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Effect of simulation education and case management on glycemic control in type 2 diabetes

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Abstract

Background: The aim of the study was to investigate whether simulation education (SE) and case management had any effect on glycemic control in type 2 diabetes (T2DM) patients.

Methods: In this single center pilot trial, 100 T2DM patients who received medication and basic diabetes self-management education (DSME) were randomly divided into a control group (n = 50) and an experimental group (n = 50), who received SE and a case management program. Evaluation of biochemical indices was conducted at baseline and after 6 months. DSME consisted of 2-hour group trainings weekly for 2 consecutive weeks followed by 2 × 30 minute education sessions after 3 and 6 months. The SE program comprised additional 50-minute video sessions 3 times in the first week and twice in the second week. The experimental group was supervised by a nurse case manager, who followed up participants at least once a month, and who conducted group sessions once every 3 months, focusing on realistic aspects of physical activity and nutrition, with open discussions about setting goals and strategies to overcome barriers.

Results: After 6 months, HbA1c, fasting plasma glucose, and postprandial blood glucose level improvements were superior in the experimental group compared with the control group ($P < 0.05$). Self-care behavior adherence scores of healthy diet ($P = 0.001$), physical activity ($P = 0.043$), self-monitoring of blood glucose ($P < 0.001$), and reducing risks ($P < 0.001$) were significantly increased in the experimental group compared with the control group.

Conclusions: Simulation education and case management added to routine DSME effectively improved glycemic control in T2DM patients.

KEYWORDS

blood glucose control, case management, diabetes self-management education (DSME), HbA1c, self-care behaviours, simulation education (SE), T2DM

Abbreviations: BMI, body mass index; CM, case management; DSCQ, diabetes self-care questionnaire; DSME, diabetes self-management education; FPG, fasting plasma glucose; HbA1c, haemoglobin A1c; HDL, high density lipoprotein; LDL, low density lipoprotein; PBG, postprandial blood glucose; SE, simulation education; T2DM, type 2 diabetes mellitus; TC, total cholesterol; TG, triglycerides

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1 | INTRODUCTION

The method of teaching patients to manage their diabetes is known as diabetes self-management education (DSME).[1] An education in self-management has been shown to be important in helping patients with T2DM to achieve enhanced awareness and control of their condition.[2]

At present, most hospitals in China adopt traditional DSME, namely doctors and nurses give lectures to patients on diabetes knowledge. However, this is a passive "instillation" way of learning, and the patient's awareness of active learning and participation is not strong. A DSME meta-analysis suggested that DSME should include training of cognitive self-monitoring and skills to generate corrective action in order to avoid barriers for maintaining HbA1c goals.[3]

In recent years, SE has come to the attention of physicians. It is a heuristic education method with an active learning mode combined with situational education. It sets patient-centered and problem-solving goals and thus enhances its educational effectiveness. It has been mainly developed for educating health care professionals[4-6] but has also been applied to patients.[7]

The model of case management, which began in the United States in the last century,[8] includes five parts, namely: basic assessment; improvement planning; management of implementation; coordination between patient and nurse care; and supervision by the medical team. A reasonable and systematic self-management plan is normally established for patients by the professional health care team. The plan is adjusted over time according to the patient's condition, and each patient is followed-up for as long as possible to promote real changes in patient behavior and to improve metabolic indicators.[9,10] It has been reported that compared with traditional diabetes education, the case management model can reduce HbA1c levels in T2DM patients by 0.89%.[11] Whether combining SE and case management can effectively promote changes in patient behavior and further improve blood glucose control of patient's remains to be unequivocally established. Therefore, we applied SE combined with case management to T2DM patients, with the aim of evaluating whether patients can improve their blood glucose control through an improvement in behavior and lifestyle.

2 | MATERIALS AND METHODS

2.1 | Design of the study

A pre-post test design was used to compare the effects of the additional intervention in the experimental group who received SE plus a case manager and DSME (DSME+SE + CM). The control group received only DSME (Figure 1).

2.2 | Patients

A total 100 patients diagnosed with T2DM between March 2013 and October 2013 were recruited, from whom written informed consent was obtained for participation in the study. Patients were randomly assigned into an experimental or control group with 50 patients in each group, in which their ages, gender, and pathology were matched (Table 1, $P > 0.05$). Among these patients, nine (five in the experimental group and four in the control group) did not finish the study or were unable to attend the follow-up examination and were therefore not included in the analysis. Final, a total of 91 patients with T2DM were included in our study for trial data analysis and to conduct an initial analysis to look for any obvious trends (Figure 1). There was a smaller attrition rate (10%) in the experimental group vs 8% in the control group (experimental group, $n = 45$; control group, $n = 46$).

