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Original Article

Strategies for Diabetes Self-Care Intervention and Education in Elderly Patients with Suboptimal Controlled Type 2 Diabetes: A Pilot Study

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The aim of this pilot study is to test the hypothesis that different diabetes self-management strategies can improve glycemic control in elderly patients with diabetes. Patients with suboptimal glycemic control were selected from outpatient clinic and randomly assigned to (1) breakfast meal-replacement; (2) peer-support; and (3) group session only groups. HbA1c reductions of 0.8% and 1.01% were noted from the baseline value to 12 weeks in the meal-replacement and peer-support groups, respectively. In addition, greater body weight reduction was observed in the meal replacement and peer-support groups. This reduction was associated with not only nutritional knowledge improvement but also decreased daily carbohydrate intake. A combination of conventional disease management education and peer-support or breakfast meal-replacement was found to be useful in elderly diabetic patients in terms of their ongoing diabetes self-care. Such combinations are easy to implement and effective for achieving glycemic control.

Keywords: meal replacement, peer support, type 2 diabetes, group education, diabetes self-management education

Introduction

In aging societies diabetes is an important health issue. About 20% of people aged 65 and above have diabetes (1- 2) and this proportion is expected to increase rapidly in the coming decades. Diabetes is a chronic disease that requires a multitude of daily self-management decisions and complex care activities. Among patients with chronic disease, there is growing interest in "self-management" programs (3). Diabetes self-management education (DSME), a complex health intervention, is generally effective for enhancing self-care behaviors, improving glycemic control, lowering health care costs, and improving quality of life (4-6).

Older adults with diabetes are at greater risk than those without diabetes for several common geriatric syndromes, such as polypharmacy, cognitive impairment, sarcopenia, injurious falls, and

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persistent pain (7-9). These conditions may impact older adults' diabetes-related self-care tasks (10) and their ability to maintain the timing and content of meals. Some elderly diabetic patients find it difficult to understand conventional dietary and nutritional education based on food exchange lists (11). Even if they do understand such a system, they may have difficulty changing their daily eating habits (12). Thus, clinicians and diabetes educators need to simplify diabetes management strategies for elderly patients.

From previous studies on diabetes education interventions, patients have difficulty maintaining intervention responses over an extended period (13-14). One possible reason is that patients who struggle with self-management and glycemic control need more structured strategies to help them develop and maintain lifestyles and behaviors over the long term (15).

A rational approach may be the reinforcement of diabetes education or development of simple skills to maintain self-care behaviors at different points throughout the course of their diabetes. However, few well-designed randomized controlled trials have examined the value of reinforcing diabetes self-care or the best method of reinforcement.

One method is telephone-based peer support using protocols with predefined processes, treatment targets, and regular feedback (16-17). Peer support has the potential to address barriers to successful diabetes self-management, as well as to emphasize sustained behavioral change (18-19). Moreover, studies have demonstrated that meal replacement is an alternative dietary approach for improving blood glucose control (20- 21). Re-organizing nutritional strategies to provide a simple meal plan can facilitate high compliance with dietary regimens on a lifelong basis (22). Thus, meal replacement is easier to understand, teach, and implement than other approaches.

To test the hypothesis that different models for reinforcing diabetes self-management can improve glycemic control in elderly patients with diabetes, we carried out a pilot study with change in glycated hemoglobin (HbA1c) as the primary outcome.

Methods

The eligibility criteria were diagnosis of type 2 diabetes according to 2016 ADA criteria, age ≥ 60 years, body mass index (BMI) ≥ 24 kg/m2, and HbA1c ≥ 8.0 %. Exclusion criteria were dementia, cancer, or other severe disease that might interfere with participation. This study was conducted between January and December 2016 in the Department of Endocrinology and Metabolism of Chung Shan Medical University Hospital in Taiwan. The Institutional Review Board of this hospital approved this study, which was conducted according to Declaration of Helsinki guidelines (IRB-CS13227). Informed consent was obtained from all participants in this study.

All participants received a structured DSME program. This program was delivered in a four-hour session, in a group format, with each group consisting of 5-10 patients, facilitated by a certified diabetes nurse educator. The themes delivered were: 1. Understanding the factors involved in managing diabetes and its complications; 2. Understanding healthy eating and being active; 3. Living with diabetes; and 4. Self-monitoring of blood glucose.

After the structured DSME program, participants were randomly assigned to one of three groups: 1) meal-replacement; 2) peer-support, and 3) group session only (Figure 1). Randomization was based on a single sequence of random assignments. A random number table was compiled from computer-generated random numbers.

