## Original Article

# The effect of the Conversation Map<sup>™</sup> program in patients with poor glycemic control with type 2 diabetes mellitus-when usual care is not enough

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Abstract: Aims: To investigate the effect of the Conversation Map<sup>™</sup> (CM) program in patients with poor glycemic control with type 2 diabetes mellitus (T2DM). Methods: T2DM patients who: (1) had A1C>8.0% with no more than a 0.5% A1C reduction for at least half a year; (2) hadparticipated in the individualized diabetes education care program for ≥1 year; (3) were being treated with ≥2 OADs/or with basal insulin, or with multiple daily insulin injections were included. Visual maps of "healthy eating and being active" and "starting insulin" were chosen as the primary interventions. Results: Ninety-nine patients fulfilled the inclusion criteria, and 56 patients participated in the CM program. In contrast to the usual care group, in which the glycemic control remained static (A1C from 9.3 ± 1.1% to 9.3 ± 1.5%), the CM group showed an improvement in A1C from 9.8 ± 1.4% to 8.9 ± 1.5% (P<0.001) after 3 months. Improvements in blood glucose monitoring, weekly activity, insulin intensification, insulin perception, dietary knowledge and healthy eating behavior were also observed in the CM group. Conclusions: CM may be helpful for T2DM patients with poor glycemic control when participating in the individualized diabetes care program.

Keywords: Conversation Map, type 2 diabetes mellitus

#### Introduction

Regardless of the increased availability of improved therapeutic agents and better practice guidelines for health providers, a substantial proportion of patients with diabetes mellitus do not achieve the target glycemic control [1, 2]. One of the important reasons for this is patients' difficulties in following suggestions regarding therapeutic regimens and lifestyle modification. Because of the complex nature of diabetes care, diabetes self-management education (DSME) has been viewed as an essential element to fill the gap between ideal and actual diabetes care [3, 4].

Conversation Map™ (CM), an innovative visual tool grounded in several learning and behavior change theories, may be a promising toolkit for DSME. In contrast to traditional DSME provided

by a one-to-one didactic method, CM is performed in a small group and allows patients to learn about key concepts through interactive discussion and choose what they can change in their daily diabetes care. In the meantime, instead of as inculcators, diabetes educators can work as facilitators by providing information to participants and helping patients to set personalized action goals to improve their diabetes care. To date, the content of CM has been recognized by several professional societies (e.g., the American Diabetes Association (ADA), International Diabetes Federation (IDF), Canadian Diabetes Association and Taiwan Association of Diabetes Educators (TADE).

Despite CM having been distributed worldwide for the past few years, scientific evidence is limited and its clinical value may also be challenged. In contrast to reports that have sup-

ported the clinical value of CM [5-7], the Journey for Control of Diabetes Interactive Dialogue to Educate and Activate (IDEA) group conducted a DSME efficacy study that randomized participants into group education (using the US Diabetes Conversation Map program), individual education and usual care, and at the end of study, the author found that the patients who received individual education had a significantly better A1C reduction than the patients who received CM (-0.51% vs. -0.27%; P=0.01) [8]. Furthermore, the CM group did not even exhibit a better A1C outcome than the usual care group (-0.27% vs. -0.21%; P=0.83) [8]. The results of the IDEA study hinted that CM may be of limited value in providing additional benefits to patients in diabetes care.

However, there were limitations in the IDEA study [8], and the study may not have reportedthe true differences between DSME interventions [9]. Furthermore, it should be noted that the delivery of DSME largely depends on the resources of the healthcare system and the clinical scenario, which vary. In the real world, including in Taiwan [10, 11], DSME provided in an individual manner remains clinically practical, and its efficacy has been proven [8, 12, 13]. However, what remains to be resolved is what the next DSME approach should be when individual DSME fails. Thus, the aim of this study was to clarify the value of CM by examination of the application of CM inpatients with type 2 diabetes mellitus (T2DM) who failed to achieve target glycemic control by individual DSME.

