiencing the interrelated epidemics of obesity, diabetes, and CKD. We have documented in 8 publications[8-15] that the rates of obesity, diabetes, and CKD in Zuni Indians are among the highest in the United States. The age-adjusted prevalence of end-stage renal disease (ESRD) is 15-fold higher among Zuni Indians than in non-Hispanic whites.[8] The recently completed Genetics of Kidney Disease in Zuni Indians (GKDZI) study, in which we recruited 1016 members of 30 extended families ascertained from a proband with CKD, was designed to identify genetic risk factors that modulate susceptibility of CKD and intermediate phenotypes. We identified CKD in 236 (23.2%) of these participants. Also, 420 individuals (41%) showed normal kidney function but had risk factors for the development of kidney disease.[16] Despite an excellent Indian Health Services (IHS) facility and several community-based health-promoting programs for the Zuni Pueblo, the prevalence of ESRD continues to rise.

There is a major gap in CKD patient management where current health-related policies focus on ESRD treatments of dialysis or kidney transplantation. However, nephrologists have now begun to examine this progressive disease across its full continuum, and acknowledge that intervention and treatment of CKD in its early stages can dramatically slow or stop the development of this expensive and debilitating illness.[17-18] In rural, high-risk communities such as Zuni, fewer primary care physicians, infrequent screening for CKD, and dearth of nephrologists result in limited access to traditional models of health care for patients with mild to moderate CKD. Novel modes of interdisciplinary health care that utilize trained and certified

community health representatives (CHRs) are required to significantly overcome the CKD patient–management gap.

In this study, we report the results of a home-based kidney care (HBKC) treatment program for management of CKD in Zuni Indians. It employed CHRs under physician supervision to deliver state-of-the-art health care in the patient's home environment using point-of-care technology. Participants were randomized to receive either HBKC or usual care (UC) for 12 months. The primary outcome was a change in Patient Activation Measure (PAM), a 13-item scale that assesses an individual's knowledge, skill, and confidence to manage one's own health and health care.[19] Patients with chronic disease who are more activated by this measure generally have better health outcomes, which are achieved at a lower cost.[20] Other outcomes included changes relative to baseline in clinical and nutritional measures, adherence to treatment, and quality of life at the end of the treatment period. Results of this pilot study are intended to be used to plan a larger trial of HBKC in another high-risk population.

**Decision-making and Contextual Considerations:** CKD is a progressive disease that may be viewed along a continuum. At present, there is no cure. Rather, CKD management focuses on early detection and treatment that may delay or slow the rate of progression and reduce the incidence of adverse health outcomes. One of the goals of CKD treatment is to provide patients with the education and support needed to encourage active participation in their care. The CKD continuum extends from the point of diagnosis to end-of-life care. Health care for individuals with CKD involves screening, diagnosis, treatment, and support of self-care management for both CKD and comorbid illness. Individuals diagnosed with CKD need to come to terms with a disease process that has an unpredictable and variable trajectory. Patients' lack of knowledge, low levels of self-efficacy, and a poor ability to self-manage CKD frequently interfere with improved outcomes associated with the implementation of provider recommendations. Due to the multiple and ongoing needs of patients with CKD, it is not feasible—in the current health care setting—for a busy practitioner to deliver all the care that is needed for optimal outcomes. Our model of HBKC uses new, effective interventions, incorporating strategies aimed at engaging CKD patients as active participants in their chronic disease management.

In this PCORI-funded study, we completed a randomized controlled trial with community engagement, comparing UC to an innovative and sustainable model of HBKC. Briefly, the HBKC model integrated the use of CHRs in contact with IHS and academic-based physicians, using point-of-care (POC) determinations of urinary albumin to creatinine ratio (UACR), hemoglobin $A_{1c}$ ($HbA_{1c}$), and serum creatinine at home. The HBKC model used motivational messaging and reminders to enhance adherence to previously proven interventions (control of blood sugar and blood pressure, use of angiotensin-converting enzyme inhibitors and angiotensin receptor–blocking agents, and healthy lifestyle interventions related to diet and exercise). The HBKC model provided the additional care necessary to bolster patient levels of disease-specific knowledge, self-efficacy, and CKD self-management, enabling them to perform the recommendations that they received during the home visit.[21-27]

**Community/Stakeholder Engagement**

We worked with the Zuni tribal council and other health programs in Zuni, including IHS, to create a tribal advisory panel (TAP). As part of our continuous bidirectional approach of community-based participatory research, we have continued to maintain close communication with the tribal governor and his council. We met with the tribal council quarterly throughout the duration of the study to update members on the study's progress, obtain input, and address members' concerns. The meeting were scheduled by invitation at the councils' convenience. We met 4 times each year from 2013 through 2016. Finally, in 2016 we presented our study-related data to the tribal leadership in the presence of all stakeholders, including TAP members; Zuni IHS; other health programs; some study participants; and Dr. Joe Selby, MD, from PCORI.

Liaisons from the tribal health programs, including Zuni IHS, were identified and invited to participate in the TAP. The TAP helped monitor study progress and identified venues for community-engagement activities. During the study, we worked with 6 TAP members in quarterly meetings. We talked about the problems in study recruitment as well as health literacy about diabetes and kidney disease in the Zuni. At the TAP's suggestion, we administered a 5-item "vital sign" instrument to assess knowledge of diabetes and kidney

disease among Zunis. Knowledge did not differ between diabetics and nondiabetics. Within diabetic status, health literacy varied significantly with age, education, and work status but not with gender or with propensity to speak a tribal language. Health literacy was significantly greater in younger participants, those with higher levels of education, and those employed. Individuals with complications due to diabetes, such as kidney disease, neuropathy, or eye disease, tended to have lower health literacy than those who did not have complications; however, those with a family member suffering from complications due to diabetes tended to have higher health literacy than those who did not have such family members, suggesting affected family members were a motivation for improving knowledge about diabetes and kidney disease.

We regularly distributed to the community newsletters on different aspects of obesity, diabetes, kidney disease, and heart disease throughout the study period. These brochures were, by design, short and written at a sixth-grade reading level, in accord with recommendations from the Zuni tribal council, Zuni heath care professionals, the University of New Mexico Health Sciences Center (UNMHSC), and IHS IRBs. We distributed these brochures by personal visits to homes throughout the Zuni Pueblo. During these visits, we spoke to residents about chronic disease and the importance of early detection and lifestyle changes. During each visit, we also encouraged and answered community members' questions. We made more than 1500 contacts in homes throughout the Zuni Pueblo. We participated in more than 10 health information events throughout the study period. We also participated in a communitywide health fair, during which study staff measure blood pressure and random plasma glucose and obtained height and weight measurements and educated participants on diabetes and kidney disease.

Involved UNMHSC faculty—including Drs. Shah, Colleran, and Struminger—and Dr. Nelson (National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), Phoenix) continued quarterly meetings with the TAP, where discussions focused on CHR training and project goals. Two of our CHR staff members received nursing education while working with us and conducted the clinical, pharmacological, and educational interventions under faculty supervision. The Zuni tribal governor and his council ensured active community engagement

and helped with tribal health priorities and policy.

## Methods

The overall purpose of this research effort was to develop, implement, and study in a randomized controlled trial a model of HBKC for use in CKD patients residing in the Zuni Pueblo in New Mexico and to initiate efforts to implement this health care model in other communities. We conducted the study in 5 discrete components: (1) We formalized the HBKC study design and approaches to the intervention in consultation with community members, patients, and stakeholders; (2) we reevaluated prior study participants in Zuni Pueblo to identify cases of CKD and to thereby find potential participants for the proposed randomized trial (specific aim 1); (3) we enrolled participants for the trial and randomized them to either the HBKC or the UC study group, maintained the intervention groups for 12 months, and obtained 12-month assessments (specific aim 2); (4) we evaluated the characteristics of how the study was conducted in order to provide information that would enhance the design of future studies of the HBKC intervention; and (5) we began to investigate this intervention in another community by initiating interactions with a second population of American Indians residing in Guadalupe, Arizona.

The UNMHSC Human Research Review Committee and the IHS IRB approved the protocol for this trial, and all participants provided written informed consent. Remuneration was provided to compensate participants for their time as they took part in study activities. This observational clinical study took place from June 2013 to December 2016, and it was retrospectively registered at ClinicalTrials.gov (NCT02915029).

### Design and Oversight of HBKC and Study Protocol

**Study Protocol:** We developed our protocol in consultation with Zuni tribal leadership, TAP members, and the Zuni IHS. We kept minutes of all meetings and discussions with the tribal governor and stakeholders. Our study aims translated and compared effectiveness of multidisciplinary HBKC interventions to bolster patient levels of kidney-specific knowledge, self-efficacy, and CKD self-management, enabling Zuni Indians to perform the recommendations in a culturally sensitive way. **Figure 1** depicts an *effect model* of the proposed intervention. All

participants received study testing at baseline, 6 months, and 12 months of intervention, as depicted in **Table 1**. Testing occurred in the morning after a 10-hour overnight fast and was performed at the clinic facility by certified study staff.

