

ORIGINAL RESEARCH

Use of Complementary Health Approaches Among Diverse Primary Care Patients with Type 2 Diabetes and Association with Cardiometabolic Outcomes: From the SF Bay Collaborative Research Network (SF Bay CRN)

Margaret A. Handley, PhD, MPH, Judy Quan, PhD, Maria T. Chao, DrPH, Neda Ratanawongsa, MD, MPH, Urmimala Sarkar, MD, MPH, Sophia Emmons-Bell, and Dean Schillinger, MD

Purpose: To describe use of complementary health approaches (CHAs) among patients with type 2 diabetes, and independent associations between CHA use and Hemoglobin A1c (A1C) and lower-density lipoprotein (LDL) cholesterol.

Methods: Participants were enrolled onto the SMARTSteps Program, a diabetes self-management support program conducted between 2009 and 2013 in San Francisco. At the 6-month interview, CHA use in the prior 30 days was estimated using a 12-item validated instrument. Demographic and diabetes-related measures A1C were assessed at baseline and 6-month followup. A1C and LDL values were ascertained from chart review over the study period. Medication adherence was measured using pharmacy claims data at 6 and 12 months.

Results: Patients (n = 278) completed 6-month interviews: 74% were women and 71.9% were non-English speaking. Any CHA use was reported by 51.4% overall. CHA modalities included vitamins/nutritional supplements (25.9%), spirituality/prayer (21.2%), natural remedies/herbs (24.5%), massage/acupressure (11.5%), and meditation/yoga/tai chi (10.4%). CHA costs per month were \$43.86 (SD = 118.08). Nearly one third reported CHA (30.0%) specifically for their type 2 diabetes. In regression models, elevated A1C (>8.0%) was not significantly associated with overall CHA use (odds ratio [OR] = 1.78; 95% confidence interval [CI], 0.7 to 4.52) whereas elevated LDL was (OR = 3.93; 95% CI, 1.57 to 9.81). With medication adherence added in exploratory analysis, these findings were not significant.

Conclusions: CHA use is common among patients with type 2 diabetes and may be associated with poor cardiometabolic control and medication adherence. (J Am Board Fam Med 2017;30:624–631.)

Keywords: Cardiovascular Disease, Complementary Health Approaches, Health Communication, Health Disparities, Medication Adherence, Type 2 Diabetes

Background

The use of complementary health approaches (CHA), defined as “health care practices outside of

the mainstream, used to complement or supplant conventional medical care,”¹ has grown rapidly.^{2–4} CHA encompass a wide range of cultural and spiritual interventions, products, and disciplines including herbal and dietary supplements; yoga; spir-

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From General Internal Medicine and UCSF Center for Vulnerable Populations at San Francisco Zuckerberg General Hospital and Trauma Center, University of California, San Francisco, CA (MAH, JQ, MTC, NR, US, DS); the Department of Epidemiology and Biostatistics, Division of Preventive Medicine and Public Health, University of California, San Francisco (MAH, SE); and Osher Center for Integrative Medicine, University of California, San Francisco (MTC).

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ity, religion or prayer, meditation; mind-body approaches such as acupuncture/acupressure, energy therapy, or massage; and other provider-led interventions.^{2,4,5} The estimates of CHA use among adults in the United States varies widely and there have been different approaches to including or excluding spirituality and prayer as a CHA that affect these estimates. In recent studies that include spirituality or prayer, an estimated 30% of American adults use CHA, with patients of higher socioeconomic status or living with chronic/debilitating diseases often reporting higher rates of use.^{4,6,7} As health care costs rise, many patients may use CHA for financial reasons.^{8,9} In a nationwide study 21% of those who used CHA reported they did so because conventional health care was too expensive.¹⁰ In 2012, CHA users spent \$30.2 billion out of pocket on treatments, with a mean per user out-of-pocket expenditure for visits to a complementary practitioner (\$433), for purchases of natural product supplements (\$368) and for self-care approaches (\$257) among the higher expenditure CHA approaches.¹¹

A majority of CHA users seem to pursue conventional and alternative health routines concurrently.^{6–8,10,12,13} Few studies though, have focused on CHA used among safety-net patients or those with chronic illnesses such as diabetes.^{7,12} In 1 safety net study, patients with type 2 diabetes who reported food or medication insecurity were more likely to be users of CHA compared with those who have never delayed food or health care for financial reasons.⁸ Two nationally sampled studies on CHA use did also include diabetes.^{30–31} These 2 studies reported significantly different prevalence estimates of CHA use (1 indicated 8%³⁰ and the other

57% among patients with diabetes³¹). As these were in English-speaking patients only and also included only relatively small numbers of patients with diabetes and CHA use in the sampled data, they do not reflect many populations regarding CHA use.