Inclusion criteria[12] were as follows: patient age $\geq$ 18 years; a fully documented diagnosis of T2DM verified by two FPG laboratory results of $\geq$140 mg/dL; taken or had taken insulin or oral hypoglycemic drugs for >1 year; the HbA1c value during the last 6 months was $\geq$7.5%; no type 1 diabetes or evidence of ketoacidosis; ability

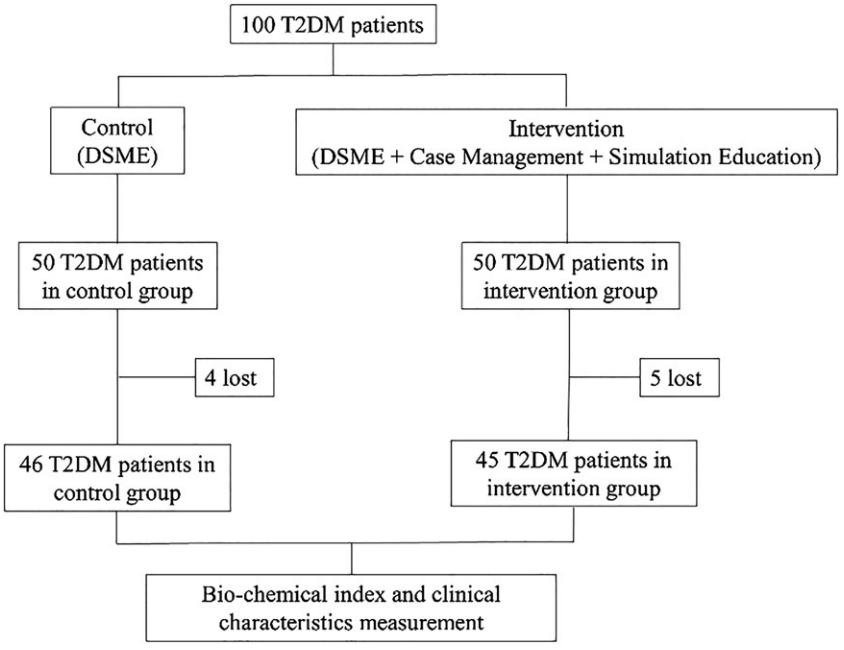

FIGURE 1 Flowchart of the present study

TABLE 1 Baseline demographics and medications of the study population (Mean ± SD or %)

	DSME (Control Group) *n* = 46	DSME + SE + CM (Experimental Group) *n* = 45	*P*-Value
Gender			0.599
Male, %	47.8	53.3	
Female, %	52.2	46.7	
Age	54.5 ± 12.7	54.2 ± 12.0	0.935
Duration of diabetes	5.6 ± 6.2	4.0 ± 4.9	0.176
Education			0.607
≤ 5th grade %	26.0	15.6	
6th-8th grade %	45.7	53.3	
9th-12th grade %	17.4	22.2	
≥ high school %	10.9	8.9	
Complication			0.933
Hypertension (%)	23.9	26.7	
Hypercholesterolemia	15.2	8.9	
Myocardial infarction (%)	4.3	6.7	
Renal disease (%)	10.9	8.9	
Visual impairment (%)	6.5	8.9	
Only insulin injection	38	30	0.095
Oral medicine plus insulin injection	8	14	0.148
Only oral medicine	0	1	0.495
The average daily dose of insulin injection (units)	42.52 + 13.91	41.45 + 12.83	0.704

Abbreviations: CM, case management; DSME, diabetes self-management education; SD, standard deviation; SE, simulation education.

to walk; no contraindications that would prevent participation in the trial (eg, peripheral vascular disease).

The exclusion criteria[10] were as follows: patients with a severe psychiatric disorder; mental retardation or visual literacy; an inability to complete the study questionnaire; or pregnancy.[13] We followed literature suggestions[13] and excluded all patients who had a baseline HbA1c > 14%, because these outlying values may be an artefact due to data miscoding or very unusual examples of very poor control of the diabetic condition.

This study was approved by the Research Ethics Board of Danyang People's Hospital (Jiangsu, China). Research coordinators conducted the initial screening and physician approval was obtained for participation of the screened patients in the study.