**Intervention:** Three Zuni community members aged 37-45 with a background in health-related work were trained and certified as lay interventionists by the University of New Mexico's Project Extension for Community Healthcare Outcomes.[28-31] They were trained on lifestyle coaching, diabetes prevention, and diet and exercise change. They assisted in teaching lifestyle classes and provided support and guidance to study participants. The CHRs also received extensive training in adult education, including (1) diabetes management, (2) the theoretical framework of intervention, (3) group management skills, and (4) implementing an interventional protocol. The initial training was approximately 100 hours in duration and was performed via telemedicine. Vallabh Shah supervised delivery of the intervention. To monitor intervention fidelity, the home-based educational intervention was codified in the Zuni Health Initiative (ZHI) *Manual of Study Operations* to assure standardization for all CHRs with continuous evaluations (monthly) and was used as the basis for continuing CHR training.

In the home-based intervention, a CHR visited participants' homes every other week and educated them on healthy lifestyles (diet, exercise, alcohol abuse, and smoking) and on management of diabetes, hypertension, and hyperlipidemia. Participants were trained in the use of home Blood pressure monitors. CHRs utilized educational materials made available by the IHS, National Kidney Foundation, American Association of Kidney Patients, NIDDK, and American Diabetes Association as well as additional material prepared by the investigators. CHRs conducted lifestyle- and diet-related motivational messaging regularly for the first 6 months in the HBKC group only. HBKC patients also received group sessions at the clinic every quarter. After the baseline visit, participants in the UC arm received their usual care provided by the IHS. The control (ie, UC) group received a health evaluation by study personnel only at the initiation of the study and at the 6-month and 12-month visits.

**Figure 1: Effect Model showing Expected Results of Experimental Intervention**

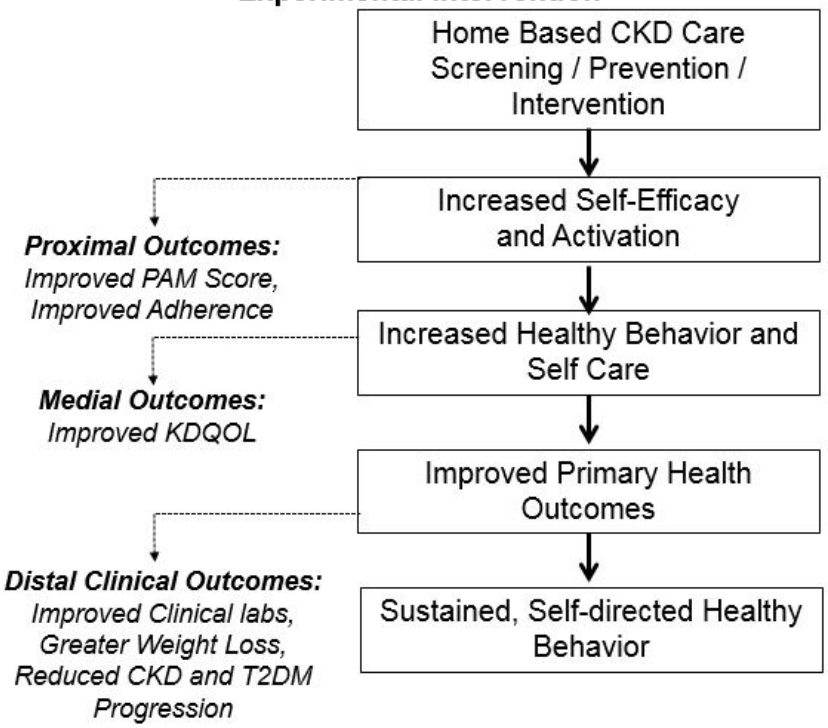


**Table 1. Study-related Testing at the Recruitment and Intervention Phase**

| Testing | Screening | Baseline | 3 Months | 6 Months | 9 Months | 12 Months |
|---|---|---|---|---|---|---|
| Consent and HIPAA | x | | | | | |
| PAM instrument | x | | | | | x |
| Adherence – Morisky 8 | x | | | | | x |
| Kidney Disease QOL-35 | x | | | | | x |
| Medical history | x | | | | | x |
| Height and weight | x | x | x | x | x | x |
| Blood pressure | x | x | x | x | x | x |
| Fasting plasma glucose | x | | | x | | x |
| $A_{1c}$ | x | | | x | | x |
| UACR | x | | | x | | x |
| POC testing $A_{1c}$ and UACR | | x | x | | x | |
| Fasting plasma lipids | x | | | x | | x |
| Biomarkers of inflammation | x | | | | | x |
| Waist to hip ratio | x | x | x | x | x | x |
| Diet questionnaire -24hrs | x | | | | | x |
| Group sessions | | | x | x | x | x |
| Medication list | | x | | x | | x |

Abbreviations: QOL, Quality of Life;

Note: Educational intervention every alternate week only for HBKC with 6 months of text messaging.

**Conduct and Evaluation of the Randomized Controlled Trial**

**Patient Recruitment:** This study enrolled individuals from households where at least 1 member had participated in prior studies with us. Therefore, we identified such households and scheduled an in-home visit. In this initial home visit, study staff explained the HBKC study and answered questions from prospective participants and interested family members. All eligible household members were invited to participate. For household members who were unsure about participation, the staff left educational material describing the study and scheduled a return home visit. After obtaining informed consent and HIPAA agreements for sharing of information with the Zuni IHS, we obtained medical records and scheduled baseline visits. For all individuals enrolled into the study at baseline, we collected anthropological and clinical information. Importantly, this included assessments of patient activation using the PAM instrument. Additional assessments included measurement of BMI; waist to hip ratio; and blood pressure, measured in accord with American Heart Association recommendations. We obtained urine and venous blood samples and used them to measure UACR, serum creatinine, estimated glomerular filtration rate (eGFR), microalbuminuria, $A_{1c}$, and lipids. We used the Kidney Disease Quality of Life (KDQOL) instrument to assess patient-reported quality of life, and we utilized the validated Morisky scale to assess adherence with prescribed medications[32] and the method described by Imamura et al to assess dietary adherence.[33] We shared screening laboratory studies with the participant's primary care physician at the Zuni IHS facility.

**Patient Eligibility:** We used the baseline assessments of willing participants to identify eligible participants. As we were conducting the study in the context of CKD, we focused on identifying participants with eGFR <60 ml/min/1.73m$^2$ or UACR ≥30 mg/g. Additional inclusion criteria included (1) reside in a household with ≥1 living GKDZI participant, (2) aged 18-80 years, and (3) negative pregnancy test in women of child-bearing age. Exclusion criteria included (1) life expectancy <1 year, (2) pregnancy or absence of reliable birth control in women of child-bearing potential, (3)

malignancy except nonmelanoma skin cancer, (4) blindness, and (5) unwilling or unable to give informed consent.

**Randomization:** For this study of HBKC, we randomized households in a 1:1 allocation to UC versus HBKC. We identified all individuals who met eligibility criteria from the baseline screening evaluation and grouped them into their household units. We then generated a randomization schedule using PROC PLAN and PROC REPORT in SAS (Cary, NC). The study's data manager kept the randomization schedule. Other study staff and investigators were blinded to which arm a given household was randomized until after the assignment had been made. Using the randomization schedule, we approached individuals in their homes to see if they were willing to participate in the intervention study. We approached eligible individuals up to 3 times before we classified them as nonparticipants. If at least 1 individual was willing to participate in the study, we enrolled the household into our prospective trial. Using the randomization schedule that had been generated previously, we then randomly assigned all consenting eligible members of the given household as a block to either the UC or HBKC arm. We ultimately randomized 48 households in 1 study arm and 49 in the other in order to enroll the targeted sample size of 125 participants. See the Statistical Considerations section for our justification of this selected sample size.

**Prospective Measurement**: We conducted POC testing for $A_{1c}$ and microalbuminuria at patient homes at the prescribed follow-up time intervals (3 months , 6 months, 9 months and/or 12 months; see **Table 1**). To measure the effect of the intensive home health care intervention, we measured the following prospectively in both the study and control groups: patient activation via the PAM instrument, BMI, blood pressure, UACR, serum creatinine, eGFR, $A_{1c}$, lipids, KDQOL, the Morisky scale, and dietary adherence. We shared all follow-up laboratory studies with the participants' primary care physicians at the Zuni IHS facility; we also notified primary care physicians of any change in participant clinical status noted at the 6-month or 12-month follow-up visits.

**Statistical Considerations**

**Power and Sample Size:** Our primary outcome was the within-person change in PAM scores over the course of the intervention period, calculated as the value measured at 1 year minus the value measured at baseline for each study participant. With this as the primary outcome, we designed our study to have enough power to detect a difference between the average PAM change scores from the treatment and control groups. The PAM is a 22-item measure that assesses patient knowledge, skill, and confidence for self-management, and the corresponding PAM total score is scaled to range from a minimum of 0 to a maximum of 100 points.[34] We performed calculations with the understanding that the PAM total score has a standard deviation of roughly 14 points.[35] Insignia Health has reported that each 1-point increase in PAM total score is associated with a 2% decrease in hospitalization and 2% increase in medication adherence (http://www.insigniahealth.com/products/pam-survey). Therefore, we powered our study to detect a difference in PAM total scores of 9 points between the treatment groups, or a medium to large effect size of 9/14 = 0.64 using the conservative assumption of there being no within-person correlation in baseline and follow-up PAM total scores; accounting for the expected positive correlation in scores would have led to a lower required sample size, but we did not have direct measures of the magnitude of the intraindividual correlation in this target population, and we wished to ensure adequate power.

The targeted difference would correspond to an expected improvement of roughly 20% in one of the reported health outcomes in change in PAM scores. Although these outcomes of hospitalization and medication adherence were not of primary interest in our study, this gave us confidence that assuming a moderate to large effect size for our primary outcome measure of PAM total score might result in our detecting meaningful effects on other health behaviors that could ultimately influence measures of CKD and diabetes severity. We computed that with 30 households per arm, each with 2 participants, and a within-household correlation of 0.50, we would have at least 80% power to detect a difference of 9 points in the PAM total score average between HBKC and UC treatment groups. If we enrolled more households, or enrolled fewer than 2 participants from each household, our expected study power would be even greater than what we calculated with the settings outlined above.

**Data Management:** We utilized the REDCap (Research Electronic Data Capture) application for data management. This secure, web-based application is designed exclusively to support data capture for research studies. REDCap provides (1) an intuitive interface for data entry (with data validation); (2) audit trails for tracking data manipulation and export procedures; (3) automated export procedures for seamless data downloads to common statistical packages (SPSS, SAS, Stata, R); (4) procedures for importing data from external sources; and (5) advanced features, such as branching logic and calculated fields. We exported data from this tool into both SAS and Excel formats to enable analyses in SAS and R.

**Data Analysis:** We obtained data from all individuals who agreed to be evaluated for potential study inclusion and otherwise met the inclusion/exclusion criteria. We used serum creatinine measures to compute eGFR measures via the CKD-EPI equation.[36] Based on these eGFR and UACR measurements, we identified those with evidence of CKD (eGFR <60 ml/min/1.73m$^2$ or UACR ≥30 mg/g) as eligible for participation. These individuals were randomized to 1 of the 2 treatment arms.

After randomization of the eligible individuals, as households, to either the HBKC or UC treatment groups, we summarized the baseline data within these groups using means and SD, or median and 25th and 75th percentiles, for quantitative variables and counts and percentages for categorical variables. We compared the observed baseline data between these 2 groups using Wilcoxon rank sum tests for quantitative measures and chi-square tests for categorical measures.

The original study plan was to analyze data in an intention-to-treat manner; however, no participants crossed over from 1 treatment arm to the other, and all participants received their interventions per protocol. However, as not all participants completed the full study, we performed 2 sets of analyses to assess the differences in outcomes between the 2 treatment groups. In the first analysis, we compared changes in measured variables from baseline to 12-month follow-up among those who completed the study. In the second analysis, we analyzed data from all individuals who were randomized to a treatment group in the study, where those who dropped out were treated as though they experienced no changes in the measured

outcome variables. This analysis has the spirit of an intention-to-treat analysis, as all data from all individuals are analyzed, but it relies on an unverifiable assumption that those who dropped out experienced no changes in their measures. Therefore, this second analysis is best viewed as a sensitivity analysis, which has results that should be biased toward the null hypothesis of no differences between groups as long as dropout patterns are similar between them (which was what we ultimately observed in this study).

As we were primarily interested in determining whether the outcome variables changed significantly over time in ways that differed between treatment groups, we focused on change variables (12-month values minus baseline values) for our assessments of treatment differences. We summarized these change scores in the same fashion as we did the baseline and 12-month values. To test for significant differences in changes over time between the 2 treatments arms, we used generalized linear model approaches (linear regression for quantitative variables and logistic regression for categorical variables). We applied generalized estimating equations to account for within-family correlations. This was an important step, as households served as the unit of randomization. We also adjusted for baseline measures of these outcomes, to account for any residual differences between groups in these measures after randomization. Our criteria for a positive result of this randomized trial was evidence of a statistically significant ($p < 0.05$) change in PAM total score between HBKC and UC treatment groups. We considered the comparisons for the other outcome measures to be preliminary summaries of treatment effect that could be used for planning future studies.

In addition to performing these tests of significance, we generated several graphs of results to further visualize differences due to the study treatments. This included bar charts, boxplots, and scatterplots of the study data. To test whether patient activation might be associated with improvements in other outcomes, we computed Spearman correlation coefficients and 95% CIs between changes in the PAM total score and changes in downstream clinical measures. We intended these correlations to serve as an initial look into whether changes in patient activation indeed are on the causal pathway influencing improvement of health outcomes, as suggested by the effect model proposed in **Figure 1**. Prior to analysis, we examined the distributions of the continuous measurements to verify that analytical

assumptions were met for the analyses that required assumptions of normal distributions. For measures that did not meet assumptions, we performed analyses on log-transformed values, after confirmation that this transformation adequately allowed the measurements to be appropriately analyzed with an approach that assumed normal distributions of outcome measures.

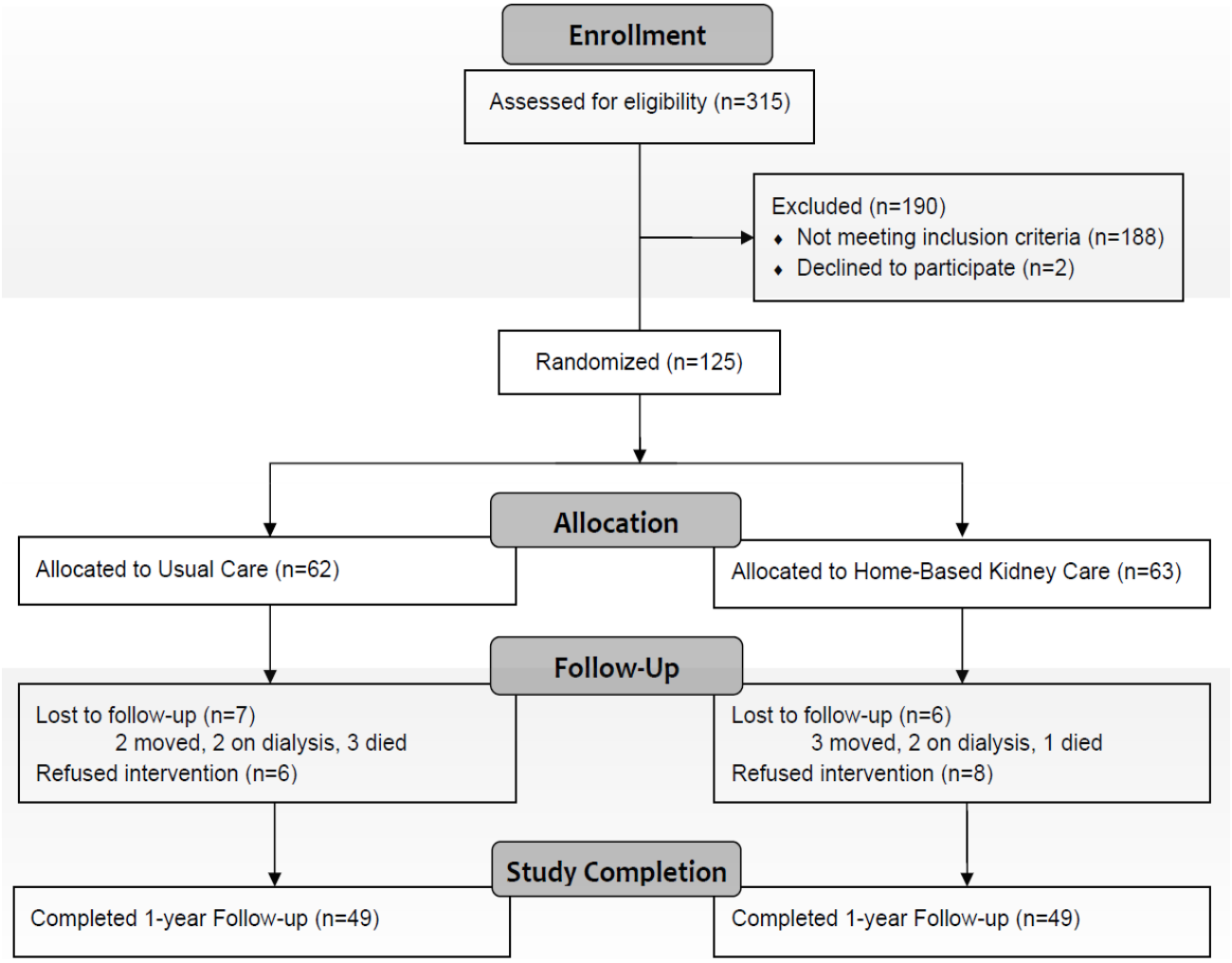
We did not test for treatment response heterogeneity as part of the primary analyses of this study. We applied the intervention in a single, homogeneous population (Zuni Pueblo in rural New Mexico), and we identified no candidate factors that might drive heterogeneity of treatment effect as being of sufficient importance to prioritize them into the primary analysis plan.