Although patients may use CHA to alleviate symptoms or improve trajectories of chronic or painful illnesses,^{2,14} some studies suggest that use of CHA may be associated with worse health. For example, in 1 study of patients with diabetes, CHA use was associated with poor glycemic control and higher disease severity.¹⁰ Studies that did not focus specifically on diabetes also had similar findings.^{15–17} CHA use patterns also vary by ethnicity and language as suggested by Nguyen et al,¹² in which both Mexican-Americans and Vietnamese-Americans, compared with whites, were significantly more likely to substitute CHA for diabetes medications or to add CHA to diabetes medications. Some studies have identified adverse drug interactions and side effects^{2,3,18,19} associated with concurrent use of complementary health alternatives and conventional medicine.

In light of physician reports of discomfort in discussing CHA with their patients (often for lack of clinical knowledge) and requests for further education,²⁰ it is necessary to clarify what factors are associated with CHA use and how CHA use impacts health outcomes, including positive benefits and adverse effects on acute and chronic illness, to aid in such discussions. In this article, we examine the prevalence and patterns of CHA use in an ethnically diverse, urban population of patients with diabetes engaged in a self-management program, the association between CHA use and diabetes-relevant cardiometabolic outcomes, such as elevated Hemoglobin A1c (A1C) and lower-density lipoprotein (LDL) cholesterol, and whether differences in these intermediate markers can be explained by socio-demographic characteristics or medication adherence.

Methods

To translate research into practice, a low-income government-sponsored managed care plan implemented a language-concordant automated telephone self-management and support program with health coaching for members at 1 of 4 clinics within an urban practice-based research network (PBRN), the SF Bay Collaborative Research Network. The

decision to submit the manuscript for publication. The funders had no role in design and conduct of the study or preparation, review, or approval of the article.

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Corresponding author: Margaret A. Handley, MPH, PhD, Building 10, 3rd floor, Zuckerberg San Francisco General Hospital and Trauma Center, 1001 Potrero Avenue, San Francisco, CA 94110 (E-mail: margaret.handley@ucsf.edu).

The San Francisco Health Plan participated in the design and implementation of the intervention and evaluation, collection, management, analysis, and interpretation of the data. MH developed the study and wrote the article; JQ conducted the data analysis and wrote the article; MC developed the study and edited the article; NR, US, DS, and SEM edited the article. All authors contributed to the conception and design, and drafting and critical revision of the article, including final approval of the version to be published.

San Francisco Health Plan's (SFHP) SMART Steps Program (Self-Management Automated and Real-Time Telephonic Support/Pasos Positivos/明智進步計劃) is a controlled quasi-experimental evaluation of the program's impact on health-related quality of life, diabetes self management, patient-centered processes of care, and cardiometabolic outcomes. Through the SMARTSteps program from 2009 to 2013, we enrolled and followed patients with diabetes; these patients were randomly assigned to receive a self-management, automated, and real-time telephonic support program, or usual care.^{5,21–22} The SMARTSteps study included 362 participants aged 18 years or older, who had type 2 diabetes and received primary care at 1 of 4 publicly funded clinics in the Community Health Network of San Francisco (CHNSF) and who spoke English, Cantonese, or Spanish. We assessed diabetes diagnosis through the CHNSF diabetes registry, a combination of SFHP pharmacy claims with confirmation of clinician-documented diagnosis of diabetes, fasting glucose ≥ 126 mg/dL, or A1C $\geq 7\%$.²³ Patients who were pregnant, lacked a touch-tone phone, were planning to leave the region, or were unable to provide verbal consent were ineligible. Eligible participants were contacted via phone and offered \$25 gift card incentives, and those participants willing to complete baseline and 6-month interviews were contacted by University of California–San Francisco (UCSF) research assistants who obtained verbal informed consent over the telephone. The Committee on Human Research at the UCSF approved the study.