Subjects in the meal-replacement group were instructed to consume a 300 kcal/day breakfast with diabetes-specific nutritional formula and choice of one serving of bread, cereal, or rice for 6 weeks. The diabetes-specific nutritional formula (Glucerna®, Abbott Nutrition) was a low-glycemic index liquid meal of 250 ml, containing 214 calories, 47.3% carbohydrates, 20% protein, and 32.7% fat. It was provided every week to ensure adherence. The peer-support group received a two-hour training course in peer communication skills following the group session. Training was conducted by diabetes nurse educator and focused on empathic listening, positive thinking, appropriate questioning, clarification of values and life goals, problem solving, and assertiveness. Peer support one-on-one meetings were held to

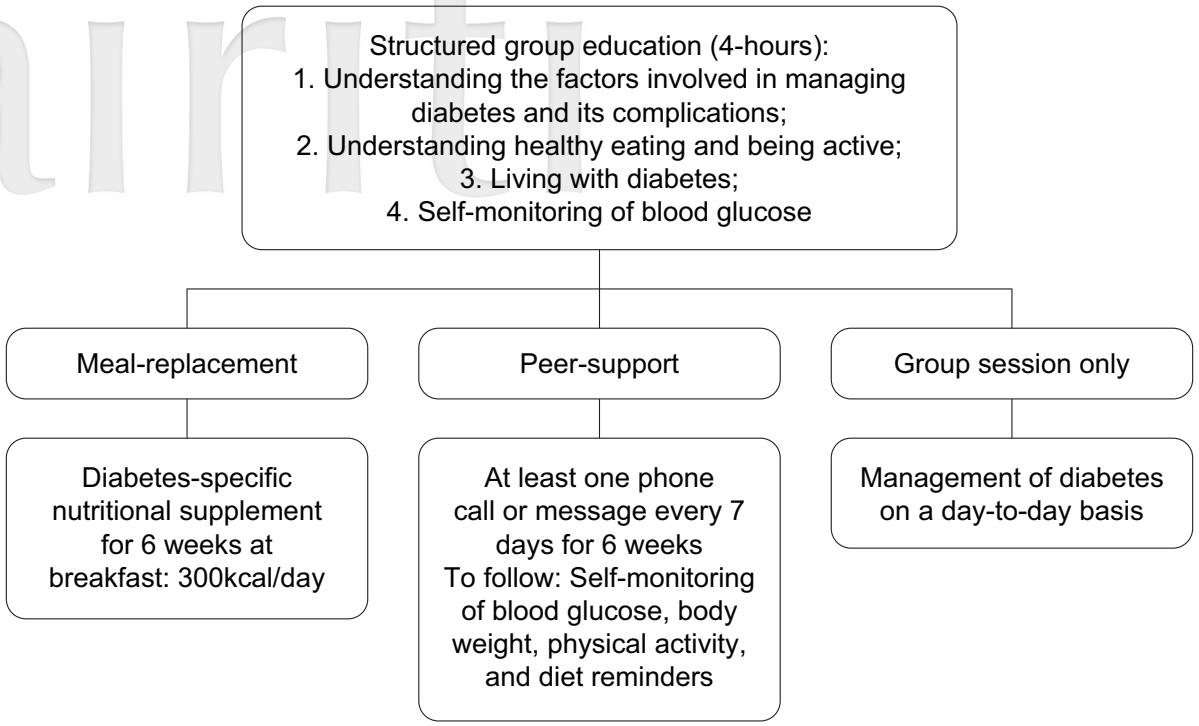

Figure. 1 Study design

listen to and discuss concerns. In addition, weekly support was provided via telephone call or message. Participants in this group were asked to record every phone call or message sent in a logbook, which was reviewed by a diabetes educator every week to ensure compliance. For group session only group, no further instruction was given following the initial 4-hour group session. During the study period, no adjustments to prescribed medications were made, unless urgent (hyperglycemia, fasting blood glucose > 300 mg/dl or hypoglycemia glucose < 70 mg/dl).

The primary endpoint was HbA1c change from baseline to 12 weeks. Changes in body weight, blood pressure, fasting plasma glucose, lipid levels, nutritional knowledge, nutritional behavior, and diet were surveyed as secondary endpoints.

Nutritional knowledge test was comprised of 10 questions, with a total score of 10 points. The higher the score, the higher the nutritional knowledge.