We performed analyses using the SAS statistical package ([computer program] Version 9.4. Cary, NC; 2013). We accomplished the generalized estimating equations analyses using the GENMOD procedure.

## Results

We identified a total of 315 individuals who agreed to be screened for potential participation in the planned randomized trial. After evaluating them for evidence of CKD, 127 individuals met our inclusion criteria. Two individuals declined further participation, and 125 were ultimately randomized into the study: 63 to the HBKC group and 62 to UC group (see the CONSORT diagram in **Figure 2**). **Table 2** summarizes the data from the 2 randomized groups at baseline and reports comparisons between these 2 arms. Of those enrolled into the study, 98 were actively participating at the 12-month follow-up period. **Table 3** compares summary data at baseline between those individuals who dropped out of the study and those who completed the 12-month evaluation.

**Figure 2. Enrollment, Randomization, and Follow-up of Study Participants[a]**




[a] All participants who completed the baseline and the 12-month follow-up visit were included in the analysis.

**Table 2**. **Baseline Characteristics of the 125 Randomized and Enrolled Participants, by Treatment Group Status**

| Characteristic | UC (n = 62) | | HBKC (n = 63) | | *P* Value |
|---|---|---|---|---|---|
| | Median or N | IQR[a] or % | Median or N | IQR or % | |
| Age (years) | 47.5 | 42.0-54.0 | 47.0 | 36.0-53.0 | 0.38 |
| Female (%) | 26 | 41.9 | 31 | 49.2 | 0.41 |
| Weight (kg) | 85.7 | 69.4-98.4 | 80.3 | 64.4-99.8 | 0.48 |
| Waist to hip ratio | 0.98 | 0.94-1.02 | 0.96 | 0.94-1.02 | 0.52 |
| BMI ($kg/m^2$) | 31.6 | 27.0-35.8 | 31.5 | 24.6-36.4 | 0.74 |
| Blood pressure (mm Hg) | | | | | |
| Systolic | 129.3 | 120.0-142.0 | 126.0 | 119.3-138.7 | 0.28 |
| Diastolic | 83.3 | 78.0-93.3 | 80.7 | 72.7-90.7 | 0.32 |
| High school graduate (%) | 37 | 58.7 | 41 | 66.1 | 0.39 |
| Diet | | | | | |
| Energy (kcal) | 2188 | 1511-3046 | 1796 | 1025-3164 | 0.24 |
| Fat (g) | 113.9 | 67.0-156.8 | 79.3 | 42.1-142.9 | 0.02 |
| Carbohydrate (g) | 189.2 | 111.1-325.4 | 205.6 | 107.4-333.4 | 0.89 |
| Protein (g) | 130.3 | 69.6-168.3 | 94.7 | 52.5-139.4 | 0.04 |
| Sugars (g) | 100.6 | 35.1-149.8 | 107.9 | 45.7-220.1 | 0.21 |
| Calcium (mg) | 4749 | 2913-7069 | 3460.5 | 2157-6932 | 0.64 |
| Sodium (mg) | 821 | 215-1217 | 558.5 | 220-1238 | 0.11 |
| $HbA_{1c}$ (%) | 6.3 | 5.7-9.8 | 6.1 | 5.7-9.6 | 0.62 |
| Serum total protein (mg/dl) | 7.6 | 7.4-8.1 | 7.8 | 7.3-8.1 | 0.29 |
| Serum cholesterol (mg/dl) | 175.5 | 147-202 | 190 | 166-220 | 0.06 |

| | | | | | |
|---|---|---|---|---|---|
| Serum triglycerides (mg/dl) | 133.5 | 90-200 | 139 | 100-182 | 0.94 |
| Serum HDL cholesterol (mg/dl) | 50 | 39-63 | 46 | 39-62 | 0.91 |
| Serum LDL cholesterol (mg/dl) | 107 | 84-129 | 112 | 95-136 | 0.24 |
| Estimated GFR (ml/min/1.73 $m^2$) | 108.2 | 91.2-117.7 | 112.4 | 101.6-124.0 | 0.13 |
| Urine ACR (mg/g) | 190.0 | 57.0-733.0 | 139.0 | 57-430 | 0.3 |
| hsCRP (mg/L) | 2.6 | 1.3-4.1 | 3.7 | 0.9-9.9 | 0.08 |
| Morisky score | 4.5 | 2.8-7.0 | 5.0 | 3.8-8.0 | 0.08 |
| KDQOL measures | | | | | |
| Symptom/problem list | 90.9 | 79.5-97.7 | 88.6 | 81.8-95.5 | 0.27 |
| Effects of kidney disease | 100.0 | 90.6-100.0 | 93.8 | 90.6-96.9 | 0.02 |
| Burden of kidney disease | 81.3 | 50.0-93.8 | 65.6 | 50.0-87.5 | 0.28 |
| SF-12 physical score | 47.6 | 40.4-51.7 | 48.0 | 39.2-52.3 | 0.67 |
| SF-12 mental score | 54.5 | 44.8-58.8 | 48.2 | 41.0-55.5 | 0.006 |
| PAM total score | 65.5 | 55.6-75 | 58.1 | 51.0-70.2 | 0.12 |
| PAM level ≥3 | 51 | 83.6 | 42 | 68.9 | 0.06 |

Abbreviations: ACR, albumin to creatinine ratio; GFR, glomerular filtration rate; HDL, high-density lipoprotein; LDL, low-density lipoprotein; PAM, Patient Activation Measure; SF-12, Short-form 12 Health Survey.

[a] IQR represents interquartile range: 25th to 75th percentile.

**Table 3. Baseline Characteristics of the 125 Randomized and Enrolled Participants, by Participation Status at End of Study**

| Characteristic | Dropped Out (n = 27) | | Completed (n = 98) | | *P* Value |
|---|---|---|---|---|---|
| | Median or N | IQR[a] or % | Median or N | IQR or % | |
| Age (years) | 44 | 35-53 | 48.0 | 42.0-54.0 | 0.19 |
| Female (%) | 11 | 40.7 | 46 | 46.9 | 0.57 |
| Weight (kg) | 84.4 | 64.9-98.9 | 81.9 | 67.1-98.4 | 0.88 |
| Waist to hip ratio | 0.95 | 0.91-1.02 | 0.98 | 0.95-1.03 | 0.13 |
| BMI ($kg/m^2$) | 31.8 | 24.6-37.9 | 31.5 | 26.6-35.8 | 0.97 |
| Blood pressure (mm Hg) | | | | | |
| Systolic | 124.7 | 120.0-150.7 | 128.0 | 119.3-140.0 | 0.54 |
| Diastolic | 82 | 77-94 | 82.3 | 76.7-92.7 | 0.74 |
| High school graduate (%) | 19 | 70.4 | 59 | 60.2 | 0.33 |
| Diet | | | | | |
| Energy (kcal) | 2459 | 1014-2868 | 2002.5 | 1394-3188 | 0.6 |
| Fat (g) | 99.0 | 42.5-147.6 | 100.9 | 52.0-155.6 | 0.33 |
| Carbohydrate (g) | 199.7 | 122.4-284.3 | 194.2 | 107.4-333.4 | 0.82 |
| Protein (g) | 80.9 | 47.2-152.1 | 109 | 64.8-161.568 | 0.13 |
| Sugars (g) | 107.9 | 62.7-140.0 | 103.3 | 25.3-203.0 | 0.54 |
| Calcium (mg) | 685 | 220-1195 | 4609 | 2488-7131 | 0.83 |
| Sodium (mg) | 4336 | 1848-6932 | 607.5 | 218-1239 | 0.33 |
| $HbA_{1c}$ (%) | 6.2 | 5.6-10.7 | 6.2 | 5.7-9.6 | 0.55 |
| Serum total protein (mg/dl) | 7.8 | 7-8.1 | 7.7 | 7.4-8.1 | 0.41 |
| Serum cholesterol (mg/dl) | 176 | 149-214 | 180.5 | 164-212 | 0.57 |