At baseline, UCSF staff conducted telephone interviews to collect data on self-reported baseline sociodemographic variables including self-reported sex, gender, language, educational attainment, race/ethnicity, nativity, annual household income, employment status, marital status, food insecurity, duration of diabetes, and health literacy.^{21,24–26} The majority of participants ($n = 278$, 76.7%) also completed a 6-month follow-up interview that included questions about use of CHA in the past 30 days and disclosure of CHA to their providers.⁵ CHA use in the prior month was assessed through 12 questions about “remedies and treatments that are not typically prescribed by medical doctors” using a survey developed for a prior multilingual study.^{7,27} Participants were asked if they had used natural remedies such as teas or herbs; manual therapies such as massage or acupuncture;

techniques such as yoga, meditation, or tai chi; vitamins or nutritional supplements; homeopathic remedies; chiropractic treatments; energy therapies such as Reiki or therapeutic touch; remedies or practices associated with a particular culture, such as Chinese medicine, Ayurveda, indigenous healing, or curanderismo; spirituality, religion, or prayer for health reasons; or other alternative treatment or remedy. For the analysis, we dichotomized CHA use in the prior 30 days as follows: “yes” meant used at least 1 complementary health approach; “no” meant did not use any approaches in the past 30 days. We included CHA use with and without spirituality, religion, or prayer in the analysis to determine whether overall CHA use was significantly increased when these modalities were included. Participants were also asked if any of the CHA were used specifically for their diabetes.

We abstracted cardiometabolic measures obtained through routine care—A1C and LDL—from the CHNSF electronic health record, clinical registry, and article and electronic charts. A time period of 45 days after a target 6-month follow-up date was used to reflect an approximately 6-month followup. Cardiometabolic outcomes were defined as follows:

A1C $> 8.0\%$ (64 mmol/mol) on last measurement or no measurement in clinical registry within preceding 6 months. LDL > 100 mg/dL on last measurement or no measurement in clinical registry within preceding 6 months. Nonadherence to medications was measured using the continuous medication gap, a well-established and previously validated measure with a prespecified cut point²⁸ as follows:

Patients with a 15-day to 6-month gap in refilling specific cardiometabolic prescriptions were considered to have a continuous multiple-interval measure of gaps (CMG) for the following medications and supplies: diabetes medications, including oral hypoglycemic and insulin; lipid-lowering medications; and glucose testing strips (for patients receiving insulin or sulfonylureas), based on pharmacy claims data available from SFHP. Poor medication adherence was defined as having a CMG $> 20\%$, as has been validated in prior studies.^{22,28} Functional health indicators included the SF-12 for the physical and mental health components, and the reported number of bed days in the previous 30 days.^{21,22}

We calculated descriptive statistics, including percentages for use of CHA and other categorical variables and means and standard deviations for

continuous variables. In bivariate analyses, we compared 1) participants who used any CHA to those participants who did not, and 2) participants who used a single CHA modality to those participants with multiple CHA modalities. We used χ^2 tests or Fisher's exact tests for categorical variables, *t*-tests for continuous variables if normally distributed and Wilcoxon rank-sum tests if continuous variables were not normally distributed, to assess statistically significant differences, defined as $P < .05$.

Logistic regression analyses were conducted to determine the independent associations between CHA use and 2 clinical measures: poor glycemic control (A1C $> 8.0\%$) and elevated LDL (>100 mg/dL). All multivariate regression models were initially adjusted for the following covariates: age, sex, language, diabetes duration, insulin use, and physical and mental functional health (SF-12). Because of the modest sample size, we reduced regression models by including covariates that were significant at $P < .10$ in bivariate analyses. Based on results from our reduced models, we derived final regression models by including as covariates, only those variables from our reduced models that were significant at $P < .05$ using a model selection of backward elimination. The final model for elevated A1C includes the variables CHA use, years of diabetes, and insulin use, and for elevated LDL, only the variable CHA use, as none of the covariates were significant at $P < .05$. In exploratory subanalyses to evaluate medication adherence and functional health status, we added, separately and together, medication adherence (dichotomous, with a CMG gap defined as $>20\%$ vs $\leq 20\%$) and functional health status (physical and mental subscales) into the final models. However, the sample sizes were smaller for these exploratory subanalyses than those for the main models ($n < 100$). Adjusted odds ratios and 95% confidence intervals were calculated for CHA use and other model variables. All analyses were conducted in SAS 9.3 (SAS Institute Inc., Cary, NC).