2.3 | Setting

The study was conducted in Danyang People's Hospital, Jiangsu province, China. All participants provided signed informed consent.

2.4 | Diabetes education curriculum

2.4.1 | DSME

Diabetes self-management education is a critical care program for all diabetics and those individuals at risk of developing the disease, with the aim of preventing or delaying the complications associated with diabetes. The items of DSME are closely related to lifestyle changes. DSME supports and assists diabetes educators in providing evidence-based education and self-management support. The standards are applicable to educators in solo practice as well as those in large multicenter programs—and everyone in between. There are many good models for the provision of diabetes education and support. The standards do not endorse any one approach, but rather seek to delineate the commonalities among effective and excellent self-management education strategies.

In the present study, both groups received a standard DSME intervention. Six educators from a health care team, who were either dietitians or registered nurses, delivered the education program on diabetes and its symptoms. The standard DSME program involved a 2-hour group training period weekly for two consecutive weeks followed by 2 × 30 minute DSME sessions at 3 and 6 months to ensure that patients followed the guidelines of the education program in their daily activities during the period of the study. All lessons focused on the knowledge and skills required for a healthy diet, exercise education, self-monitoring of blood glucose levels and drug management specifically for insulin injection participants, problem solving related to diabetes, and changes in lifestyle to facilitate a reduction in the risks and complications associated with diabetes.[14]

2.4.2 | Simulation education (SE)

For the experimental group, besides a standard DSME intervention, we developed an educational video to introduce diabetes self-management information including diabetes knowledge, diet/exercise education, insulin injection, and self-monitoring of blood glucose levels. This SE program offered 20-minute video watching and then let patients imitate the actor in the video by carrying out 30-minutes role-play. This SE education was delivered 3 times in the first week and twice in the second week. Family members who lived in the same property were encouraged to attend the SE education sessions. SE consisted mainly of role-playing and problem solving among patients. During the role-play the patients given the role of a dietitian learned actively the significance of diet calculation methods and how to make diabetic food. For example, a diabetic patient who was a manager had social gatherings 5-6 times per week and thus consumed 350 to 400 g of spirituous liquor per social occasion before he joined the case

manage project. Through role-playing, the patient fully understood the importance of a diabetes diet and knew how to control the calorie intake every day. As a result, when the nurse followed-up by phone, he told that he had already reduced the consumption of spirituous liquor and ate diabetic foods consciously; fasting blood glucose (FBG) level was now ideally controlled.

2.4.3 | Case management

An experienced nurse case manager was added to the experimental intervention. The goal of the nurse case manager was to follow up participants at least once a month, for 30-minute sessions, including an office appointment and telephone calls. Group sessions were given once every 3 months, and twice within the 6-month period in the present study. These sessions focused on realistic aspects of physical activity and nutrition, open discussion of setting goals, and a strategy to overcome any obvious barriers, further complemented by food preparation demonstrations.

The overall intention of the experimental interventions was to provide patients with practical skills, knowledge, and an ability to manage T2DM. In addition, support for informed decision-making, problem solving, self-care behavior, and an active collaboration with their health care team was encouraged.[15]

2.5 | Study measurements

Patients who received DSME alone (Controls) were compared with DSME + case-management + SE patients, to determine whether differences in patients and their clinic symptoms were evident before the intervention. The baseline demographics of the study population were recorded using individual assessments, which were carried out in parallel with clinical assessment and included factors such as age (years), gender, marital status, and the level of education (years), and also the duration of diabetes. Clinical characteristics and biochemical indices and physiological factors including HbA1c, FPG, PBG, TC, TG, HDL, LDL, SBP, DBP, and BMI were all analysed at baseline and at 6 months. A validated and reliable DSM self-efficacy scale (see **supplementary files**) was used to evaluate changes in self-care behavior for a Chinese diabetic population.

The tailored diabetes self-care questionnaire was developed by Xian et al using concepts from an internationally developed program,[16] and it was unique for the social and ethnic environment of China. This novel scale included 24 items in six domains (physical activity, a healthy diet, self-monitoring of blood glucose levels, the diabetes medication regimen, problem solving and reducing risks). The higher the score, the better the behavior outcomes. The scale was previously pre-tested and modified to best assess the target population and demonstrated good internal reliability with Cronbach's alpha (α) 0.816, retest reliability 0.906, and content validity CVR $\geq$ 0.75.[16]

2.5.1 | The primary and secondary endpoints

Primary endpoint HbA1c was determined based on laboratory examinations.