| | | | | | |
|---|---|---|---|---|---|
| Serum triglycerides (mg/dl) | 144 | 100-172 | 133 | 88-200 | 0.91 |
| Serum HDL cholesterol (mg/dl) | 45 | 41-61 | 49.5 | 39-65 | 0.6 |
| Serum LDL cholesterol (mg/dl) | 109 | 81-129 | 112 | 91-136 | 0.43 |
| Estimated GFR (ml/min/1.73 $m^2$) | 116.4 | 95.1-128.4 | 110.9 | 94.5-119.7 | 0.16 |
| Urine ACR (mg/g) | 131 | 57-1402 | 167 | 57-514 | 0.61 |
| hsCRP (mg/L) | 2.95 | 1.4-6.5 | 2.9 | 1.1-6.2 | 0.82 |
| Morisky score | 4.5 | 2.8-7.0 | 4.9 | 3.3-8.0 | 0.44 |
| KDQOL measures | | | | | |
| Symptom/problem list | 95.5 | 81.8-97.7 | 89.8 | 79.5-95.5 | 0.16 |
| Effects of kidney disease | 96.9 | 93.8-100.0 | 96.9 | 87.5-100.0 | 0.34 |
| Burden of kidney disease | 62.5 | 50.0-93.8 | 75.0 | 56.3-93.8 | 0.36 |
| SF-12 physical score | 47.8 | 39.2-51.4 | 47.9 | 40.4-52.3 | 0.83 |
| SF-12 mental score | 54.2 | 45.5-58.4 | 51.5 | 41.6-57.6 | 0.4 |
| PAM total score | 64.3 | 55.6-77.7 | 60.6 | 55.6-75.0 | 0.64 |
| PAM level ≥3 | 20 | 76.9 | 73 | 76 | 0.93 |

Abbreviations: ACR, albumin to creatinine ratio; GFR, glomerular filtration rate; HDL, high-density lipoprotein; hsCRP, High Sensitivity C-Reactive Protein; LDL, low-density lipoprotein; PAM, Patient Activation Measure; SF-12, Short-form 12 Health Survey.

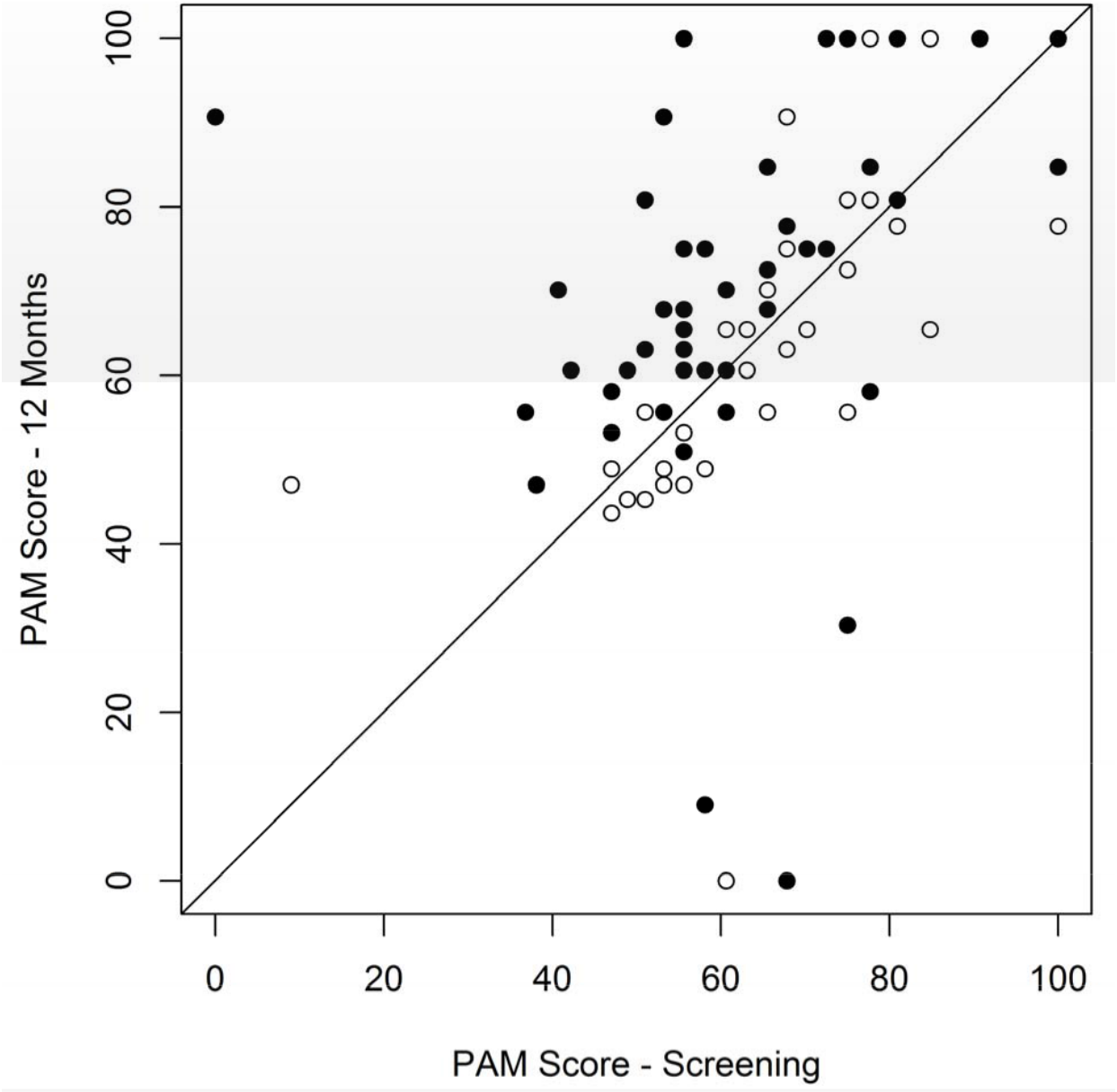
[a] IQR represents interquartile range: 25th to 75th percentile.

HBKC was effective in improving patient activation, as reflected in the primary outcome measure of the PAM total score, which was designed to range from 0 to 100. The average PAM total score increased by 8.6 points (95% CI, 1.2-16.0; $p = 0.023$) more in the HBKC group than in the UC group. In a sensitivity analysis that included patients who did not complete the study, this difference was 6.2 points (95% CI, 0.34-12.09; $p = 0.038$). **Figure 3** contains a scatterplot of the PAM total scores observed at baseline and at study end for those who completed the study; we observed a positive shift for those in the HBKC group. Similarly, PAM levels increased significantly ($p = 0.002$). After 12 months, 38.5% of patients were at stage 4 of activation (45.8%

in HBKC and 31.3% in UC), compared with 28.1% at baseline (27.1% in HBKC and 29.2% in UC). **Figure 4** contains histograms of the percentage of individuals who changed PAM levels from baseline to study end, with those in the HBKC group shifting to a PAM level higher than that of participants in the UC group.