#### Materials and methods

#### Subjects

To examine the effectiveness of CM, our study focused on T2DM patients who were followed-up regularly in a specialized diabetes care clinic [14-17] and had the following characteristics: 1. they had persistent A1C>8.0% with no more than a 0.5% A1C reduction for at least half a year; 2. they had participated in a comprehensive care program characterized by individual DSME for at least one year; 3. they were being treated with  $\geq$ 2 OADs, or  $\geq$ 2 OADs plus basal insulin, or with multiple daily insulin injections (MDI). The exclusion criteria were: (1) patients who had participated any group DSME pro-

gram; (2) patients with type 1 diabetes mellitus; (3) patients who had been hospitalized within the last 6 months prior to enrollment; (4) patients who had received medical treatment that may cause fluctuation of glycemic control (e.g., steroid treatment, carcinogenic disease undergoing therapy); (5) patients with a psychological disorder.

#### Study design

To examine the applicability of CM in routine clinical practice, the study was designed as a controlled before-and-after study. Patients who fulfilled the study criteria were introduced to CM, which was developed with the collaboration of Eli Lily®, Healthy Interactions, Inc. and IDF. Owing to these patients having already been educated (e.g., in terms of what is diabetes, the importance of self-monitoring of blood glucose, the importance of healthy eating and being active) in a diabetes care program with a certified diabetes educator (CDE) and registered dietitian (RD) for more than 1 year, two visual maps (i.e., "healthy eating and being active" and "starting insulin") were chosen as our primary interventions after experienced CDEs (Shi-Yu Chen [18] and Hui-Chun Hsu [19]) and trainers in CM in Taiwan reached a consensus. The main reason for this decision was that content that includes these two visual maps might meet the needs of T2DM patients with poor glycemic control under complex regimens. Each CM course consisted of visual maps of "healthy eating and being active" and "starting insulin", and was based on one 2-hour session. Patients who were not willing to join the program were managed in the usual care program, which adopted the AADE 7 Self-Care Behaviors principle for DSME (ME-2306, World Diabetes Congress 2013 in Melbourne). One CDE and one RD, who have trained for CM by TADE, servedas facilitators in the CM group. Before initiating CM, the facilitators started with a 20~30-minute introduction to participants of the content of these two visual maps. After participants completed the CM, the facilitators followed-up on the success in the predetermined goals set by each participant at two-week intervals via telephone and gave suggestions to assist patients in overcoming barriers. Once a predetermined goal had been achieved, the facilitator checked the continuity after a one-

**Table 1.** Baseline characteristics of the study participants

	Conversation Map (n=56)	Usual care (n=43)	Р
Age (yr)	63.9 ± 9.2	62.0 ± 8.6	0.306
Gender (F/M)	21/35	20/23	0.414
Disease duration (yr)	12.7 ± 6.8	10.8 ± 6.2	0.152
BMI (kg/m²)	$26.7 \pm 4.3$	25.8 ± 5.5	0.391
Educationallevel			
≤9 years	39	36	0.153
>9 years	17	7	
Smoking (yes)	12	12	0.486
Alcohol (yes)	13	6	0.308
Exercise (≥150 min/week)	23	21	0.541
SMBG (yes)	39	22	0.095
SMBG (per week)	$2.0 \pm 2.3$	1.5 ± 2.0	0.284
HbA1c (%)	9.8 ± 1.4	9.3 ± 1.1	0.104
sBP (mmHg)	135.4 ± 17.4	$137.0 \pm 17.9$	0.661
dBP (mmHg)	$75.4 \pm 8.1$	75.4 ± 11.0	0.590
Cholesterol (mmol/l)	4.86 ± 1.10	4.77 ± 0.81	0.926
LDL-C (mmol/I)	$2.72 \pm 0.95$	$2.54 \pm 0.64$	0.454
Triglycerides (mmol/l)	1.24 ± 0.54	1.54 ± 1.13	0.337
Regimens (%)			
≥2 OADs	42.9	37.2	0.680
With insulin	57.1	62.8	-

BMI: body mass index; SMBG: self-monitoring of blood glucose; sBP: systolic blood pressure; dBP: diastolic blood pressure; LDL-C: low-density lipoprotein cholesterol; OAD: oral anti-hyperglycemic drug.

month interval. The study was approved by the institutional review board of Tri-Service General Hospital (TSGHIRB: 1-103-05-138) and informed consent was obtained from each patient.

#### Measurements

Basic physical information, including body height, body weight and blood pressure, was obtained in the study. Blood samples were collected after at least an 8-hour overnight fast. A1C was measured in whole blood using ion exchange high-performance liquid chromatography (BIO-RAD®, VARIANTTM II Turbo, Hercules, CA). A biochemical automatic analyzer (Beckman-Coulter Inc. Fullerton, CA) was used to analyze blood samples and measure plasma glucose, total cholesterol, low-density-lipoprotein cholesterol (LDL-C) and triglycerides. Our laboratory analyses were under internal and external quality control at the laboratory of the College of American Pathologists surveys. The Chinese version of the DAWN insulin perception questionnaire (http://www.dawn-study.tw/question02/question02-Q01.asp) was used to evaluate the participants' attitudes towards insulin. Validated Chinese questionnaires were used to assess the participants' knowledge (10 items) and behavior (16 items) regarding dietary intake for Chinese patients with type 2 diabetes mellitus. Patients' satisfaction was assessed using a 5-point Likert scale. Self-assessments after the Conversation Maps program were also evaluated.

#### Statistical analysis

Data analysis was carried out using SPSS (version 14.0). Mann-Whitney tests were used to compare the differences between the two groups. Wilcoxon tests were used to investigate the before-after differences. Chi-square tests were used to compare categorical parameters. Mc Nemar tests were used to compare the paired nominal data. The statistical power was calculated using G\*power 3.1.9.2 software [20].

#### Results

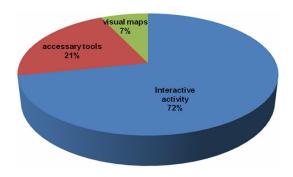
A total of 99 patients (mean age:  $62.5 \pm 9.1$  years; disease duration:  $11.3 \pm 6.6$  years) who had been enrolled in the comprehensive program for  $5.5 \pm 2.0$  years fulfilled the inclusion criteria. CM was introduced to all of the candidates; however, 43 patients (43.4%) refused to participate, and they were defined as the usual care group. The most common reason for refusal was the time-consuming nature of CM or the lack of schedule flexibility for the session. During the study period, a total of 15 courses of CM were held, with a median number of 4 participants on each course. Finally, 56 patients formed the CM group.

The baseline characteristics of the study candidates are presented in **Table 1**. There were no differences in terms of age, gender distribution, diabetes disease duration, body mass index, education level ordaily behaviors (i.e., smoking, alcohol drinking, exercise and self-monitoring

Table 2. Changes at the 3-month follow-up

	Conversatio	Conversation Map (n=56)		Usual care (n=43)	
	Baseline	3-mo	Baseline	3-mo	
BMI (kg/m <sup>2</sup> )	26.7 ± 4.3	26.4 ± 3.8	25.8 ± 5.5	26.1 ± 3.8	
Exercise (≥150 min/week)	23 (41%)	35 (63%) <sup>‡</sup>	21 (49%)	18 (42%)	
SMBG (yes)	39 (70%)	46 (82%)	22 (51%)	20 (47%)	
SMBG (per week)	$2.0 \pm 2.3$	3.5 ± 3.8‡	1.5 ± 2.0	$1.0 \pm 1.4$	
HbA1c (%)	$9.8 \pm 1.4$	8.9 ± 1.5 <sup>‡</sup>	9.3 ± 1.1	9.3 ± 1.5	
sBP (mmHg)	135.4 ± 17.4	133.4 ± 21.8	137.0 ± 17.9	133.2 ± 20.6	
dBP (mmHg)	$75.4 \pm 8.1$	$73.1 \pm 10.4$	75.4 ± 11.0	75.9 ± 13.3	
Cholesterol (mmol/l)	4.86 ± 1.10	4.58 ± 1.02	$4.77 \pm 0.81$	4.67 ± 1.50	
LDL-C (mmol/l)	$2.72 \pm 0.95$	$2.45 \pm 0.89$	$2.54 \pm 0.64$	$2.34 \pm 0.84$	
Triglycerides (mmol/I)	$1.24 \pm 0.54$	1.17 ± 0.59	1.54 ± 1.13	1.84 ± 1.15	
Regimens (%)					
≥2 OADs	42.9	21.4	37.2	34.9	
With insulin	57.1	78.6 <sup>‡</sup>	62.8	65.1	

<sup>‡</sup>P<0.05. BMI: body mass index; SMBG: self-monitoring of blood glucose; sBP: systolic blood pressure; dBP: diastolic blood pressure; LDL-C: low-density lipoprotein cholesterol; OAD: oral anti-hyperglycemic drug.



**Figure 1.** Patients' satisfaction with the conversation maps program.

of blood glucose (SMBG)) between the study groups. There were no differences in baseline blood pressure, total cholesterol, triglycerides, LDL-C or A1C levels between the study groups. There was no difference in anti-hyperglycemic prescriptions between groups.

The biochemical marker changes after 3 months are presented in **Table 2**. The usual care group did not show an improvement in A1C (from  $9.3 \pm 1.1\%$  to  $9.3 \pm 1.5\%$ ; P=0.697) at 3 months. On the contrary, the CM group demonstrated a significant A1C reduction (from  $9.8 \pm 1.4\%$  to  $8.9 \pm 1.5\%$ ; P<0.001) at 3 months. As compared with no change in the daily behaviors of patients in control group, the CM group showed a significant improvement in the behavior of exercise ( $\geq 150$  min/week), which increased from 41% to 63%. Although there was no significant increase in patients in terms

of performing SMBG (from 70% to 82%; P=0.122), there was asignificant increase in the weekly SMBG frequency (from 2.0  $\pm$  2.3 to 3.5  $\pm$  3.8; P<0.001). In addition, as compared with inertia in the change in anti-hyperglycemic agents in the usual care group, there was a significant increase in insulin therapy (from 57.1% to 78.6%; P=0.015) in the CM group.

As compared with the usual care group, patients who were enrolled in the CM program exhibited significant improvements in all aspects of insulin perception (P<0.001). In addition, there were also significant improvements in dietary knowledge (from  $4.7 \pm 2.1$  to 7.4  $\pm$  1.6; *P*<0.001) and healthy eating behavior (from  $9.5 \pm 2.0$  to  $11.5 \pm 1.8$ ; P < 0.001). To our surprise, instead of the visual maps provided by the CM program (7%), the participants reported they felt more interested in the social interaction among CM group members (72%) while using the program (Figure 1). In the relationship to the educational purpose of the program, 59% of participants reported the association between blood glucose, dietary intake and insulin therapy as their leading subject (Figure 2). Our results also showed a good satisfaction with CM, with an average score of 4.1 ± 0.8 assessed on a 5-point Likert scale.

#### Discussion

In the present study, our results clearly demonstrated that the CM program is helpful for poor-

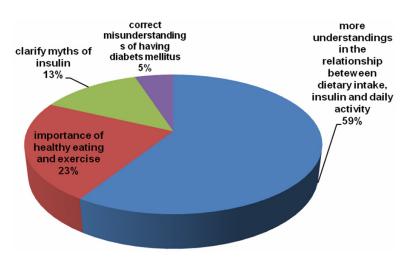


Figure 2. Ways in which patients benefit most from the conversation maps program.

ly-controlled T2DM patients who had received individualized DSME for more than a year. Despite over 50,000 facilitators in over 120 countries in 38 languages having been trained in the CM program (http://www.healthyinteractions.com/about-us; access at Jan, 2015), there have been few studies that have discussed scientific evidence regarding its efficacy. In a descriptive report, