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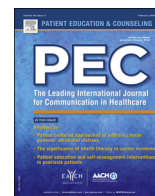


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Effect of case management on glycemic control and behavioral outcomes for chinese people with type 2 diabetes: A 2-year study

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ABSTRACT

Objective: To examine the effect of case management on glycemic control and behavioral outcomes in adults with Type 2 diabetes in China.**Methods:** Participants were randomly assigned to a 1-year case management (CM) group (n=60) or control group (n=60). Monthly case management visits included identifying individuals' diabetes-related problems, setting goals, planning self-care, and evaluating progress. During a 1-year follow-up, all participants attended visits every 3 months without intervention.**Results:** In the CM vs. the control group, HbA1c was reduced at 6 months compared to baseline ($P=0.034$), with trends at 12 and 24 months, and empowerment ability improved ($P<0.05$). Also in the CM vs. controls, total self-care behaviors, the frequency of exercise, blood glucose testing, and foot care were higher ($P<0.001$) at 12 months, and the percentage of individuals with HbA1c $\leq 7.0\%$ was higher ($P=0.035$) at 24 months.**Conclusion:** The case management intervention in China was effective at 6 months and, based on trends in HbA1c at 12 and 24 months and results for behavioral outcomes, the intervention shows promise and warrants more research.**Practice implications:** A case management approach can enhance behavior change and glycemic control in Chinese with diabetes.

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1. Introduction

Diabetes mellitus is reaching epidemic proportions globally; 1.3 million deaths resulted from diabetes in 2010 [1]. The global prevalence of diabetes in adults is 8.3% (382 million people) [2]. In China, the most populous country, the prevalence of diabetes is high at 11.6% (affecting 113.9 million people) [3] compared to the United States at 9.9% [4] and Europe at 8.1% [5]. Less than one-third (30.1%) of Chinese diabetic patients are aware of their condition [3]. Also in China, prediabetes is extremely high at 50.1% (affecting

493.4 million people) [3], compared to the United States at 35.3% [6] and Europe at 9.6% [5].

Recent changes in China, including economic prosperity, environmental issues, and changes in life style such as poor diet with more fat and sugar have been documented in the Chinese literature as barriers to maintaining diabetics' self-care regimens [7]. Once diagnosed, adults with diabetes in China see a physician monthly. To meet this demand, doctors throughout China see 50–100 patients per day. Patients undergo a 3–10 min outpatient visit and get their medications and diabetic supplies at the clinic. About 5–10% of diabetic adult outpatients at our hospital are referred to a certified diabetes educator because they are newly diagnosed or unable to manage basic care.

Diabetes is a major risk factor for ischemic heart disease and stroke, the most common cause of chronic kidney disease, and a leading cause of blindness [6,8,9]. Improvement in glycemic control is key in preventing such complications [6]. In China among

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patients with diabetes, one-quarter receive medical treatment for diabetes and slightly more than one-third of patients treated for diabetes have adequate glycemic control [3]. Effective glycemic control cannot be assured through medications alone. Health promotion is essential, yet behavior change is not automatic [10].

Quality care managers and nurses in China identified health care-related factors (such as lack of team management and ongoing support), and patient-related factors (such as lack of adherence by patients to regular follow-up care and to self-care) that lead to poor glycemic control [11]. Clearly, adults with diabetes in China need a long-term self-care plan [12]. One strategy that can be used by diabetes educators is an individually-focused case management approach in outpatient settings to increase the intensity of diabetic education and psychosocial support.

The purpose of this study is to examine the effect of case management on the primary outcome of HbA1c and secondary outcomes of self-care behavior (diet, exercise, blood glucose monitoring, foot care, and medication taking) and empowerment ability in adults with Type 2 diabetes in China. Empowerment ability refers to being able to handle psychosocial adjustments related to problems caused by diabetes [13].

2. Methods

2.1. Design and participants

This study was a two-arm, parallel, randomized control trial examining the effect of case management. Participants with Type 2 diabetes were randomized to the case management (CM) group or the control group based on random numbers generated through Proc Plan (SAS9.2) and block randomization procedures with a block size of 4. This process was accomplished by a statistician with no clinical involvement in the trial, and the process was concealed from the researchers. Group assignment for each participant was pulled from a sequentially numbered, opaque, sealed and stapled envelope. Blinding was not possible. One certified diabetes educator executed the protocol for the CM group; another was responsible for the protocol in the control group. The primary outcome was HbA1c and the secondary outcomes were behavioral (self-care and empowerment ability).

