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RANDOMIZED CONTROLLED TRIAL

Impact of chronic disease self-management programs on type 2 diabetes management in primary care

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Abstract

AIM: To assess the effectiveness of the Chronic Disease Self-Management Program (CDSMP) on glycated hemoglobin A1c (HbA1c) and selected self-reported measures.

METHODS: We compared patients who received a diabetes self-care behavioral intervention, the CDSMP developed at the Stanford University, with controls who received usual care on their HbA1c and selected self-reported measures, including diabetes self-care activities, health-related quality of life (HRQOL), pain and fatigue. The subjects were a subset of participants enrolled in a randomized controlled trial that took place at seven regional clinics of a university-affiliated integrated healthcare system of a multi-specialty group practice between January 2009 and June 2011. The primary outcome was change in HbA1c from randomization to 12 mo. Data were analyzed using multilevel statistical models and linear mixed models to provide unbiased estimates of intervention effects.

RESULTS: Demographic and baseline clinical characteristics were generally comparable between the two groups. The average baseline HbA1c values in the CDSMP and control groups were 9.4% and 9.2%, respectively. Significant reductions in HbA1c were seen at 12 mo for the two groups, with adjusted changes around 0.6% ($P < 0.0001$), but the reductions did not differ significantly between the two groups ($P = 0.885$). Few significant differences were observed in participants' diabetes self-care activities. No significant differences were observed in the participants' HRQOL, pain, or fatigue measures.

CONCLUSION: The CDSMP intervention may not lower HbA1c any better than good routine care in an integrated healthcare system. More research is needed to understand the benefits of self-management programs in primary care in different settings and populations.

Key words: Type 2 diabetes; Self-management; Chronic Disease Self-Management Program; Glycemic control; Glycated hemoglobin; Chronic disease

Core tip: Diabetes is a serious chronic disease. One of the most studied evidence-based behavioral or self-care programs targeting chronic conditions including diabe-

tes is the Stanford Chronic Disease Self-Management Program (CDSMP). Although the CDSMP has been studied extensively, its impact on glycemic control has not been thoroughly evaluated in a randomized controlled trial to date. To the best of our knowledge, this is the first study to evaluate the effectiveness of the CDSMP in a randomized controlled trial. Our finding that the CDSMP intervention may not lower hemoglobin A1c any better than good routine care in an integrated healthcare system calls for further research.

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INTRODUCTION

Diabetes is a serious chronic condition affecting millions of people worldwide. According to estimates by the World Health Organization, about 350 million people have diabetes globally[1]. Diabetes has a severe and significant health and economic impact on all nations. It is the 6th leading cause of death in Canada and the 7th leading cause of death in the United States, costing an estimated $174 billion[2,3]. The bulk of this cost is attributable to the serious long-term complications associated with the condition including limb amputations, blindness, coronary health disease, stroke, and kidney disease[3]. Type 2 diabetes accounts for 90%-95% of all diabetes[3]. Although type 2 diabetes is more prevalent among people aged 40 years or older, the prevalence among younger populations is increasing dramatically because of the rise in obesity and physical inactivity in children and the youth[4].

Supportive programs to enhance patient self-care have been touted as a pre-requisite to diabetes management in spite of differences in individual needs to cope with this debilitating condition[5]. The traditional didactic models of care that involved teaching patients to improve the knowledge of their health condition are giving way to the current models that focus on behavioral or self-care approaches aimed at providing patients with the skills and strategies to promote and change their behavior[6]. In fact, several national organizations including the American Diabetes Association and the American Association of Diabetes Educators consider self-care an essential component of effective diabetes management[7-9].

One of the most studied evidence-based behavioral or self-care programs targeting chronic conditions is the Chronic Disease Self-Management Program (CDSMP). Developed at the Stanford University, the program offers the potential to improve overall health of individuals with chronic conditions, while preventing further decline in their general health status[10-12]. Designed as a 6-wk, community-based self-care education program, CDSMP focuses on assisting participants to gain confidence or self-efficacy and acquire skills to better manage their chronic conditions. It is taught by trained leaders using a structured protocol.