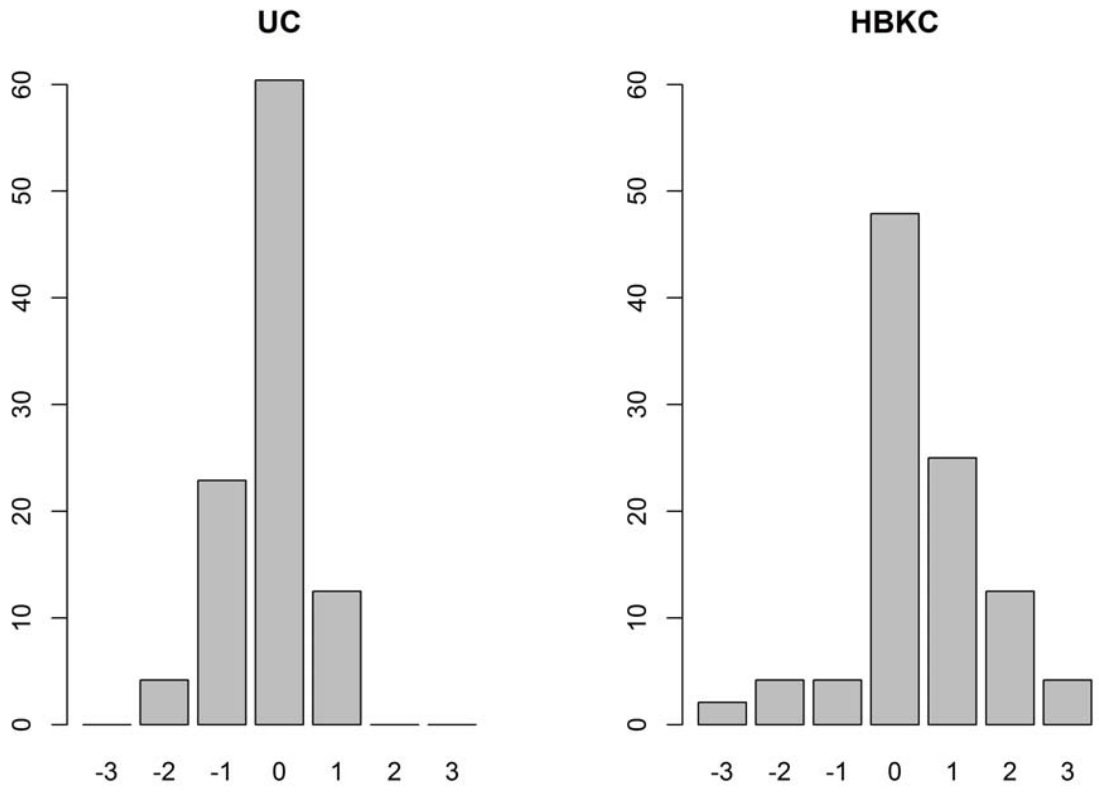
In the completed-cases analysis (**Table 4**), we examined 27 secondary outcomes. A total of 21 displayed differences between groups that were in the direction that would be expected if the HBCK intervention provided a benefit to the participants; however, only 5 of these secondary outcomes were statistically significant at the $p = 0.05$ level, unadjusted for multiple comparisons. In particular, BMI in the HBKC group decreased 1.05 $kg/m^2$ more than what we observed in the UC group (95% CI, 0.3-1.8; $p = 0.007$). Similarly, $A_{1c}$ levels in the HBKC group decreased 0.92% more than they did in the UC group (95% CI, 0.86-0.99; $p = 0.022$). The hsCRP levels in the HBKC group decreased by 5.6 mg/L on average and increased by 5.7 mg/L in the UC group ($p < 0.001$). We also observed a greater increase in the Short-form 12 Health Survey (SF-12) mental score (KDQOL-36) in the HBKC group compared with the UC group ($p = 0.028$); this is even after statistically adjusting for the baseline differences between the 2 groups. The HBKC group was originally 4 points lower than the UC group, but was 2.7 points higher on this scale at the end of the 12-month follow-up period. **Table 5** reports results from sensitivity analyses, which we performed including data from patients who did not complete the study.

**Figure 3. PAM Scores for 2 Study Groups at Baseline and After 12 Months of Treatment[a]**




[a]Participants would fall along the diagonal line if there were no change in PAM score over time; the open circles represent the UC group, and the closed circles represent the HBKC group.

**Figure 4. Percentage of Participants Who Changed PAM Levels From Baseline to the 12-month Follow-up Period for Both Groups[a]**




[a] Numbers on the *x*-axis reflect the changes in PAM level experienced by a study participant; for instance, a value of 0 reflects no change in PAM level, a value of 1 reflects an improvement of 1 PAM level, and so forth.

**Table 4. Comparison of Changes in Clinical Measures From Baseline to 12 Months Between the 2 Treatment Groups for All Participants Who Completed the Study[a]**

| Characteristic | Treatment Effect: HBKC Minus UC | | | *P* Value[b] |
|---|---|---|---|---|
| | Estimate | Lower 95% | Upper 95% | |
| Weight (kg) | –0.53 | –2.67 | 1.61 | 0.62 |
| Waist to hip ratio | –0.02 | –0.04 | 0.01 | 0.14 |
| BMI (kg/m$^2$) | –1.05 | –1.81 | –0.29 | 0.007 |
| Blood pressure (mm Hg) | | | | |
| Systolic | –2.84 | –8.60 | 2.92 | 0.33 |
| Diastolic | –0.78 | –4.21 | 2.65 | 0.66 |
| Diet | | | | |
| Energy (kcal)[c] | 1.05 | 0.79 | 1.41 | 0.73 |
| Fat (g)[c] | 0.88 | 0.50 | 1.53 | 0.65 |
| Carbohydrate (g)[c] | 1.15 | 0.81 | 1.64 | 0.43 |
| Protein (g)[c] | 0.98 | 0.63 | 1.54 | 0.94 |
| Sugars (g)[c] | 0.84 | 0.51 | 1.37 | 0.48 |
| Calcium (mg)[c] | 0.88 | 0.49 | 1.58 | 0.68 |
| Sodium (mg)[c] | 1.01 | 0.66 | 1.55 | 0.95 |
| $HbA_{1c}$ (%)[c] | 0.92 | 0.86 | 0.99 | 0.022 |
| Serum total protein (mg/dl) | –0.07 | –0.22 | 0.07 | 0.34 |
| Serum cholesterol (mg/dl) | –0.39 | –14.55 | 13.78 | 0.96 |
| Serum triglycerides (mg/dl)[c] | 0.97 | 0.81 | 1.16 | 0.75 |
| Serum HDL cholesterol (mg/dl)[c] | 1.04 | 0.94 | 1.15 | 0.46 |
| Serum LDL cholesterol (mg/dl) | –0.94 | –13.60 | 11.72 | 0.88 |
| Estimated GFR (ml/min/1.73 m$^2$) | 5.04 | –0.43 | 10.50 | 0.071 |

| | | | | |
|---|---|---|---|---|
| Urine ACR (mg/g)[c] | 0.63 | 0.33 | 1.22 | 0.17 |
| hsCRP (mg/L)[c] | 0.38 | 0.26 | 0.55 | <0.001 |
| Morisky score | –0.34 | –1.08 | 0.40 | 0.37 |
| SPL | -3.75 | –8.33 | 0.83 | 0.11 |
| EKD | –0.14 | –2.66 | 2.37 | 0.91 |
| BKD | 7.08 | –1.14 | 15.30 | 0.092 |
| SF-12 physical score | 1.98 | –1.09 | 5.05 | 0.21 |
| SF-12 mental score | 3.54 | 0.39 | 6.69 | 0.028 |
| PAM total score | 8.57 | 1.18 | 15.96 | 0.023 |
| PAM level ≥3 | 4.31 | 1.36 | 13.64 | 0.013 |

Abbreviations: ACR, albumin to creatinine ratio; BKD, bacterial kidney disease;EKD, early kidney disease;GFR, glomerular filtration rate; HDL, high-density lipoprotein; LDL, low-density lipoprotein; PAM, patient activation measure; SF-12, Short-form 12 Health Survey;SPL, sound-pressure level[a] Estimates represent adjusted differences between the changes in the HBKC group minus the change in the UC group; N = 98 for all comparisons.

[b] Adjusted for baseline value of each clinical characteristic.[C] Relative, rather than direct, differences. Negative differences or ratios <1 favor HBKC for measures where lower values are preferred, and positive differences or ratios >1 favor HBKC for measures where higher values are preferred.

**Table 5. Comparison of Changes in Clinical Measures From Baseline to 12 Months Between the 2 Treatment Groups for All 125 Participants Who Were Randomized[a]**

| Characteristic | Treatment Effect: HBKC Minus UC | | | *P* Value[b] |
|---|---|---|---|---|
| | Estimate | Lower 95% | Upper 95% | |
| Weight (kg) | –1.39 | –5.89 | 3.12 | 0.55 |
| Waist to hip ratio | –0.02 | –0.04 | 0.01 | 0.17 |
| BMI (kg/m$^2$) | –0.97 | –1.67 | –0.27 | 0.007 |
| Blood pressure (mm Hg) | | | | |
| Systolic | –4.93 | –10.00 | 0.14 | 0.057 |
| Diastolic | –2.53 | –6.02 | 0.96 | 0.16 |
| Diet | | | | |
| Energy (kcal)[c] | 0.89 | 0.70 | 1.13 | 0.35 |
| Fat (g)[c] | 0.80 | 0.51 | 1.25 | 0.33 |
| Carbohydrate (g)[c] | 0.79 | 0.66 | 0.95 | 0.01 |
| Protein (g)[c] | 0.91 | 0.63 | 1.32 | 0.62 |
| Sugars (g)[c] | 0.67 | 0.44 | 1.01 | 0.057 |
| Calcium (mg)[c] | 0.84 | 0.53 | 1.34 | 0.47 |
| Sodium (mg)[c] | 0.94 | 0.66 | 1.33 | 0.72 |
| $HbA_{1c}$ (%)[c] | 0.93 | 0.88 | 0.98 | 0.011 |
| Serum total protein (mg/dl) | –0.07 | –0.21 | 0.06 | 0.27 |
| Serum cholesterol (mg/dl) | –1.21 | –12.54 | 10.12 | 0.83 |
| Serum triglycerides (mg/dl)[c] | 0.99 | 0.84 | 1.16 | 0.86 |
| Serum HDL cholesterol (mg/dl)[c] | 1.03 | 0.94 | 1.12 | 0.54 |
| Serum LDL cholesterol (mg/dl) | –10.73 | –21.87 | 0.41 | 0.059 |
| Estimated GFR (ml/min/1.73 m$^2$) | 2.55 | 0.40 | 4.70 | 0.020 |
| Urine ACR (mg/g)[c] | 0.53 | 0.30 | 0.93 | 0.028 |

| | | | | |
|---|---|---|---|---|
| hsCRP (mg/L)[c] | 0.70 | 0.59 | 0.83 | <0.001 |
| Morisky score | –0.39 | –1.00 | 0.21 | 0.2 |
| SPL | –2.42 | –5.83 | 0.98 | 0.16 |
| EKD | –0.11 | –2.41 | 2.19 | 0.93 |
| BKD | 6.64 | –0.92 | 14.21 | 0.085 |
| SF-12 physical score | 1.19 | –1.52 | 3.90 | 0.39 |
| SF-12 mental score | 0.62 | 0.41 | 0.83 | 0.012 |
| PAM total score | 6.21 | 0.34 | 12.09 | 0.038 |
| PAM level ≥3 | 2.96 | 1.03 | 8.50 | 0.044 |

Abbreviations: ACR, albumin to creatinine ratio; BKD, bacterial kidney disease;EKD, early kidney disease;GFR, glomerular filtration rate; HDL, high-density lipoprotein; LDL, low-density lipoprotein; PAM, patient activation measure; SF-12, Short-form 12 Health Survey;SPL, sound-pressure level.

