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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 ≤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.

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 $\geq$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

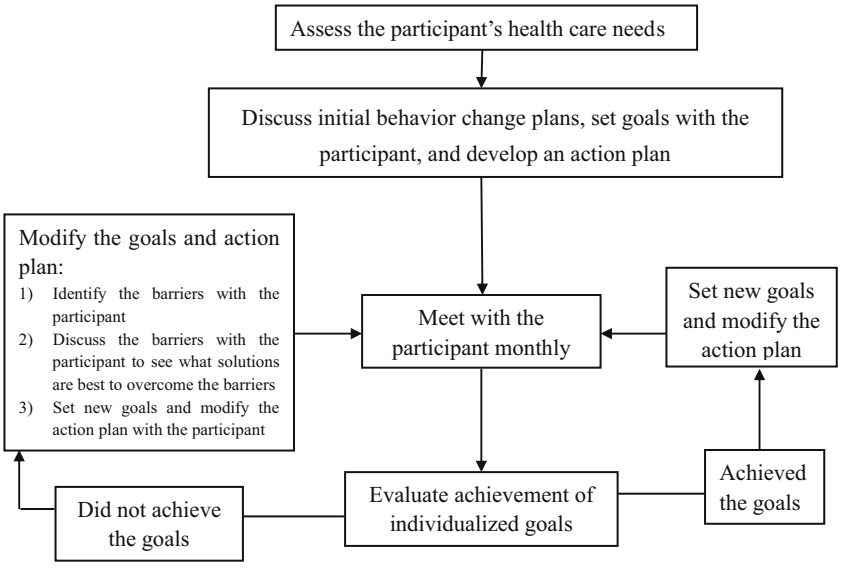

Fig. 1. Process of behavior change used for participants in the case management group in the first 12 months.

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