There were 16 questions on the eating behavior test, with a total score of 80 points. The higher the score, the better the eating behavior.

Demographic data, medical history, laboratory data, and food records were collected at baseline and subsequent visits. Dietary intake was evaluated using the patient's three-day food records at baseline and 12 weeks.

Statistical analysis

Continuous variables are presented as mean ± standard deviation (SD) for the descriptive characteristics of the patients in each group. Categorical variables are presented as percentages. The differences between baseline and 12-week measurements determined the changes within each educational setting for most of the study variables, with paired Student's t-tests and one-way ANOVA used to examine the data among the three groups. $\chi 2$ tests were applied to comparisons of categorical variables between treatment arms and at 12-weeks and two sample t-tests were applied to comparisons of continuous variables.

Results

The 60 participants, 20 in each group, who completed the 12-week trial were included in the

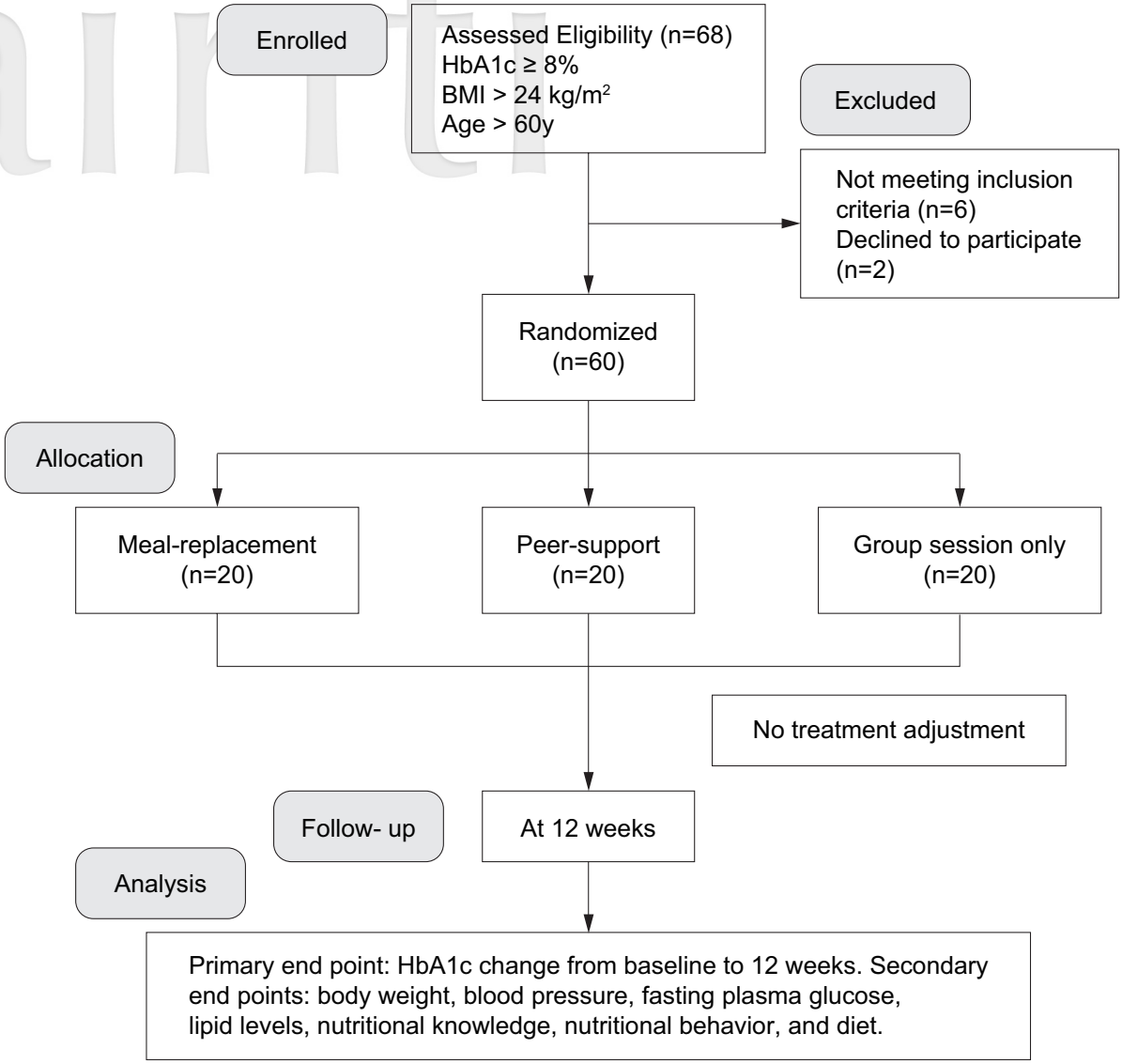

Figure. 2 Study flow chart for intervention

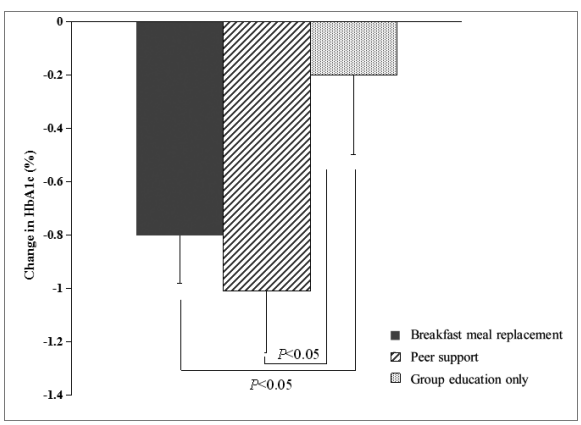

Figure. 3A Changes in HbA1c in the three groups from baseline to 12 weeks

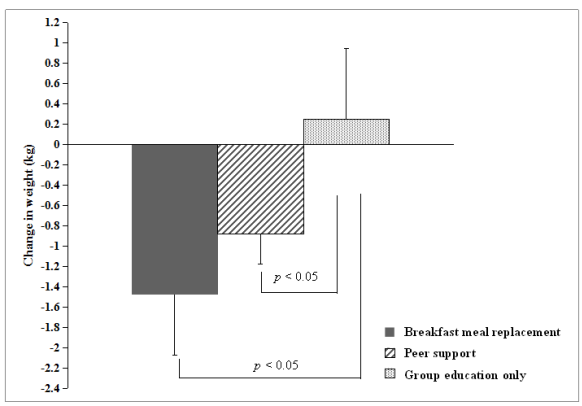

Figure. 3B Changes in body weight in the three groups from baseline to 12 weeks

Table 1. Baseline Characteristics of Study Participants