The CDSMP has been found to be highly effective in improving general health and lowering hospitalization rates[10]. It has therefore been implemented worldwide for several chronic conditions such as heart disease, lung disease, arthritis, and diabetes as well as evaluated in various settings including the United States, Canada, United Kingdom, Australia, New Zealand, Bangladesh, China, Hong Kong, and The Netherlands[13-20]. While the original CDSMP validation study found improvements in general health status, health behaviors, and healthcare utilization[10], the findings of more recent studies from a variety of self-management programs have been inconsistent[5,21-27]. A recent literature review of randomized controlled trials comparing self-management support interventions for general chronic diseases *vs* usual care revealed mixed results. While positive findings were found regarding self-efficacy, less positive ones were found for quality-of-life measures[5]. Also although the CDSMP has been studied extensively, its impact on glycemic control has not been thoroughly assessed. In particular, its effectiveness on glycemic control has not been evaluated in a randomized controlled trial in the United States to date. A recent study concluded that the CDSMP is a useful and appropriate program for lowering glycated hemoglobin A1c (HbA1c) among those out of control[28]. However, this was a longitudinal study with no comparison group. Another related study found the CDSMP to improve lifestyle behaviors among patients with type 2 diabetes[23,29]. But again this was a single-group design.

The aim of this study was to assess the effectiveness of the CDSMP on glycemic control and selected self-reported measures among patients with type 2 diabetes in a large integrated healthcare organization in central Texas that serves large racially/ethnically diverse populations.

MATERIALS AND METHODS

Design

This study was a comparison of one intervention arm, the CDSMP, and the control arm from an open-label, 4-arm randomized controlled trial that was designed to evaluate the effectiveness of two different type 2 diabetes mellitus (T2DM) self-care interventions (implemented singly and in combination) on glycemic control. Designed with the acknowledgment that both patients and researchers would be aware of the random assignment, the study protocol consisted of screening potential subjects for eligibility, randomizing them to one of four study arms, and following them over a 24-mo period. However, the primary end-point was change in HbA1c from randomization/baseline to 12 mo of follow-up. The current study reported here focuses on participants in two of the four original study arms.

The study protocol was approved by the Institutional Review Boards (IRB) of Scott and White Healthcare System and Texas A and M Health Science Center. All quali-

fied participants accepted the conditions of the study and gave informed written consent at enrollment/orientation. Enrollment occurred between January 2009 and June 2011 and data collection was completed in July 2012. We adhered to the CONSORT protocol[30] and registered the trial with clinicaltrials.gov (NCT01221090).

Setting, participants, and recruitment

Participants represent a subset of subjects that were recruited from seven participating clinics of a large integrated healthcare system, a university-affiliated, multispecialty group practice associated with a 250000-member Health Maintenance Organization in central Texas. Potential participants were identified through electronic medical records if they: (1) had a diagnosis of T2DM; (2) were ≥ 18 years; (3) had a lab assessed HbA1c value ≥ 7.5% (≥ 58 mmol/mol) within the last six months; and (4) were able to communicate in English. Subjects were excluded if they: (1) had documented reports of alcoholism or drug abuse; (2) were pregnant or planning to become pregnant within 12 mo; or (3) were unwilling to sign an informed consent. Recruitment was solicited by physicians within the seven clinics who agreed to invite their patients to participate in the study.

Physicians were provided with IRB approved invitation-to-participate letters and a list of their T2DM patients meeting the threshold HbA1c level at their last visit. Contact was initiated with potential subjects through physician-sent letters, describing the study and requesting a completed screening enrollment card if interested. Subjects who returned a screening enrollment card were contacted by project coordinators, who provided additional information and screened them to determine eligibility. To verify the inclusion and exclusion criteria, subject permission was obtained to review their medical records. Other recruitment strategies included oral referrals by physicians and patient educators and posting messages in waiting areas of study clinics.