Participants in both groups got an equal number of study visits, to control for attention. Specifically, during the first 12 months, all

the patients spent 15–30 min at a monthly visit, only the content (presence of the intervention) was different between the groups. In the second year, all the patients spent 15–30 min at visits every 3 months and both the content (without intervention) and the time were the same for the patients in the two groups.

Study recruitment in the area surrounding one hospital in Eastern China occurred through flyers at community health centers, recruitment posters, and announcements at diabetic lectures. The study protocol was approved by the hospital Institutional Review Board, and the process was in accordance with the revised Declaration of Helsinki. Participants provided written informed consent.

Two hundred volunteers were screened to determine eligibility. Adults with a diagnosis of Type 2 diabetes [7,14] for ≥ 3 months, aged 19–80 years and with ability to care for themselves were included. Exclusion criteria were pregnancy or concurrent diseases (including myocardial infarction, malignancy, serious neurological or psychiatric disorders, severe infections, or organ failure). Participants were enrolled in the study from April 2012 to February 2013. For safety purposes, each participant received basic diabetes education when they were enrolled. Furthermore, all patients received usual medical care.

2.1.1. The case management intervention occurs in the first 12 months

The patient-centered CM intervention was a systematic, evidence-based protocol focused on diabetes-related health behavior change [15]. It was individually tailored, initially according to the participant's pre-existing lifestyle habits and preferences, and later according to answers to a standard set of questions at monthly visits. Teaching the participant how to use blood glucose testing data to adjust diet, exercise, and medication taking to achieve goals was implemented according to Chinese clinical guidelines [7].

The process of behavior change used for the CM group is presented in Fig. 1. The diabetes educator assessed the participant's health care needs. Next, she discussed initial behavior change plans, focusing on the most important barriers to disease control. She gave sufficient information, suggested strategies for change, and answered questions to help participants (a) make decisions related to self-care or managing diabetes-related problems and (b) apply strategies to self-care at home. An individualized action plan was created by the diabetes educator and the participant. Goals

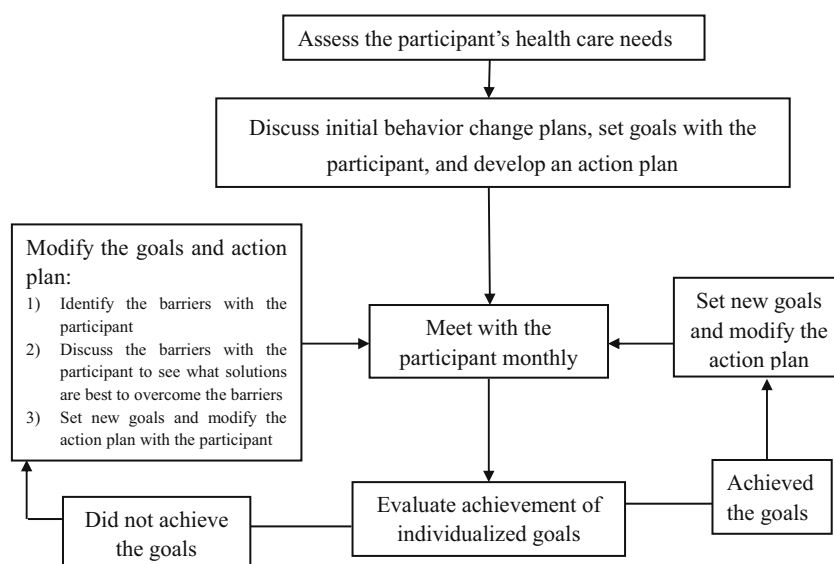


Fig. 1. Process of behavior change used for participants in the case management group in the first 12 months.

were set for dietary changes, physical exercise, and self-monitoring.

The diabetes educator and the participant met face-to-face monthly to assess difficulties toward achieving lifestyle modification goals and to detect emerging problems in implementing the care plan. Participants' diabetes self-care regimens were evaluated with a standard set of questions: (1) How often did you go to the hospital to see the doctor? (2) What kind of medication do you use now? (3) Have you checked your blood glucose, BP, weight, HbA1c, and lipid levels? What were the results? (4) How often did you exercise? (5) Have you suffered from hypoglycemia this month? How did you deal with it? If the participant met the individualized goals, the diabetes educator and participant set new goals and modified the action plan. If participants did not, the educator helped the patient identify barriers and find solutions.