	Meal-replacement (n = 20)	Peer-support (n = 20)	Group session only (n = 20)	*p*
Age, years	65.8±1.3	66.4±1.5	65.2±1.4	0.246
Gender (Men)	8 (40)	9 (45)	10 (50)	0.825
Educational level				0.840
Illiterate	4 (20)	4 (20)	5 (25)	
Elementary school	6 (30)	5 (20)	6 (30)	
Junior high school and above	10 (50)	11 (60)	9 (45)	
Duration of diabetes (years)	12.6±6.2	12.5±8.4	12.4±10.4	0.998
Family history of diabetes (yes)	8 (40)	10 (50)	10 (50)	0.774
Weight (kg)	64.2±12.7	65.4±8.0	68.4±13.2	0.628
SBP (mmHg)	144.3±19.6	138.3±18.0	130.5±20.5	0.094
DBP (mmHg)	75.2±11.0	71.5±8.5	72.7±12.3	0.544
FPG (mg/dl)	177.6±51.0	158.4±58.1	181.2±84.6	0.509
HbA1c (%)	8.6±1.3	8.5±2.0	8.5±1.1	0.957
LDL-cholesterol (mg/dl)	95.4±22.8	101.7±33.3	97.9±28.0	0.785
Triglycerides (mg/dl)	176.5±173.0	174.8±136.9	123.3±73.9	0.378
HDL-cholesterol (mg/dl)	44.1±11.3	42.5±11.7	42.6±14.6	0.904
Total-cholesterol (mg/dl)	173.6±38.4	178.4±35.3	173.5±38.8	0.927
Nutritional knowledge (score)	5.9±2.1	6.1±1.8	5.8±1.5	0.901
Nutritional behavior (score)	49.0±12.7	48.9±10.6	50.1±10.3	0.754
Energy (kcal/day)	1693.5±149.4	1737.1±219.5	1600.5±237.3	0.116
Carbohydrate (g/day)	225.7±38.1	227.4±40.2	210.1±37.7	0.321
Protein (g/day)	65.0±11.6	65.0±11.9	61.3±13.2	0.572
Fat (g/day)	67.0±14.3	63.1±13.8	57.2±12.9	0.091

Data expressed as mean ± standard deviation (SD) or percentage in parentheses.
SBP, systolic blood pressure; DBP, diastolic blood pressure; FPG, fasting plasma glucose.