Lab assessments were continuously monitored at each phase of the study recruitment to ensure that enrolled participants had HbA1c values ≥ 7.5% (≥ 58 mmol/mol) within the last six months since individuals who previously met this criterion may no longer fulfill that requirement at orientation. A follow-up telephone interview was conducted to determine participation interest. Lab results were screened to ensure that the participant met qualifying HbA1c and if needed, tests were scheduled.

Intervention

Participants randomized to the CDSMP arm were invited to attend a 6-wk, classroom-based program for diabetes self-management. The effectiveness of the CDSMP has been described elsewhere[10]. With the goal of increasing self-efficacy to ultimately decrease chronic disease related symptoms and avoidable healthcare utilization, the CDSMP teaches participants techniques to facilitate enhanced decision making, action planning, and effective communication. CDSMP workshops were hosted in clinical environments and community-based settings. While fidelity to the individual classes was not monitored, CDSMP license requires that lay leaders use pre-scripted materials and that experienced master trainers/lay leaders (who attend a required four-day training program) lead the workshops.

Participants randomized to the control arm did not receive any treatment other than their usual clinical diabetes care, along with some publicly available Texas Diabetes Council patient education materials.

Data collection

Study measures were obtained at orientation/baseline, 6 mo, and 12 mo of follow-up. Participants received monetary compensation in the form of a gift card for travel expenses and time, consisting of $20 at orientation and at the 12-mo follow-up visit.

At orientation, a questionnaire was administered to obtain several pieces of information including: (1) demographics such as age, gender, and race/ethnicity; (2) diabetes self-care activity monitoring (number of days, 0-7, that any specific self-care activity was performed in the past week) as measured by the Summary of Diabetes Self-Care Activities instrument; (3) self-reported health-related quality of life (HRQOL) measures (*e.g.*, number of days physical/mental health was not good); and (4) pain and fatigue measures (on a scale of 1-10, 1 indicating none and 10 severe). Questionnaires were administered every 6 mo. However, as our primary end point was 12 mo, analyses were only conducted for this time period.

Anthropometric data were obtained at orientation and at subsequent follow-up visits. Height in inches was measured without shoes. Weight was measured in pounds on a balance beam scale or an electronic scale without shoes. Body mass index (BMI) was computed from height and weight measurements. Blood pressures were recorded with either a mercury sphygmomanometer or a validated automated device. Participants who were unable to come in for their follow-up appointments had their height, weight, and blood pressure data abstracted from electronic health records (EHRs). Measures recorded fell within the range of 10 d prior to and 45 d after participants' scheduled follow-up dates. This was done to obtain participant visits as close to their target dates as possible, but also allow for enough time after the target date to accommodate for scheduling errors (*i.e.*, missed appointments, rescheduling).

Measures of HbA1c were collected from EHRs dating back 6 mo prior to orientation to the last day of study participation (45 d after the 12-mo follow-up period). If a participant did not have any HbA1c value within the EHR for any particular follow-up visit, a lab test was scheduled to obtain a measure. Of the HbA1c collected 6 mo prior to orientation, the value measured closest to the orientation date was considered as the baseline HbA1c value. HbA1c values that were measured on dates preceding the baseline HbA1c were not included; *i.e.*, HbA1c values included in the analysis were those collected since the baseline HbA1c and until the last day of study participation.

Definition of a completed follow-up participation

A participant was considered to have completed a follow-up if there was an available HbA1c within the designated follow-up period, *i.e.*, within the cut-off dates, defined as within 45 d after the scheduled follow-up dates. For the 6-mo follow-up measure, if at least one HbA1c was available after baseline and before the 6-mo cut-off, the participant was considered to have completed a follow-up. For the 12-mo follow-up measure, the designated range was between the 6-mo cut-off date and the 12-mo cut-off date. Participants who were unable to complete an assessment at one time period were not excluded from future assessments. For instance, if a participant did not have any HbA1c measured within the specified time period for their 6-mo follow-up but had one available for their 12-mo follow-up, he/she was considered to have completed the 12-mo follow-up, but not the 6-mo.

Outcome measures

The primary study outcome measure was change in HbA1c from randomization to 12 mo of follow-up. Secondary outcome measures included BMI and blood pressure, along with several self-management behavioral measures (*e.g.*, foot care) from randomization to 12 mo of follow-up.