The diabetes educator updated the participant's progress monthly in the research record during the 12-month intervention. If necessary, participants were referred short-term to a doctor, a nutritionist, or psychologist who provided feedback to the diabetes educator through a case report form. This referral was recorded in the medical record.

2.1.2. The control condition in the first 12 months

In the control group, the diabetes educator met with the participants monthly to go through the same standard set of questions that was used with the CM group. The control group received no CM intervention. If a participant asked questions about how to deal with diabetes, she did not give this information and asked the participant to talk with his/her doctor about these questions.

2.1.3. The follow-up from 12 to 24 months

In the second year, neither group received an intervention. All participants visited with the same designated diabetes educator every three months. Both groups were asked the same questions as in the first 12 months, except that the time frame in the second year was every 3 months.

2.2. Outcome measures

The primary outcome measure, HbA1c, was measured by high-performance liquid chromatography. Self-care behavior was measured using the Chinese version of the Summary of Diabetes Self-care Activities (SDSCA) Scale [16], which is from a revised version by Toobert et al. [17]. The 11-item scale, used to measure the frequency of performing diabetes self-care behaviors in the last 7 days, has five dimensions: diet, exercise, blood glucose testing, foot care, and medication taking. The Cronbach's α is 0.62, and the test-retest reliability is 0.83 [16]. In the current study, the Cronbach's α is 0.79. Empowerment ability was measured using the Chinese version of the Diabetes Empowerment Scale-Short Form (DES-SF) [18]. The 8-item scale uses a Likert scale (not agree-always agree). The Cronbach's α is 0.85, and the test-retest reliability is 0.82 [19]. In the current study, the Cronbach's α is 0.82.

2.3. Data collection

Data were collected by the diabetes educators, one assigned to the CM and one assigned to the control group. In the first year, data on demographics and clinical variables from the medical record about treatment, medication use, and co-morbidities were obtained at baseline. In all participants, HbA1c was measured at baseline, 6, 12, and 24 months and self-care and empowerment ability were measured at baseline and 12 months.

2.4. Data analysis

The sample size calculation considered a HbA1c reduction of 0.89% [20] in the CM group vs. the control group with a standard deviation for HbA1c of 1.6 and a statistical power of 80% ($\alpha = 0.05$). To this end, the study required 52 participants per group. A sample size of 60 participants per group (120 total) was needed in anticipation of a 15% dropout rate.

For demographic variables, categorical data were analyzed using frequencies and percentages as well as chi-square tests;

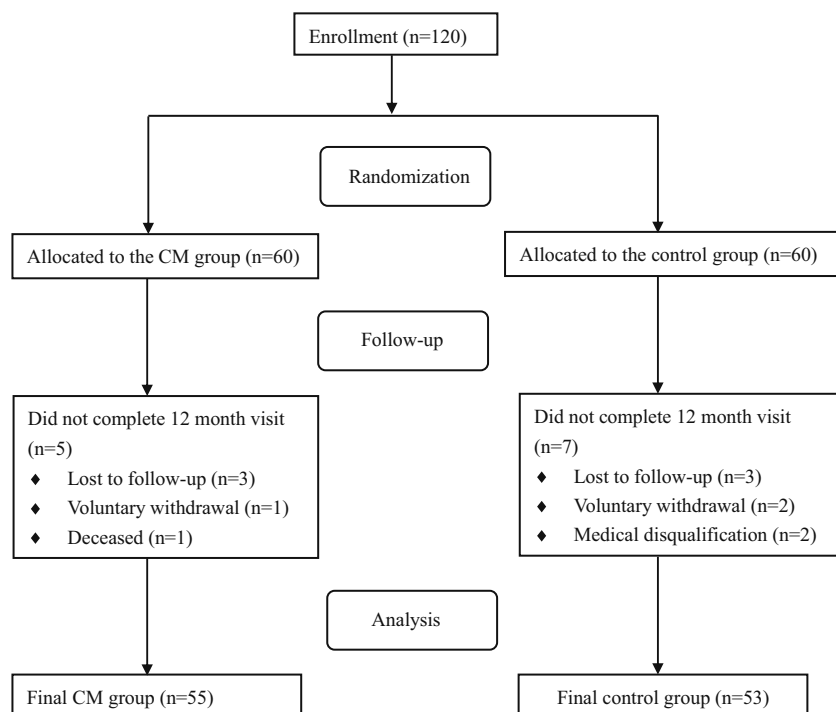


Fig. 2. CONSORT flow diagram.

continuous data were reported as means (\pm standard deviation) and compared using the independent sample *t*-test. For the primary outcome, HbA1c, a mixed model was used after adjusting for baseline HbA1c, treatment group, time, and the interaction of group \times time; 95% confidence intervals of the differences are provided.