analyses (Figure 2). Baseline characteristics are shown in Table 1. There were significant changes in HbA1c in the meal-replacement and peer-support groups (Figure 2A). Reductions in HbA1c of 0.8% and 1.01% from baseline values were noted in meal-replacement and peer-support groups, respectively. Mean HbA1c decreased from 8.6% ±1.3% to 7.7% ± 0.8% and from 8.5% ± 2.0% to 7.5% ± 7.5% in meal-replacement and peer-support groups, respectively. In the group session only group, mean HbA1c decreased from 8.5% ± 1.1 % to 8.3% ± 0.9% (P=0.693). At the end of the study period, there were significant differences in body weight reduction among the groups. Mean body weight decreased from 64.2 ± 12.7 kg to 62.8 ± 12.1 kg and from 65.4 ± 8.0 kg to 64.4 ± 8.3 kg in meal-replacement and peer-support groups, respectively (Figure 2B). In group session only group, the mean body weight changed from 68.4 ± 13.2 kg to 68.6 ± 12.5 kg (P=0.473). The comparisons of

Table 2. Comparisons of blood pressure, fasting plasma glucose, and lipid levelsamong groups

	Meal-replacement			Peer-support			Group session only			
	Baseline	12 weeks	P^1	Baseline	12 weeks	P^1	Baseline	12 weeks	P^1	P^2
Weight (kg)	64.2±12.7	62.8±12.1	0.000	138.3±18.0	64.4±8.3	0.002	68.4±13.2	68.6±12.5	0.473	0.247
SBP (mmHg)	144.3±19.6	133.5±16.7	0.025	138.3±18.0	130.4±16.8	0.064	130.5±20.5	134.1±22.7	0.252	0.808
DBP (mmHg)	75.2±11.0	70.8±10.7	0.039	71.5±8.5	70.5±10.8	0.832	72.7±12.3	78.6±27.4	0.224	0.296
FPG (mg/dl)	177.6±51.0	153.2±46.1	0.021	158.4±58.1	136.2±28.5	0.089	181.2±84.6	175.2±44.2	0.890	0.013
HbA1c (%)	8.6±1.3	7.7±0.8	0.001	8.5±2.0	7.5±1.2	0.049	8.5±1.1	8.3±0.9	0.693	0.029
LDL-cholesterol (mg/dl)	95.4±22.8	93.1±22.0	0.363	101.7±33.3	87.4±23.2	0.027	98.0±28.0	87.0±24.4	0.030	0.672
Triglycerides (mg/dl)	176.5±173.0	140.6±109.7	0.332	174.8±136.9	129.4±62.8	0.192	123.3±73.9	123.7±73.7	0.351	0.818
HDL-cholesterol (mg/dl)	44.1±11.3	43.1±10.7	0.391	42.5±11.7	41.3±9.5	0.391	42.6±14.6	41.7±14.2	0.193	0.877
Total-cholesterol (mg/dl)	173.6.2±38.4	168.6±31.2	0.287	178.4±35.3	195.9±65.9	0.184	173.5±38.8	167.7±39.4	0.090	0.113

SBP, systolic blood pressure, DBP, diastolic blood pressure; FPG, fasting plasma glucose, HbA1c, glycated hemoglobin
Values are means ± SD. P^1: differences within groups; P^2: differences between groups

Table 3. Change in knowledge and behavior among groups.

	Meal-replacement			Peer-support			Group session only			
	Baseline	12 weeks	P^1	Baseline	12 weeks	P^1	Baseline	12 weeks	P^1	P^2
Nutritional knowledge	5.9±2.1	9.2±1.0	0.000	6.1±1.8	8.4±1.2	0.000	5.8±1.5	6.8±1.2	0.000	0.000
Nutritional behavior	49.0±12.7	64.6±8.8	0.003	48.9±10.6	60.3±6.8	0.010	50.1±10.3	56.1±8.8	0.001	0.007
Energy (kcal/day)	1693.5±149.4	1446.1±129.7	0.000	1735.2±213.9	1532.8±191.4	0.025	1600.5±237.3	1617.6±200.9	0.400	0.014
Carbohydrate (g/day)	225.7±38.1	167.9±25.3	0.000	227.4±40.2	202.8±28.7	0.043	210.1±37.7	209.6±37.4	0.331	0.000
Protein (g/day)	65.0±11.6	60.5±7.5	0.133	65.0±11.9	60.6±8.0	0.058	61.3±13.2	60.6±13.1	0.331	0.998
Fat (g/day)	67.0±14.3	59.1±10.1	0.069	63.1±13.8	54.6±12.1	0.018	57.2±12.9	56.5±13.21	0.331	0.521

Values are means ± SEM. P^1: differences within groups; P^2: differences between groups

blood pressure, fasting plasma glucose, and lipid levels among groups are shown in Table 2. At the 12-week examination, the three groups reported significantly beneficial changes in nutritional knowledge and behavior. The meal-replacement group improved the most, followed by the peer-support and group session only groups ($p< 0.001$ between groups). In regards to diet, daily caloric, carbohydrate, protein, and fat content is shown in Table 3. A significant reduction was noted in total daily caloric and carbohydrate intakes in meal-replacement and peer-support groups, compared to group session only group ($p < 0.05$), with this reduction most prominent in the meal-replacement group.

Overall, compliance was good. About 90% of the peer-support group made a phone call or sent a message every week. Moreover, meal-replacement consumption rate as reported by participants was around 86%.

Discussion

In this study, we examined the use of peer-support and meal-replacement after traditional DSME group session in elderly patients with suboptimal controlled diabetes. The results showed greater improvements in HbA1c, weight, and dietary behavior in the peer-support and meal-replacement groups compared to group session only group. Roughly 20% of all adults aged over 65 have diabetes (1,2). How to best provide diabetes self-management support to this group remains unclear due to limited randomized controlled trial data (1,2). Older adults are often underrepresented in diabetes education interventions due to subtle changes in their functional, cognitive, and psychosocial statuses, which may affect diabetes self-care (23). As a result, evidence-based guidelines for this age group are not well established.

A recent analysis of the benefits to older adults with diabetes (aged 60–75 years) of self-management interventions, suggested that older adults receive equal glycemic benefits, when compared with younger adults, from participation in group or individual self-management educational programs (24).

Group education is the most common form of DSME. These educational programs are usually delivered in multiple sessions, such as five 2-h sessions over 6 weeks. However, it has been found that few participants attend all sessions. Unmet personal preferences (e.g. parking, timing) are a barrier to continuous attendance (25). Another study showed that older age and the presence of mental health conditions or other medical comorbidities are associated with low attendance (26). Therefore, developing a simple and effective educational program for the elderly is mandatory. Although physical and mental capacities may have deteriorated in older adults, they still retain the ability to learn and to manage their diabetes.

A single session of DSME with reinforcing of self-care through peer-support or meal-replacement may help elderly patients improve their day-to-day self-management of diabetes. As shown in our study, nutritional knowledge improved in the three groups. However, at 12 weeks, only meal-replacement and peer-support group had better glycemic control and reduced daily carbohydrate intake. Therefore, knowledge alone is not sufficient for good metabolic control.

Continuous behavioral change requires behavioral, educational, psychosocial, or clinical support. In our study, the peer-support concept is of the psychosocial type and meal-replacement is of the clinical type. Our findings show agreement with the use of meal replacements as a nutritional strategy for glycemic control in type 2 diabetes. They are also consistent with the findings of an earlier study that demonstrated that one meal replacement per day results in HbA1c reduction of 0.6% at 12 weeks (27). Moreover, they are consistent with most studies on peer-support interventions. According to a systematic review, although studies on peer-support are generally heterogeneous in terms of setting, intervention, study design, length of follow-up, and outcome measures, the average HbA1c reduction is around 0.5% (95% CI, 0.25%-0.70%) (28). The number of participants in this study was relatively small. However, the overall compliance was good, reflecting the feasibility of such interventions for the elderly.

The duration of this study was 12 weeks.

Although this could be considered reasonably long for dietary intervention, a larger sample and a longer follow-up are needed to show whether peer-support intervention or meal replacement has longer term effects on maintaining glycemic control. During the study period, unless there was severe hyperglycemia or hypoglycemia, no adjustment of prescribed medications was allowed. We recorded a low percentage of prescription adjustment (~5%). Activity may also affect glycemic status and body weight. However, we did not measure activity in this study, which may have impacted on the results.

In conclusion, using different models for reinforcing diabetes self-management strategies, such as peer-support or meal-replacement, can improve glycemic control in elderly patients with diabetes.

Conflicts of interest

YS Yang has received research grants from Chung Shan Medical University Hospital. CT Wen, CN Huang, Edy Kornelius, CR Li, YC Wu, and YT Lin declare no conflicts of interest.

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