Results

Among the 278 SMARTSteps participants who were administered the CHA survey questions, 143 participants (51.4%) reported use of any CHA overall in the previous 30 days. Of the 278 SMARTSteps participants, specific CHA use was as follows; vitamins/nutritional supplements (25.9%), spirituality/prayer (21.2%), natural remedies/herbs (24.5%), massage/acupressure (11.5%), and meditation/yoga/

tai chi (10.4%). CHA costs per month were \$43.86 (SD = 118.08). Excluding the 10 participants who only used spirituality, religion, or prayer, the overall result was similar with any CHA use at 49.6%.

Among the 143 CHA users, the prevalence of reported use of specific modalities in the previous 30 days was 50.3% vitamins or nutritional supplements; 47.6% natural remedies including teas or herbs; 41.3% spirituality or prayer; 22.4% massage or acupressure; 20.3% yoga, meditation, or tai chi; 15.4% Chinese medicine and chiropractic treatments; 6.3% additional categories of practices such as acupuncture and energy therapies; and less than 5% for "other" practices. Sixty percent reported use of multiple CHA modalities, with 28.7% using 2, 19.6% using 3, and 11.9% using 4 or more CHA in the previous 30 days. The 3 most common modalities among users of multiple modalities were natural remedies including teas or herbs (64.0%), vitamins or nutritional supplements (60.5%), and spirituality or prayer (57.0%).

Approximately one third of CHA users (29.6%) reported using CHA specifically for diabetes. The most common modalities used specifically by these participants were natural remedies including teas or herbs (64.3%), vitamins or nutritional supplements (42.9%), spirituality or prayer (35.7%), yoga, meditation or tai chi (31.0%), and massage or acupressure (28.6%). The average amount of money spent per month for CHA by this group was similar to all other CHA users, although slightly higher at \$52.18 (vs \$43.86).

Table 1 presents comparisons between CHA users and nonusers, on selected sociodemographic characteristics and diabetes-related clinical, medication adherence, and functional health indicators. Of the sociodemographic characteristics, significant differences were found in race/ethnicity ($P = .01$) and language ($P = .001$), and significantly higher CHA use with being US born ($P = .01$) and adequate (vs limited) health literacy ($P = .009$). On further examination of race/ethnicity and language, CHA users compared with nonusers were more likely to be Latinos versus non-Latinos (66.7% vs 47.1%; $P = .007$) and English-speakers versus non-English speakers (61.5% vs 47.5%; $P = .04$; data not shown).

CHA use was also associated with diabetes-related clinical, medication-adherence, and functional health measures (Table 1). CHA users had similar duration of diabetes as nonusers, but were

Table 1. Socio-Demographic and Health Characteristics of SMARTSteps Participants by Reported Use of Complementary Health Approaches (CHA) N = 278

Sociodemographic Characteristics	CHA Use Reported, n, % (N = 143) [§]	No CHA Use Reported, n, % (N = 135)	P-Value
Age, years (SD)	55.4 (9.3)	55.9 (7.5)	.90
Women	77.6%	70.4%	.17
Race/ethnicity			
Latino	29.4%	15.6%	.01
Black/African-American	11.2%	5.9%	
Asian/Pacific Islander	51.0%	69.6%	
White/Caucasian	7.0%	6.7%	
Multi-ethnic/other	1.4%	2.2%	
Born outside the United States	80.2%	91.3%	.01
Language			
Cantonese speaking	42.0%	63.7%	.001
Spanish speaking	24.5%	14.1%	
English speaking	33.6%	22.2%	
Educational attainment			
Some high school or less	48.4%	57.1%	.09
High school graduate or GED	20.6%	23.0%	
Some college, college graduate, or above	31.0%	19.8%	
Employment status			
Employed full time	24.6%	18.3%	.80
Part time	46.8%	49.2%	
Unemployed	10.3%	11.1%	
Disabled	7.1%	8.7%	
Homemaker/Retired/Other	11.1%	12.7%	
Annual household income <\$20,000	65.3%	61.3%	.55
Insurance type			
Medicaid/MediCal	18.2%	23.1%	.48
Medicare	7.0%	3.7%	
Healthy worker/healthy SF	74.1%	71.6%	
Other	0.7%	1.5%	
Limited health literacy	34.9%	51.2%	.009
Diabetes-related clinical, medication			
Adherence and functional health indicators*			
Years with diabetes, mean (SD)	7.2 (6.1)	6.8 (5.2)	.99
Hemoglobin A1c (A1C) > 8.0%	33.8%	16.2%	.01
Hemoglobin A1c (A1C), mean (SD)	7.91 (1.7)	7.41 (1.3)	.06
Low density lipoprotein (LDL), mg/dL, mean (SD)	100.9 (35.2)	84.7 (28.8)	.02
Non-adherence-oral diabetes medication [†]	39.5%	24.2%	.03
Non-adherence-cardiometabolic medication [†]	39.6%	22.5%	.01
Food insecurity [‡]	9.5%	5.6%	.04
SF-12 physical component, mean (SD)	44.9 (9.8)	47.9 (8.8)	.009
SF-12 mental component, mean (SD)	47.8 (11.6)	52.2 (9.9)	.002
Bed days in last month, mean (SD)	1.9 (5.2)	0.7 (3.4)	<.000
Insulin use	19.6%	15.6%	.38