For secondary outcomes, a paired *t*-test was used for within-group comparisons; between-group differences in the treatment effect were analyzed using an ANOVA test together with 95% confidence intervals. A chi-square test was used to analyze the HbA1c (good \leq 7.0% vs. poor $>$ 7.0%) between the groups at the end of the follow-up period at 24 months [7]. All analysis was performed by SPSS version 16.0 software. A two-sided *P*-value of 0.05 was considered statistically significant.

3. Results

3.1. Baseline characteristics and drop out

A total of 120 participants were enrolled in the study and were randomly assigned to the intervention group ($n=60$) or the control group ($n=60$). By the end of the study, 5 participants withdrew from the CM group and 7 participants from the control group (Fig. 2). The demographic characteristics and clinical variables are presented in Table 1. For the overall sample, the mean age was 58.7 years, on average they had a normal BMI, lipid profile and blood pressure, and a mean duration of diabetes of 7.5 years. About 96% of participants in both groups had health insurance. No difference was apparent in education level between groups. The two groups did not differ significantly at baseline (Table 1).

3.2. Changes in glycemetic control

HbA1c at different time points is presented in Fig. 3. At baseline, there was no difference between the groups (7.75 ± 1.52 vs. 7.44 ± 1.66 , $P=0.312$). Overall, we did not find a statistically significant difference between the two groups through 24 months ($P=0.6705$) or an interaction of group \times time ($P=0.1609$), however, a significant time effect was observed ($P=0.0007$).

Table 2 details the changes in HbA1c from 6 to 24 months. Results shows that HbA1c was significantly ($P=0.034$) reduced in the CM group compared to the control group at 6 months compared to baseline with a least mean of -0.43 (95% CI: $-0.83, -0.03$). This pattern persisted at 12 months and 24 months but did not achieve statistical significance (-0.32 (95% CI: $-0.70, 0.06$), $P=0.094$; -0.32 (95% CI: $-0.79, 0.14$), $P=0.167$, respectively).

Using good and poor categories for HbA1c, the percentage of participants whose HbA1c was good at $\leq 7.0\%$ was higher over time in the CM group (45.5% at baseline, 54.5% at 6 months, 60.0% at 12 months, and 61.8% at 24 months). At the 24-month time point, the percentage of the participants whose HbA1c was $\leq 7.0\%$ was higher in the CM group than in the control group (61.8% vs. 41.5%, $P=0.035$).

3.3. Changes in self-care behavior and empowerment ability

Behavioral outcomes did not differ significantly between groups at baseline. Self-care behavior (total, exercise, blood glucose testing, and foot care) was improved ($P<0.001$) in the CM group vs. the control group at 12 months compared to baseline (Table 3). Within the CM group, self-care behavior total score as well as diet, exercise, foot care, and medication taking subscales were improved ($P<0.05$) between baseline and 12 months. Within the control group, blood glucose testing and foot care subscales were improved ($P<0.05$) between baseline and 12 months.

Empowerment ability was improved ($P<0.05$) in the CM group vs. the control group for the total score and the items about turning diabetes goals into a workable plan, and trying different ways to overcome barriers to attain diabetes goals at 12 months compared to baseline. Within the CM group, empowerment ability was enhanced ($P<0.01$) for the total score and the items about dissatisfaction with parts of diabetes care, positive ways to cope, asking for support, and diabetes care choices between baseline and 12 months. Within the control group, participants' empowerment ability was enhanced ($P<0.05$) for the total score and for items about dissatisfaction with parts of diabetes care and staying motivated to care for the diabetes between baseline and 12 months (Table 4).

Table 1
Demographic characteristics and clinical variables at baseline.

| Variable | CM group (n=55) | Control group (n=53) | <i>P</i> |
|---------------------------------------|--------------------|----------------------|----------|
| Gender, n (%) | | | 0.335 |
| Male | 23 (41.8) | 28 (52.8) | |
| Female | 32 (58.2) | 25 (47.2) | |
| Diagnosis of hypertension, n (%) | | | 1.000 |
| Yes | 23 (41.8) | 22 (41.5) | |
| No | 32 (58.2) | 31 (58.5) | |
| Diagnosis of hyperlipidemia, n (%) | | | 0.409 |
| Yes | 15 (27.3) | 19 (35.9) | |
| No | 40 (72.7) | 34 (64.1) | |
| Diabetes medication modalities, n (%) | | | 0.848 |
| Oral agents | 23 (41.8) | 21 (39.6) | |
| Insulin | 9 (16.4) | 5 (9.4) | |
| Oral and insulin | 19 (34.5) | 25 (47.2) | |
| None | 4 (7.3) | 2 (3.8) | |
| Age | 58.35 \pm 12.34 | 59.04 \pm 10.67 | 0.756 |
| Duration of diabetes (years) | 7.08 \pm 6.95 | 7.94 \pm 5.69 | 0.482 |
| BMI (kg/m ²) | 24.49 \pm 3.49 | 24.55 \pm 3.24 | 0.925 |
| TG (mmol/l) | 1.55 \pm 1.17 | 1.71 \pm 1.70 | 0.583 |
| HDL (mmol/l) | 1.27 \pm 0.31 | 1.29 \pm 0.47 | 0.776 |
| LDL (mmol/l) | 2.91 \pm 0.93 | 2.87 \pm 0.91 | 0.841 |
| SBP (mmHg) | 134.53 \pm 17.33 | 130.25 \pm 19.66 | 0.237 |
| DBP (mmHg) | 81.16 \pm 8.43 | 79.10 \pm 10.52 | 0.265 |

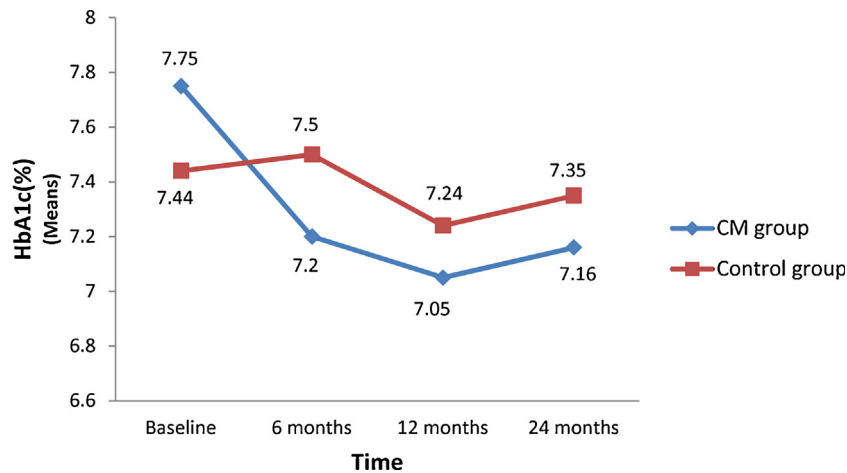


Fig. 3. Mean HbA1c for the intervention (CM) and control groups at each study time period. No statistical significance between the two groups through 24 months ($P=0.605$) and interaction of group \times time ($P=0.1609$). Significant time effect between two groups ($P=0.0007$).

Table 2

Comparison of reduction of HbA1c from baseline between the groups.

| Variable | CM group (n = 55) Mean \pm SD | Control group (n = 53) Mean \pm SD | Group Difference (95% CI) ^a | P |
|--------------|------------------------------------|---|--|-------|
| 6 months, % | -0.55 \pm 1.34 | 0.06 \pm 1.44 | -0.43 (-0.83, -0.03) | 0.034 |
| 12 months, % | -0.71 \pm 1.23 | -0.20 \pm 1.40 | -0.32 (-0.70, 0.06) | 0.094 |
| 24 months, % | -0.59 \pm 1.70 | -0.08 \pm 1.44 | -0.32 (-0.79, 0.14) | 0.167 |

^a Adjusted baseline HbA1c, group, time, group \times time.

Table 3

Self-care behavior between the groups.

| Item | CM group (n = 55) Mean \pm SD | | Control group (n = 53) Mean \pm SD | | Group difference (95% CI) | P |
|-----------------------|---------------------------------|-------------------------------|--------------------------------------|------------------------------|---------------------------|--------|
| | Baseline | 12 m | Baseline | 12 m | | |
| Total score | 48.89 \pm 16.55 | 58.58 \pm 8.62 ^b | 44.69 \pm 14.68 | 45.98 \pm 18.22 | 8.40 (4.28, 12.52) | <0.001 |
| Diet | 18.87 \pm 7.16 | 22.72 \pm 4.56 ^b | 19.14 \pm 7.34 | 19.36 \pm 8.45 | 1.54 (-0.38, 3.46) | 0.114 |
| Exercise | 10.31 \pm 4.72 | 12.45 \pm 2.26 ^b | 8.42 \pm 4.92 | 9.30 \pm 4.74 | 2.52 (1.35, 3.70) | <0.001 |
| Blood glucose testing | 4.07 \pm 4.04 | 3.57 \pm 2.92 | 2.26 \pm 2.15 | 1.20 \pm 1.11 ^b | 2.09 (1.22, 2.96) | <0.001 |
| Foot care | 9.00 \pm 5.61 | 13.17 \pm 2.68 ^b | 7.72 \pm 6.05 | 9.28 \pm 5.03 ^a | 2.58 (1.21, 3.96) | <0.001 |
| Medication taking | 5.87 \pm 2.53 | 6.68 \pm 1.24 ^a | 6.26 \pm 1.93 | 5.92 \pm 2.45 | 0.18 (-0.39, 0.76) | 0.528 |

^a Within-group comparison, $P < 0.05$.

^b Within-group comparison, $P < 0.01$.

4. Discussion and conclusion

4.1. Discussion

Study results support the effectiveness of a case management intervention in reducing HbA1c in one hospital outpatient setting in China. Although recent (2006 and 2010) *meta*-analyses in the literature support case management [20,21], this approach in the care of adult diabetics is introduced in a review in 2013 in China [22]. Although several reports were published about case management in China in the nearly two years, these studies were different from ours: the duration of the intervention was shorter and the outcome measures were different, and behavior change was not the focus [23,24]. Therefore, the current study extends the literature on case management in China by taking a longer-term, more comprehensive approach to providing information and skills, and helping adults enhance their own innate ability to attain their diabetes goals.

Diabetes educators in China were used to using a “teach to” and “I know the right thing for you” approach which were found to be generally ineffective [11]. The case management approach

developed for the current study was adapted to Chinese contexts. We set goals with the patients (not for the patients), referred to the Chinese guidelines when setting up the education portion and metabolic control targets for patients, and aligned the intervention with habits (diet, exercise) of Chinese people.

Interventions implemented at our setting are feasible largely because the diabetes education clinics are well established in our hospital and the clinics are a frequent site for a variety of research studies. When tested at the onset of the study, we found this study's protocol to be feasible. It is likely that the individualized approach used in this study was easier for participants to accept. Using blood glucose testing data to adjust diet, exercise, and medication taking was important and well-received by participants.

In the current study, the reduction of HbA1c in the CM group compared with the control group was significant at 6 months, with trends observed at 12 months and 24 months. These results agree with studies in other countries that found an improvement in HbA1c after case management interventions [20,21,25]. The reduction of HbA1c after case management over a 24-month period in the current study is similar to recent findings of Hsu et al.

Table 4
Empowerment ability between the groups.