[a] In this sensitivity analysis, the last observation was carried forward for those participants who left the study.

[b] Adjusted for baseline value of each clinical characteristic.

[C] Relative, rather than direct, differences. Negative differences or ratios less than 1 favor HBKC for measures where lower values are preferred, and positive differences or ratios greater than 1 favor HBKC for measures where higher values are preferred.

We also explored correlations between changes in the PAM total score and in the patient characteristics of interest. Overall, only weak correlations exist between changes in PAM scores and changes in these various parameters. Only 1 correlation was statistically significant at the 0.05 level, without correcting for multiple statistical tests. Increases in PAM were associated with decreases in BMI (correlation coefficient [*r*]–0.23; 95% CI, –0.41 to 0.03). Although many of the other correlations were small and not significant, the directions of most were consistent with the direction that would be predicted if patient activation improved outcomes, as proposed by the effect model contained in **Figure 1**. More follow-up observation postintervention would be required to determine whether the intervention was able to induce real and lasting changes in these secondary outcomes, but this study was not designed to directly assess this.

An additional purpose of this study was to determine the feasibility and safety of conducting a full-scale study in potentially more than 1 study site. From the 315 individuals who participated in the original screening study that took place in the year 2000, we approached 127 individuals in 97 family units identified with CKD and invited them to participate in the randomized trial. All but 2 of these individuals (98.4%) agreed to participate; 62 were randomized to UC, and 63 were randomized to HBKC. Over the course of the study, 14 participants (22%; 95% CI, 12.0-33.2) ultimately refused to continue in the study from the HBKC group and 15 (23.8%; 95% CI, 13.1-34.5) refused to continue from the UC group. The refusal rate did not differ significantly between study groups ($p = 0.87$).

As a first step to initiating the evaluation of the HBKC intervention in another setting, we conducted a community-based screening and a survey of patients' perceptions concerning clinical studies in Guadalupe, Arizona, which has a mixed population of Hispanics and American Indians who are at high risk for diabetes. We randomly screened 50 participants from the community of about 6000 individuals where all participants completed the survey. Demographically, the patient mean age was 51 years; 64% were women; mean BMI was 33.8 with a waist-hip ratio of 0.95; 72% of the participants had $A_{1c}$ ≥6.5%; 60% were Hispanic; and 40% were Yaqui Indians.

Eleven patients (22%) reported previous participation in clinical trials. Most of the remaining participants were unaware of information about clinical trials (28, 57%), were satisfied

with their current knowledge (39, 78%), expected their treating physician to inform them about their results (39, 78%), and showed equal interest in participating in conventional or home-based intervention trials (34, 68%). Of the 50 respondents, 38 (77.6%) found it appropriate to be contacted by mail and 32 (64%) by telephone regarding study participation. Most patients (39, 78%) wanted to be informed about research findings or else would not participate in future clinical trials (29, 58%).

## Discussion

### Context for Study Results

Compared with those who received UC at IHS, on average, Zuni adults in the HBKC intervention group experienced significantly greater improvement in the primary outcome of patient activation and in several secondary outcomes of clinical measures of physical health and quality of life at 12 months.

- Patient activation: Participants in the HBKC group increased their PAM total scores by 9.5 points; participants in the control group saw a 0.7-point decrease ($p < 0.039$).
- Clinical measures of physical health: Three measures differed between the 2 groups. BMI in the HBKC group decreased by 1.23 kg/m2, compared with a decrease of 0.09 kg/m2 in the UC group ($p = 0.009$). Hemoglobin $A_{1c}$ levels in the HBKC group decreased by 0.52%, compared with an increase of 0.12% in the UC group ($p = 0.016$). The hsCRP levels in the intervention group decreased by 4.3 mg/L, compared with an increase of 4.7 mg/L in the control group ($p < 0.001$).
- Quality of life: The HBKC members increased their SF-12 mental subscale score by 7.5 points; members in the control group saw a 0.2-point decrease ($p < 0.017$). There were no significant differences between the 2 groups in the SF-12 physical health, burden of kidney disease, effects of kidney disease, and symptoms and problems of kidney disease KDQOL-36 scales.
- Adherence: The study did not find significant differences between the 2 groups in adherence to prescribed medications or dietary guidelines.

Attempts to manage the care of CKD patients, who often have multiple coexisting chronic conditions, under the traditional model of medical care has led to a lower quality of care, poor outcomes, and a financial strain on current medical coverage options. Many indications signal a need for change in the current system—hence the emergence of various models and interventions to improve CKD care. However, a specific treatment or intervention to correct each deficiency is not required; rather, what is needed is a total system change to a model, such as the HBKC used in our current study, which demonstrated effective CKD care.

We successfully engaged with the Zuni tribal government, IHS, and the existing health-promoting programs active at Zuni to implement innovative programs of home-based screening and treatment for CKD. Our CHR staff members, who had backgrounds in nursing, along with Zuni college students conducted the educational interventions. UNMHSC-based faculty members, including Drs. Shah, Colleran, and Struminger, were involved in conducting the intervention and monitored it regularly via site visit and telemedicine.

Our intervention was made more effective through specifically designed, culturally appropriate materials and interactions that were facilitated by culturally sensitive CHRs. To inform Zuni Pueblo residents about the study and to educate them about diabetes and kidney disease, we used a combination of community meetings: meetings at the ZHI clinic and the IHS facility; posters; health fairs; and notices in the *Shiwi Messenger,* the Zuni newspaper. We received and sustained strong support from the Zuni governor and tribal council members, who consistently contributed to our robust recruitment record. We created a TAP in consultation with the tribal council and IHS. We continued monthly meetings with the CHRs and quarterly meetings with TAP members throughout the study period; discussions focused on CHR training and project-related activities. PCORI program liaisons attended the regular TAP meetings via conference call. To update the community, we held education sessions throughout the Zuni Pueblo in schools, senior and wellness centers, the Zuni Kidney Project (ZKP) Office, tribal buildings, and the Zuni IHS facility.

All participants who were screened for the study were assigned their own primary care provider from Zuni IHS; this is significant because patients who now have a physician can continue preventive care measures. We also worked very closely with IHS providers, and study staff volunteered to bring participants to the clinic for further evaluations and health education. The study involved HBKC by CHRs, and 1 of the unintentional consequences of visiting homes was that

CHRs observed abuses (children and women). The project personnel are not able to report those abuses due to personal safety in a small close-knit community where everyone knows one another; however, we met with the Zuni governor and his council, discussed the issue of how to report abuse, and came to an agreement that the staff should anonymously report to the relevant agencies, including the IHS hospital.