*, Sample size: for A1C, n = 148; for LDL, n = 89.

[†]Non-adherence was measured using the continuous medication gap and a 15-day to 6-month gap in refilling specific prescriptions.

[‡]Replied “often” or “sometimes” to having put off paying for diabetes medicine so would have money for food in last 12 months.

[§]With spirituality, prayer, religion excluded, n = 133 CHA users.

Table 2. Any Use of Practitioner-Delivered, Herbal-Ingested Supplements, and Other Modalities Among CHA Users by Language (N = 143)*

	Spanish, n, % (n = 35)	English, n, % (n = 48)	Cantonese, n, % (n = 60)	P-Value
Practitioner Delivered				
Massage, acupressure, acupuncture (n = 34)	13 (38.2)	13 (38.2)	8 (23.5)	.01
Chiropractic (n = 9)	3 (33.3)	5 (55.6)	1 (11.1)	.09
Chinese medicine (n = 22)	0	3 (13.6)	19 (86.4)	.01
Herbal-ingested supplements				
Teas and herbs [†] (n = 68)	15 (22.1)	24 (35.3)	29 (42.7)	.16
Vitamins and packaged herbal supplements [‡] (n = 72)	12 (16.7)	28 (38.9)	32 (44.4)	.06
Homeopathic remedies (n = 5)	0	5 (100)	0	NA
Other CHA modalities				
Yoga, meditation, tai chi (n = 29)	1 (3.5)	14 (48.3)	14 (48.3)	.01
Spirituality, religion or prayer for health (n = 59) [§]	26 (44.1)	30 (50.9)	3 (5.1)	.1
Other (n = 7)	1 (14.3)	5 (71.4)	1 (14.3)	.03

*Excluding types with less than 5 observations.

[†]Exclusive use noted among 13 (19.1%) of users of teas and herbs (n = 9 Cantonese, and n = 2 each English and Spanish speakers).

[‡]Exclusive use noted among 20 (27.8%) of users of vitamins and packaged herbal supplements (n = 14 Cantonese, n = 5 English, and n = 1 Spanish speakers).

[§]Exclusive use noted among 10 (17.0%) of users of spirituality, prayer or religion (n = 7 Spanish and n = 3 English speakers).

more likely to have A1C values >8.0% (33.8% vs 16.2%; $P = .01$). CHA users were also more likely to have higher mean LDL values (100.9 vs 84.7; $P = .02$). Regarding medication non-adherence, CHA users were more likely to be without sufficient cardiometabolic medications (39.6% vs 22.5%; $P = .01$). CHA users were also more likely to report putting off paying for diabetes medicine to have money to pay for food (9.5% vs 5.6%; $P = .04$). Functional health status was poorer among CHA users than nonusers, with the former reporting greater number of bed days in the previous month (mean days = 1.9 vs 0.7; $P < .0001$) and lower SF-12 measures for physical ($P = .009$) and mental health components ($P = .002$).

There were several important differences among use of CHA types by language, as shown in Table 2. Cantonese speakers, for example, were more likely to use Chinese herbs and less likely to use massage or acupressure/acupuncture than either English or Spanish speakers ($P = .01$). Yoga, meditation, and tai chi were less likely to be used by Spanish speakers than English or Cantonese speakers ($P = .01$).