| Item | CM group (n = 55) Mean ± SD | | Control group (n = 53) Mean ± SD | | Difference (95% CI) | P |
|--|-----------------------------|--------------------------|----------------------------------|--------------------------|---------------------|-------|
| | Baseline | 12 months | Baseline | 12 months | | |
| | Total score | 34.72 ± 4.10 | 36.85 ± 2.94 ^b | 33.96 ± 4.18 | | |
| Know what part(s) of taking care of my diabetes that I am dissatisfied with | 4.26 ± 0.73 | 4.72 ± 0.50 ^b | 4.12 ± 0.88 | 4.49 ± 0.55 ^b | 0.18 (-0.005, 0.37) | 0.057 |
| Be able to turn my diabetes goals into a workable plan | 4.33 ± 0.78 | 4.42 ± 0.69 | 4.04 ± 0.82 | 4.10 ± 0.65 | 0.30 (0.10, 0.51) | 0.004 |
| Can try out different ways of overcoming barriers to my diabetes goals | 4.31 ± 0.72 | 4.45 ± 0.72 | 4.10 ± 0.77 | 4.18 ± 0.60 | 0.24 (0.05, 0.44) | 0.016 |
| Can find ways to feel better about having diabetes | 4.33 ± 0.85 | 4.57 ± 0.50 | 4.33 ± 0.80 | 4.31 ± 0.68 | 0.13 (-0.07, 0.33) | 0.187 |
| Know the positive ways I cope with diabetes-related stress | 4.02 ± 0.91 | 4.42 ± 0.57 ^b | 4.16 ± 0.75 | 4.31 ± 0.59 | -0.02 (-0.22, 0.18) | 0.860 |
| Can ask for support for having and caring for my diabetes when I need it | 4.46 ± 0.61 | 4.75 ± 0.43 ^b | 4.43 ± 0.71 | 4.55 ± 0.54 | 0.12 (-0.04, 0.28) | 0.143 |
| Know what helps me stay motivated to care for my diabetes | 4.62 ± 0.53 | 4.79 ± 0.50 | 4.55 ± 0.68 | 4.76 ± 0.43 ^a | 0.05 (-0.09, 0.20) | 0.473 |
| Know enough about myself as a person to make diabetes care choices that are right for me | 4.37 ± 0.73 | 4.75 ± 0.43 ^b | 4.59 ± 0.61 | 4.63 ± 0.49 | -0.05 (-0.21, 0.11) | 0.541 |

^a Within-group comparison, $P < 0.05$.

^b Within-group comparison, $P < 0.01$.

[25], although those authors provided the intervention for a longer time, over a 36-month period.

Recent clinical guidelines support lowering HbA1c to 7% or less to reduce microvascular complications of diabetes [12]. At the 24-month time point, the percentage of the participants whose HbA1c was $\leq 7.0\%$ was significantly higher in the CM group than in the control group, indicating a clinically meaningful finding of more successful glycemic control in the CM group at the end of the study.

The current study demonstrated that case management led to significant improvements in the secondary outcomes. Participants' total self-care behaviors and also diet, exercise, blood glucose testing, and foot care were significantly improved in the CM group vs. the control group at 12 months. These findings agree with Shin et al. [26], and Chang et al. [27] who reported positive self-care behavior changes 1 year after case management.

Given the large numbers of patients seen by the Chinese health care system each day, it is imperative that diabetic adults (a) have the appropriate skill set to manage psychosocial adjustments related to problems caused by diabetes, and (b) have support to help them adjust daily to their diabetes within their lifestyle and environmental situation. Based on the Empowerment measure, participants in CM group reported that they were able to turn diabetes goals into a workable plan and could try out different ways to overcome barriers to attain diabetes goals, compared with the control group. Higher empowerment ability is desirable because, in that case, patients had an enhanced capacity to accept responsibility for their behavior change. Moreover, empowerment ability has been found in the literature to be a significant predictor of self-care behavior and HbA1c [28].

The study has several limitations. First, this study was conducted at one hospital in China and lacked blinding. Second, this study did not analyze health care cost, because of incomplete data. Third, due to time factors, we did not measure participants' self-care behavior and empowerment ability at 24 months. Finally, just the mere action of asking questions could be interpreted as a mild intervention in itself, as it might have raised patients' awareness of topics that were important. This could be a factor which might account for changes observed in the control group. A strength of the current study is the lack of attrition during the follow-up period. Another strength is the study's feasibility. Finally the CM intervention may have been successful because of its intense focusing on the participant, and on the individualization of care.

4.2. Conclusion

The case management intervention in China was effective at 6 months and, based on trends in HbA1c at 12 and 24 months and results in self-care behavior, shows promise and warrants more research. This study provides valuable information to guide diabetes educators in using case management to promote better control of HbA1c and self-behavior change for people with Type 2 diabetes.

4.3. Practice implications

In China currently, doctors do not have enough time to educate people with diabetes. The diabetes educator, using a case management approach, can help overcome this limitation. Due to the high prevalence of Type 2 diabetes and prediabetes in China and the low numbers of certified diabetes educators, there is a great need for future research on what timing and length of program are most effective. Case management may lead to improved quality of care, but quality processes and outcomes must be studied. Attention must be focused on the sustainability of the effects of case management over time. Due to the labor

intensity of a 1-year CM intervention and the need for many patients to be seen by the diabetes educators, perhaps a shorter three-month CM intervention might be considered on a long-term basis in the clinic; its clinical effectiveness would need to be determined.

Conflict of interest

All authors declare no conflicts of interest.

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