Statistical analysis

Analysis was based on intent-to-treat. Descriptive statistics were used to describe baseline demographic, anthropometric, and clinical characteristics by study arm. Analysis of variance as used to compare average changes in self-management behaviors between study arms. To determine whether the treatment had an effect on the rate of change in HbA1c level over time, we used linear mixed models that included time as a continuous variable. A spatial power covariance structure with time as the distance measure accounted for the time-series correlation among repeated measurements on each subject. Forward selection was utilized, in which powers of time were added one at a time to the base model including treatment group effects only. Time and treatment effects were then added gradually and evaluated with likelihood ratio tests to assess any effect modification. The final mixed model included time, time squared, treatment group, and the interaction between time and treatment group as fixed effects. HbA1c values included in the analysis were those falling within the time frame of 6 mo prior to orientation until the 12-mo follow-up cut-off point.

RESULTS

Subject enrollment, participation and retention

The flow diagram of participant enrollment and disposition in the trial has been described elsewhere[31]. Of the subjects randomized, 101 entered the CDSMP arm and 95 entered the control arm. Of the participants assigned to the CDSMP, 75.6% attended 4 of 6 sessions required for successful completion.

Demographic data and baseline comparison of study population

Demographic and baseline clinical characteristics were generally comparable between the two groups (Table 1). The mean age of participants was 57.6 ± 10.9 years. Slightly more than a third (36.4%) was of minority status, self-reporting as either African American or Hispanic. The majority of participants had received post-secondary education; 40% had attended some college or vocational school, 20% were college graduates, and 13% had completed higher forms of education. Approximately one-third reported annual incomes greater than $50000, while almost 40% reported annual incomes between $25000 and $49999.

An overwhelming majority (92.9%) of the participants were either overweight or obese, with a mean BMI of 34.3 ± 7.4 kg/m^2. While measures of systolic blood pressure were comparable between study arms, with a mean of 134.8 ± 19.3 mmHg, measures of diastolic blood pressure were significantly different ($P < 0.002$). The mean baseline HbA1c for participants was 9.3% ± 1.6% and did not differ significantly between the two groups.

Table 2 summarizes participants' diabetes self-care activity (DSCA) monitoring, HRQOL measures, and pain and fatigue measures at baseline. Participants in the control arm reported checking their feet more frequently than those in the CDSMP arm ($P = 0.04$). Although participants in the control group reported inspecting the inside of their shoes more frequently and also tended to report fewer unhealthy physical days and experience less limited days due to physical and mental health, these did not reach statistical significance ($P \geqslant 0.05$).

Changes in HbA1c from baseline to 12 mo

There were modest but statistically significant reductions in HbA1c from baseline to 12 mo of follow-up. The results of the linear mixed model are presented in Table 3. The adjusted reductions in HbA1c over the 12 mo of follow-up for the CDSMP and control groups were 0.559% and 0.576%, respectively ($P < 0.0001$). However, the interaction term of the treatment group and time was not statistically significant ($P = 0.885$), implying no significant difference in HbA1c reductions by treatment assignment.

Changes in DSCA monitoring, HRQOL measures, and pain and fatigue measures

The mean difference in the number of days (within the last 7 d), from baseline to 12 mo of follow-up, that participants reported using specific diabetes self-care activity features were compared between the CDSMP and control arms (table not shown). While there were no differences on 12 of the 14 self-care indicators, participants in the control arm had a higher rate of change in checking their feet than those in the CDSMP arm (increase of 0.28 d/mo *vs* 0.20 d/mo; $P = 0.02$). Similarly, participants in the control arm reported an increase of 0.15 d/mo eat-

Table 1 Characteristics of study participants (n = 196)