Secondary endpoints: a healthy diet status, patient self-monitoring of blood glucose levels, physical activity, diabetes medication regimen, problem solving and reducing risks (measured by a self-care behavior scale), and other biochemical index and physiological factors were recorded. Baseline measurements were noted and compared with those recorded at the 6-month follow-ups.

2.5.2 | Randomization

Subjects were randomized 1:1 according to random numbers generated in Excel. To ensure that the risk of bias remained low, patients were registered in the database by means of ID codes so that assessors and educators were blinded. Only the primary investigator knew the allocation. A special evaluation team (laboratory technicians and diabetes specialist nurses) undertook evaluation work. The outcome assessors did not contact the patients to ensure accuracy of the assessments.

2.5.3 | Statistical analysis

Data are expressed as the means ± standard deviations (SD) for normally distributed continuous covariates (diabetes duration, BMI, age, HbA1c, FPG, PBG, blood pressure, and lipid profiles) or median and interquartile range for non-normally distributed continuous covariates (education level, complications, male or female). A Kolmogorov-Smirnov test was used to test the parameter distribution. Categorical covariates are described as numbers and percentages. In addition, Student's *t*-tests or Mann-Whitney U tests were used for comparison of continuous variables and a chi-squared test for categorical variables. All tests were two-sided, and $P < 0.05$ was considered to be statistically significant.

3 | RESULTS

3.1 | General data and comparability of the two groups

The general characteristics of the patients are documented in **Table** 1. One hundred patients were initially randomized to the two study groups excluding those not fitting inclusion criteria. Finally, 91 T2DM patients were included (experimental group [DSME + SE + CM], $n = 45$; control group [DSME], $n = 46$). Of the patients, 46.7% were female in the experimental group and 52.2% in the control group ($P > 0.05$). The mean age in the control and experimental groups was 54.5 years (SD = 12.7) and 54.2 years (SD = 120), respectively. The duration of diabetes in the experimental group was 4.0 years (SD = 4.9) as compared with 5.6 years (SD = 6.2) in the control group. In addition, 60.4% of the study population had diabetic complications, with 60% in the experimental group and 60.9% in the control group.

The majority of patients received insulin injections in both groups, and some of the patients were additionally treated with oral medication, but there were no significant differences between the two groups (all *P*-values >0.05).

3.2 | DSME and DSME + SE + CM can reduce HbA1c, FBG, FPG, and lipid levels

There were no significant differences between the two groups regarding all included baseline levels of the indices. Although HbA1c, FBG, and PBG values were significantly improved in both groups, the improvements in the experimental group were significantly superior. Other outcome comparisons revealed that in both groups diastolic BP, TC, and HDL values were significantly improved, but systolic BP was only significantly improved in the experimental group, whereas LDL values were only significantly improved in the control group (Table 2).

3.3 | DSME + SE + CM can improve more significantly self-care behaviours

In this study, self-care behavior was measured using a tailored DSCQ (see supplementary Tables 1 and 2). At baseline, the groups were virtually identical on adherence scores of physical activity and diabetes medication regimens, with the exception that the experimental group showed lower adherence scores for a healthy diet and self-monitoring of blood glucose at baseline, being 0.87 ± 0.22 vs 0.99 ± 0.30 and 0.82 ± 0.43 vs 1.01 ± 0.38 in the control group. Scores of healthy diet, physical activity, self-monitoring of blood glucose, and risk reduction were significantly improved in the experimental group. Scores for healthy diet, physical activity, self-monitoring of blood glucose, and diabetes medication regimens, and reducing risks were significantly improved in both groups, whereas only in the experimental group were problem solving scores significantly improved by the treatment (Table 3).

4 | DISCUSSION

According to the literature, only 50% of T2DM patients have adequate glycemic control,[17,18] which raises the demand for more self-management of inadequate glucose levels. The American Diabetes Association recommends that after diagnosis, patients with diabetes should receive DSME following national guidelines, which are similar to the guidelines of the Chinese diabetes society[19] and should continue receiving the education thereafter as required.[20] Those patients who completed DSME were more likely to follow the recommended guidelines for diabetic care and also maintain better adherence to the their drug treatment regimens.[21] As expected, the primary outcome of the present study, the HbA1c level (an index of control over 2-3 months), was improved (in terms of reduced HbA1c) after receiving DSME (Table 3). This finding is consistent with reports of previous studies in which the HbA1c level of diabetic patients was significantly decreased after DSME interventions.[22]