Among CHA users, there were several significant differences between those who used multiple modalities compared with only 1 type of CHA. For example, multiple modality use was more common among women compared with men (83.7% vs

16.3%; $P = .03$) and among younger patients (mean age, 54.2 vs 57.2 years; $P = .005$). As well, English speakers were more likely to use multiple CHA modalities compared with non-English speakers ($P = .03$). Multiple CHA modality users reported higher monthly expenditures on CHA than single-modality users (mean, \$56.73 compared with \$23.83 per month; $P = .0005$). For diabetes-related clinical measures, users of multiple CHA modalities were more likely to have A1C $\leq 8.0\%$ compared with single-modality users (75.0% vs 53.3%; $P = .05$). There were no differences between the 2 groups for other sociodemographic characteristics including household income ($P = .66$), less than high school education (vs high school or greater; $P = .51$), limited (vs adequate) health literacy ($P = .14$), food insecurity with regard to tradeoffs in purchases for affording diabetes medicine and supplies ($P = .23$ and $P = .93$, respectively), mean years with diabetes ($P = .82$), and whether or not they were born in the United States ($P = .89$). With the exception of A1C, noted above, none of the other diabetes-related clinical, medication adherence, or functional health indicators described in Table 1, differed between the 2 groups of CHA users, and thus were not examined in multivariate analyses.

In the multivariate model for A1C, which included any CHA use (and not specifically for dia-

betes), years of diabetes and insulin use, the association of CHA use with the clinical outcome of elevated A1C was no longer significant (odds ratio [OR] = 1.78; 95% CI, 0.7 to 4.52). In the final regression model for the clinical outcome of LDL (which included only CHA use), CHA use remained significant (OR = 3.93; 95% CI, 1.57 to 9.81). In the exploratory subanalyses that added only medication adherence, only functional status, or both medication adherence and functional status into the final regression model, the association with CHA use and elevated A1C was not statistically significant (Adjusted Odds Ratio [AOR] = 2.22; 95% CI, 0.71 to 6.92), [AOR = 1.81; 95% CI, 0.68 to 4.8], [AOR = 2.67; 95% CI, 0.78 to 9.17], respectively), although the magnitudes of associations were similar to those in the final regression models without medication adherence and functional status. For LDL > 100 mg/dL, CHA use remained statistically significant (AOR = 3.49; 95% CI, 1.34 to 9.06) when functional status alone was added to the final regression model. However, when medication adherence alone or both medication adherence and functional status together were added to the final regression model, CHA use was no longer statistically significant ([AOR = 2.1; 95% CI, 0.49 to 9.06] and [AOR = 1.83; 95% CI, 0.41 to 8.19], respectively). Similar findings were produced from analyses that excluded the 10 participants reporting exclusive spirituality, religion, or prayer use (data not shown).

Discussion

In this study we found that diverse safety net patients with diabetes in San Francisco commonly use a wide range of CHA modalities, spend an average of \$43.86 a month on CHA, and often apply their use specifically for their diabetes as well as for their overall health. The association between CHA use and elevated A1C or LDL were not significant when insulin use or medication adherence was taken into account. For both clinical outcomes, however, the sample sizes were not large and the magnitude of the associations remained similar. That patients with diabetes who are CHA users could potentially have worse cardiometabolic control is consistent with studies indicating an association of diabetes severity and CHA¹⁰ and raises important questions for clinical care and medication-related conversations in health care settings.

In addition, as a greater proportion of CHA users in this study reported poor functional health status, it would be important to further examine reasons for CHA use and determine whether patients are adopting CHA use in response to worsening symptoms or if instead, for other reasons. For family medicine physicians in urban environments, tasked with helping patients with limited resources manage their diabetes, learning more about their patients' interest in alternative medicine may provide additional information regarding the medical management of their diabetes. In addition, the information garnered from this PBRN is one of the first of its kind to characterize CHA use among patients with diabetes receiving care in low-income communities.

There are several limitations to these findings, including the sample sizes being insufficient for subanalyses and that the study was conducted among patients who also received a health-coaching intervention, which can potentially influence medication-related behaviors. In addition, that CHA use was estimated at only 1 time point and for only the previous 30 days limited our ability to characterize patterns of CHA use and examine associations with clinical outcomes. Larger prospective studies could help disentangle to what extent patients using CHA are alternating or supplementing their diabetes and cholesterol medications. As such, these findings raise important questions about why patients are using CHA, how their views about their CHA use conflict or complement their use of prescription medications for chronic disease, and to what extent the use of CHA reflects strategies by patients to control aspects of their illness that fall outside the clinical environment.²⁹

To see this article online, please go to: <http://jabfm.org/content/30/5/624.full>.

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