	Controls (n = 95)		CDSMP (n = 101)		*P*-value
	No.	%	No.	%	
Age group (yr)					0.32
30-44	15	15.8	12	11.9	
45-64	55	57.9	69	68.3	
⩾ 65	25	26.3	20	19.8	
Gender					0.74
Female	53	55.8	54	53.5	
Male	42	44.2	47	46.5	
Hispanic					0.46
Yes	15	15.8	20	19.8	
No	80	84.2	81	80.2	
Minority[1]					0.32
Yes	32	33.7	41	40.6	
No	63	66.3	60	59.4	
Race/Ethnicity					0.60
African American	17	17.9	21	20.8	
Hispanic	15	15.8	20	19.8	
Neither Hispanic or African-American	63	66.3	60	59.4	
Income					0.40
< $15000	9	10.5	12	13.6	
$15000-$24999	16	18.6	11	12.5	
$25000-$49999	30	34.9	41	46.6	
$50000-$75000	17	19.8	12	13.6	
> $75000	14	16.3	12	13.6	
Education					0.48
High school graduate or less	25	26.3	26	25.7	
Some college/vocation school	36	37.9	46	45.5	
College graduate or higher	34	35.8	29	28.7	
HbA1c (%), mean ± SD	9.2	1.6	9.4	1.7	0.48
SBP (mm/Hg), mean ± SD	132.9	21.7	131.9	14.1	0.73
DBP (mm/Hg), mean ± SD	75.8	13.6	79.4	9.8	0.05
BMI (kg/m^2), mean ± SD	33.9	7.7	33.5	8.0	0.70

[1]African American or Hispanic. CDSMP: Chronic Disease Self-Management Program; HbA1c: Hemoglobin A1c; SBP: Systolic blood pressure; DBP: Diastolic blood pressure; BMI: Body mass index.

Table 2 Baseline diabetes self-care activities monitoring, health-related quality of life, pain and fatigue measures

Measure	Controls	CDSMP	*P*
Diabetes self-care activity monitoring (d/wk)			
30 min of any physical activity?	3.01	3.50	0.17
Daily exercise session?	2.23	2.53	0.40
Test your blood sugar?	4.22	4.38	0.70
Test sugar times provider recommends?	3.58	3.29	0.50
Check your feet?	5.20	4.41	0.04
Wash your feet?	6.58	6.36	0.29
Soak your feet?	1.73	1.21	0.14
Dry between your toes?	5.21	5.37	0.68
Inspect inside of shoes?	3.25	2.43	0.06
Follow a healthful eating plan?	3.80	3.92	0.71
Space carbohydrates evenly?	3.25	3.12	0.74
Eat ⩾ 5 fruit/vegetable servings?	3.80	3.44	0.30
Eat high-fat products (red meat, full-fat diary)?	3.63	3.63	0.98
Eat packaged or bakery goods?	2.05	2.16	0.71
Health related quality of life (d/mo)			
Physical health not good	3.98	5.96	0.07
Mental health not good	4.09	4.72	0.56
Physical/mental health hindered usual activities	1.82	3.65	0.05
Pain and fatigue measures (scale 1-10)			
Average daily pain in the past 2 wk	3.74	3.74	1.00
Average daily fatigue in the past 2 wk	4.41	4.54	0.72

CDSMP: Chronic Disease Self-Management Program.

Table 3 Results from the linear mixed models

	Controls (n = 95) Mean ± SE[1]	CDSMP (n = 101) Mean ± SE[1]	Difference between the two groups Mean ± SE[1]
Baseline	9.018 ± 0.153	9.175 ± 0.149	0.157 ± 0.213
12 mo	8.442 ± 0.160	8.615 ± 0.156	0.173 ± 0.218
12 mo-Baseline	-0.576 ± 0.093[a]	-0.559 ± 0.091[a]	0.016 ± 0.112

[1]Adjusted means from linear mixed models. [a]P < 0.0001 for test *vs* H$_0$: mean equals to 0.

ing 5 or more servings of fruits and vegetables compared to an increase of 0.01 d/mo reported by those in the CDSMP arm (P = 0.02).