However, the addition of SE and CM techniques to the standard DSME saw a significant higher decrease in HbA1c levels in the experimental group (−1.13, CI95% [−1.66 to −0.60], $P < 0.001$), and FPG, PBG, and self-care behaviours were better improved in patients trained with DSME + SE + CM for 6 months (Table 2), indicating that SE and CM had a pronounced effect. These results are in agreement

TABLE 2 Comparison of clinical characteristics between control and experimental groups at baseline and after intervention

	At baseline			Intergroup Comparisons After intervention			Intragroup Comparisons Intervention minus baseline diff within groups (95% CI)			
	DSME (n = 46)	DSME + SE + CM (n = 45)	*P*-value	DSME (n = 46)	DSME + SE + CM (n = 45)	Outcome diff between groups (95% CI)	*P*-value	DSME (n = 46)	*P-value*[a]	DSME + SE + CM (n = 45)	*P-value*[a]
HbA1c (%)	10.45 ± 2.10	10.49 ± 1.69	0.927	8.35 ± 1.46	7.22 ± 1.06	−1.13 (−1.66 to −0.60)	< 0.001	−2.10 (−2.60 to −1.60)	< 0.001	−3.27 (−3.88 to −2.66)	< 0.001
FPG (mmol/L)	11.96 ± 4.00	11.98 ± 2.56	0.972	8.09 ± 1.47	7.19 ± 1.89	−0.90 (−1.60 to −0.19)	0.013	−3.87 (−5.03 to −2.71)	< 0.001	−4.79 (−5.63 to −3.96)	< 0.001
PBG (mmol/L)	17.30 ± 3.76	17.11 ± 3.97	0.815	11.96 ± 2.02	10.22 ± 2.4	−1.74 (−2.66 to −0.82)	< 0.001	−5.33 (−6.48 to −4.19)	< 0.001	−6.88 (−8.37 to −5.39)	< 0.001
BMI (kg/m^2)	25.06 ± 3.09	24.51 ± 3.62	0.436	24.87 ± 2.65	24.36 ± 2.99	−0.52 (−1.69 to 0.66)	0.385	−0.19 (−0.48 to 0.11)	0.210	−0.15 (−0.53 to 0.23)	0.435
BP systolic (mmHg)	133.70 ± 14.35	135.11 ± 19.67	0.697	131.85 ± 10.77	131.22 ± 11.64	−0.63 (−5.29 to 4.04)	0.791	−1.85 (−4.02 to 0.33)	0.094	−3.89 (−7.50 to −0.28)	0.035
BP diastolic (mmHg)	83.37 ± 8.82	82.00 ± 10.08	0.492	80.43 ± 6.04	78.89 ± 6.56	−1.55 (−4.17 to 1.08)	0.245	−2.93 (−4.49 to −1.38)	< 0.001	−3.11 (−4.96 to −1.26)	0.002
TC (mmol/L)	4.83 ± 1.04	4.65 ± 1.08	0.406	4.24 ± 0.70	4.34 ± 0.90	0.10 (−0.23 to 0.44)	0.547	−0.59 (−0.95 to −0.23)	0.002	−0.30 (−0.60 to −0.01)	0.045
TG (mmol/L)	2.81 ± 2.75	2.01 ± 1.64	0.097	1.98 ± 1.46	1.59 ± 0.76	−0.39 (−0.88 to 0.09)	0.110	−0.83 (−1.42 to −0.23)	0.007	−0.42 (−0.86 to 0.01)	0.056
HDL(mmol/L)	1.10 ± 0.31	1.07 ± 0.27	0.627	1.32 ± 0.53	1.22 ± 0.19	−0.10 (−0.27 to 0.07)	0.245	0.22 (0.07 to 0.37)	0.006	0.15 (0.06 to 0.23)	< 0.001
LDL (mmol/L)	2.76 ± 0.76	2.61 ± 0.75	0.348	2.45 ± 0.54	2.43 ± 0.68	−0.03 (−0.28 to 0.23)	0.843	−0.31 (−0.56 to −0.06)	0.016	−0.19 (−0.37 to 0.00)	0.052

[a]indicates the comparison of the changes before and after intervention.

Abbreviations: BMI, body mass index; BP diastolic, blood pressure systolic; BP systolic, blood pressure systolic; CM, case management; DSME, diabetes self-management education; FPG, fasting plasma glucose; HbA1c, haemoglobin A1c; HDL, high density lipoprotein; LDL, low density lipoprotein; PBG, postprandial blood glucose; SD, standard deviation (± SD); SE, simulation education; TC, total cholesterol; TG, triglycerides.