Our original ZKP study described the epidemic of kidney disease in the Zuni Indians, in a population-based cross-sectional study identifying high prevalence of incipient and overt albuminuria in both diabetic and nondiabetic subjects. The subsequent investigation of GKDZI described the heritability of kidney disease and its intermediate phenotypes in a study of extended Zuni families. For the current PCORI study, we rescreened the participants from previous studies of ZKP and GKDZI, identified the incident cases of CKD, and estimated the progression rates. This analysis of a cohort of individuals from the ZKP/GKDZI/PCORI studied at 3 time points over up to 14 years shows a progression of CKD and its risk factors, including diabetes and obesity as reported by another major study of diabetic CKD in Pima Indians followed over 24 years.[37]

We expanded the evidence base on the relationships between patient characteristics, health-related outcomes, and patient activation among people with CKD. The mean patient activation level of respondents was greater than 60 on a theoretical scale of 0 to 100 and resembled that of the members with diabetes as reported by Kaiser Permanente Medical Care program of about 57.[38,39] Many studies reported such higher patient activation levels among both people with diabetes and the chronically ill.[39-44]

Multiple studies show that PAM scores predict health behaviors, including prevention behaviors (eg, obtaining screenings), healthy behaviors (eg, healthy diet and regular exercise), self-management behaviors (eg, monitoring and medication management), and health information seeking.[45-48] Individuals with higher levels of activation have better health outcomes and lower rates of health care utilization, such as emergency department visits and hospitalization.[39,49] There is further evidence that it is possible to increase activation levels with education and appropriate intervention.[50-51] Studies have demonstrated that patients at lower activation levels do not take control of their own health and often lack basic knowledge about their condition, whereas patients with high activation scores tend to possess the knowledge, skills, and confidence to self-manage their disease under adverse circumstances. Patients with higher activation scores are also

more likely to exercise on a regular basis, eat a low-fat diet with more fruits and vegetables, and abstain from smoking, resulting in better self-reported health and fewer emergency department visits.[52] A retrospective analysis showed that patients with higher PAM scores had lower $A_{1c}$ levels and lower rates of all-cause hospitalization.[53]

We observed that a home-based, CHR-implemented educational intervention using POC testing and individualized therapeutic goals significantly increases PAM and occurs concomitantly with improvements in metabolic parameters relevant to diabetes, including BMI; $A_{1c}$; and kidney disease measure of serum creatinine, microalbuminuria, and eGFR. While it is possible that these metabolic improvements are attributable to factors other than the intervention, it seems likely that our home-based intervention was responsible for these improvements and that the inability to establish a correlation between improvement in PAM and improvement in metabolic parameters is a by-product of our inclusion of several participants who had high levels of activation (and thereby, self-efficacy) at baseline, as discussed below. The PAM instrument has been validated in several populations, including older adults.[54,55] Various interventions increase patient activation and possibly improve outcomes, but previous studies have not shown this increase to translate into improved diabetes and CKD. Mayberry et al demonstrated that high levels of patient activation correlated with self-management behaviors, but not with glycemic control, and concluded that for PAM to affect glycemic control, the highest level of activation may need to be achieved.[52]

In our study, PAM levels increased significantly. After 12 months, 38.5% of patients were at stage 4 of activation (45.8% in the HBKC group and 31.3% in the UC group), compared with 28.1% at baseline (27.1% in HBKC and 29.2% in UC). However, we observed statistically nonsignificant baseline difference in PAM scores between HBKC and UC participants. We acknowledge that the baseline difference in PAM scores between the HBKC and UC groups may contribute some bias to favor the HBKC group; however we adjusted for baseline differences while we made our primary comparisons of changes in each of the outcomes of interest—and especially in our primary outcome. In the full sample (n = 125), the PAM total score was 7.4 points higher in the UC group, and the proportion who were activated (PAM level ≥3) was higher (83.6% versus 68.9%). In the final sample (n = 98), at baseline, the proportions were 81% versus 71%, respectively. This suggests that the dropouts were not different from those who had a 12-month assessment. There

are likely to be several reasons PAM scores increased in our study. Using CHRs who were members of the participant community likely meant that they had an increased knowledge of patient culture, language, resources, and barriers, thereby allowing provision of education in a culturally sensitive manner and at an appropriate level of health literacy. Such CHRs, when appropriately trained, can work individually with patients to tailor care programs to available community resources and overcome barriers through local knowledge. Numerous studies demonstrate beneficial outcomes from having CHRs as part of the diabetes care team,[56-58] and patients report feeling more empowered in their care because of CHR interventions.

We were able to successfully enroll the numbers of patients required by our initial study design; in fact, we had greater success in enrollment than anticipated. Attrition was higher than ideal, at more than 20%, suggesting that future studies should focus on better engaging study participants. However, there was no differential attrition between study groups, so we conclude that this intervention is well tolerated—at least not any less well than UC.

It is not possible to determine which individual aspect of the intervention (CHR home visits, POC testing, patient preferences, text messaging, or group sessions) may have contributed to the beneficial changes observed in PAM. Regardless, we demonstrated that an innovative, 12-month, patient-centered randomized intervention can empower patients to become active participants in their care, and such activation can result in improved clinical outcomes. Although we observed improvement in hsCRP, a biomarker of inflammation and metabolic control that we collected among the subjects who participated in our educational intervention, we were unable to relate this improvement to an improvement in the PAM score. This likely reflects the relatively large number of participants who had high PAM scores at baseline, suggesting a greater degree of self-efficacy at the outset. Additionally, by forcing the raw PAM scores into 4 categories, we lost important information, and potentially power, in our regression analysis. Future studies will need to be powered to include only those who can realistically improve their PAM score at baseline.

**Implementation of Study Intervention**

This study provides important information for the design of future studies of this intervention. First, it suggests that enrollment is likely to be limited primarily by the availability of eligible participants in the target communities, as many of those invited to participate were willing to

enroll in the study. Second, it suggests that there will be a need to work with study participants to keep them engaged. Third, it suggests that we should plan to enroll 20% to 25% more patients than needed to successfully address the goals of the study, to ensure that adequate numbers of participants provide follow-up information postintervention.

In our previous study detailing diabetes focus groups, patients reported that access to care, including travel to clinic visits, prolonged wait times, and the lack of a relationship with care providers were major impediments to care. Home-based visits are thus an attractive alternative, offering patient convenience, avoidance of waiting rooms, and the sterile atmosphere of clinics, allowing patients to be in a comfortable and familiar environment during the intervention sessions. POC testing also offers many benefits. Receiving laboratory results at the time of the visit allows the medical team and the patient to make immediate decisions based on those test results, including recommended changes to self- care behaviors, medication adjustments, and/or referral to a specialist. POC testing is accurate as long as the equipment is certified and routinely calibrated, and it is cost effective.[59] In gestational diabetes patients who received a simple exercise program without behavioral recommendations, POC testing was associated with a reduction in maternal postprandial glucose, $A_{1c}$, C-Reactive Protein, triglycerides, and maternal or neonatal complications, but not in fasting glucose values.[60]

**Results in Subgroups**

As indicated previously, because of the homogeneity of the study sample and the relatively small sample size, we did not test for subgroups in which the comparative effectiveness of the intervention versus control was different from in the study population as a whole.

**Study Limitations**

- Our pilot study tested a culturally tailored intervention with an ethnically homogenous population in a geographically isolated area, so study findings may not be generalizable beyond the study population.
- The difference in primary outcome, while statistically significant, had wide CIs, reflecting our small sample size.
- There was a substantial but statistically nonsignificant difference in the baseline PAM score in HBKC versus UC groups; however, we adjusted for baseline differences while we

made our primary comparisons of changes in each of the outcomes of interest, including changes in PAM score.

- The community of Zuni Pueblo is a close and stable community; however, we saw approximately 20% loss to follow-up due to refusal, transition of participants to ESRD on dialysis, and mortality in both HBKC and UC groups, suggesting a need to maintain the continuous engagement of study participants.
- Our study did not look at the individual components of the HBKC intervention program that might have contributed to improvement in primary outcomes of PAM score and secondary outcomes of clinical parameters.

**Future Research**

- Future research could test if the program works as well in other locations or with a larger group of people with kidney disease. In 2017 we received PCORI funding to implement the full study in 4 communities of Native Americans in New Mexico.
- Future research could also look at how each part of the intervention leads to changes in health and individuals' ability to care for themselves.

## Conclusion

People with CKD are increasingly expected to be active participants in their own health and the health care they receive. One way to accomplish this goal is by educating and training patients to get involved, be well informed, and be able to adjust their behaviors to maintain good health. The theoretical concepts of patient activation and disease self-management, as applied to diabetes and CKD, guided our PCORI-supported HBKC study.

Our study showed that patient activation was greater in patients who received HBKC from trained Zuni CHRs than in those who did not. Trained CHRs successfully promoted active involvement in daily diabetes and CKD care to patients. These results suggest that PAM may be a useful clinical tool to help identify people with CKD who are most in need of lifestyle education and that interventions that involve trained community members can enhance the educational process and help get patients more involved in their own care. The evidence for this conclusion is strong, given the randomized design of the study, which greatly enhances the likelihood that the 2 intervention groups are similar in all respects except for the intervention itself.

Higher activation was also associated with positive secondary clinical outcomes, including decreases in $A_{1c}$, BMI, and UACR. These observations further support our confidence in the primary results. These findings suggest that delivery of effective care for complex diseases is possible using local community resources. Demonstration of these findings in another high-risk population will help us determine whether this alternative approach to patient care should be adopted in clinical practice.

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## Publications

Cukor D, Cohen L, Cope EL, et al. Patient and other stakeholder engagement in Patient-centered Outcomes Research Institute funded studies of patients with kidney diseases. *Clin J Am Soc Nephrol.* 2016;4:122.



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