DISCUSSION

In this study, we sought to assess the effectiveness of the CDSMP on HbA1c and selected self-reported measures among patients with type 2 diabetes who were out of control. We found no significant differences between the CDSMP intervention and usual care in this integrated healthcare system. To the best of our knowledge, this is the first study to evaluate the effectiveness of the CDSMP in a randomized controlled trial in the United

States. It is also one of the first studies to evaluate and compare these interventions in a racially/ethnically diverse population in a practice setting outside of testing done by the original program developers. It therefore provides important exploratory data, shaping our knowledge and understanding of factors which may be important to minority and ethnic populations in adopting diabetes self-management techniques.

Our results corroborate the findings of others that participation in the CDSMP may be associated with better glycemic control[28]. However, a comparison with the control group indicates that usual care might do equally well. Therefore, our study findings need to be tempered due to the possibility of methodological confounds such as unaccounted group demographic and health differences at baseline, relatively small sample sizes, and better awareness among those in a clinical trial or high quality routine diabetes care that emphasizes the importance of glycemic control. For example, participants in this study were, on average, younger than those studied in other recent CDSMP studies[23,29]. Additionally, the controls in this study appeared slightly healthier and better educated than their counterparts in the CDSMP intervention which might have made them more receptive to both clinical and community-based diabetes self-management and obesity prevention messages. It should be noted that Scott and White Health System employs diabetes educators for their patients with diabetes. Scott and White also employs dedicated endocrinologists and their usual care for diabetes exceeds the recommendations set by the Texas Diabetes Association.

Other study limitations need to be noted. First, our subjects were selected from a randomized controlled trial with three interventions, restricting the numbers available in any one group. Second, post-hoc analysis showed that we were somewhat under-powered: we only had 60% power to detect a difference of 0.5% HbA1c reduction between the two groups at the current sample size. Other future analyses should focus on randomizing a larger number of participants in the treatment arm being investigated. Third, there were notable differences between the intervention and control groups, with the control group appearing to be healthier at baseline. Fourth, there was attrition in terms of treatment completion for the intervention group (75.6% attended 4 of 6 sessions required for successful completion) as well as differential research attrition between the two groups (14.9% or 15% participants in the treatment group and 23.2% or 22% participants in the control group did not have 12 mo data). Finally, this study was conducted in only one integrated health care system, limiting generalizability to other settings and populations.

There is also a debate in the self-management field regarding whether generic *vs* disease-specific self-management is more beneficial[24,32]. While our view was that a generic program would be valuable for patients experiencing several comorbidities including diabetes, more positive results might have been observed if the diabetes specific CDSMP was utilized (which was not evidence-based at the time of initial program selection for English speaking patients)[33].

In conclusion, we found in this study that although a behavioral intervention such as the CDSMP can result in some modest improvements in glycemic control, the same improvements may be found among participants that receive usual care. The reduction in HbA1c levels found in our control group that received usual care suggests that good routine care in an integrated healthcare system can also lead to better glycemic control. More research is needed to understand the benefits of self-management programs both independently and in conjunction with primary care. For example, are there settings where self-management programs might be especially needed, *e.g.*, in medically underserved areas? What kinds of participants might improve most with self-management programs? Such knowledge is important for providing better tailoring diabetes care to patients.

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COMMENTS

Background

The Stanford Chronic Disease Self-Management Program (CDSMP) represents one of the most studied evidence-based behavioral or self-care programs for chronic diseases including diabetes.

Research frontiers

The CDSMP has been found to be highly effective in improving the general health of people with several chronic conditions such as heart disease and arthritis. Recent evidence indicates that the CDSMP is a useful and appropriate program for lowering glycated hemoglobin A1c (HbA1c) among people with type 2 diabetes who are out of control.

Innovations and breakthroughs

This study demonstrated that the CDSMP may not lower HbA1c among people with type 2 diabetes any better than good routine care in an integrated healthcare system.

Applications

Findings from this study show that people with type 2 diabetes managed with good routine care in an integrated healthcare system can also have good glycemic control. Nonetheless more research is needed to understand the benefits of self-care programs in primary care.

Peer review

The study by Forjuoh *et al* aimed to assess the effectiveness of the CDSMP on the metabolic control. This is an interesting investigation from a practical point of view.

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