TABLE 3 Inter-group comparison of behavioural outcomes at baseline and after intervention as well as the changes after intervention based on baseline

	Intergroup Comparisons							Intragroup Comparisons Intervention-baseline diff (95% CI)			
	At baseline			After intervention							
	DSME (*n* = 46)	DSME + SE + CM (*n* = 45)	*P*-value	DSME (*n* = 46)	DSME + SE + CM (*n* = 45)	Diff (95% CI)	*P*-value	DSME (*n* = 46)	*P*-value[a]	DSME + SE + CM (*n* = 45)	*P*-value[a]
Healthy diet	0.99 ± 0.30	0.87 ± 0.22	0.026	1.41 ± 0.16	1.51 ± 0.11	0.10 (0.04 to 0.15)	0.001	0.42 (0.35 to 0.49)	< 0.001	0.64 (0.57 to 0.71)	< 0.001
Physical activity	1.13 ± 0.32	1.08 ± 0.27	0.438	1.40 ± 0.61	1.46 ± 0.35	0.06 (0.00 to 0.13)	0.043	0.27 (0.20 to 0.34)	< 0.001	0.38 (0.30 to 0.47)	< 0.001
Self-monitoring of blood glucose	1.01 ± 0.38	0.82 ± 0.43	0.025	1.30 ± 0.31	1.62 ± 0.22	0.32 (0.21 to 0.43)	< 0.001	0.29 (0.19 to 0.39)	< 0.001	0.80 (0.66 to 0.94)	< 0.001
Diabetes medication regimen	1.72 ± 0.87	1.43 ± 0.73	0.089	2.26 ± 0.52	2.42 ± 0.22	0.05 (−0.02 to 0.12)	0.060	0.54 (0.30 to 0.78)	< 0.001	0.99 (0.72 to 1.26)	< 0.001
Problem solving	1.15 ± 0.20	1.13 ± 0.18	0.626	1.14 ± 0.20	1.16 ± 0.18	0.02 (−0.06 to 0.09)	0.694	−0.01 (−0.05 to 0.03)	0.543	0.02 (0.00 to 0.04)	0.018
Reducing risks	5.92 ± 0.76	5.97 ± 0.43	0.705	6.87 ± 0.76	7.64 ± 0.38	0.78 (0.53 to 1.03)	< 0.001	0.95 (0.75 to 1.15)	< 0.001	1.67 (1.53 to 1.82)	< 0.001

[a]indicates the comparison of the changes before and after intervention.

Abbreviations: CM, case management; DSME, diabetes self-management education; SD, standard deviation (± SD); SE, simulation education.

with previous findings in which increased hours of engagement and primary care in combination with DSME significantly improved glycemic control in diabetics.[2,23] A meta-analysis revealed that CM elicited a clinically significant improvement in the control of blood glucose levels.[11]

The behavioural mechanisms responsible for blood glucose level changes following the interventions were also investigated, and we found that there were significant differences in adherence scores evaluated with DSCQ (supplementary Tables 1 and 2) between the DSME + SE + CM group and the DSME alone group (Table 3). The extended educational program produced significantly better improvements in behavioural outcomes, as evidenced by improved adherence scores of physical activity, self-monitoring of the levels of blood glucose, a healthy diet and reduced risks compared with traditional DSME.

Our comprehensive diabetes training program not only considers how efficiently diabetes care knowledge is delivered to the patient, but also the role of a patient's perception of the importance of maintaining self-efficacy regarding behavioural changes, by integrating SE and CM into traditional DSME. Considering the huge potential economic burden for diabetes care in the near future in China, integrating this program into the existing health care system, albeit with considerable increase in patient-educator contact hours should provide cost effective and efficient care. However, due to the limited sample size analysed in the present study, further investigations into the long-term benefits of the SE + CM combination with DSME in different age groups and in larger cohorts of patients will be required.

5 | CONCLUSIONS

DSME + CM + SE can improve the behavior of patients with T2DM and effectively improve their control of blood glucose levels.

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COMPETING FINANCIAL INTERESTS

The authors declare that they have no competing financial interests.

ETHICAL APPROVAL

All procedures performed involving human participants were in accordance with the ethical standards of the ethical committee of the Danyang People's Hospital and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards. Written informed consent was obtained from all participants.

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SUPPORTING INFORMATION

Additional supporting information may be found online in the Supporting Information section at the end of the article.

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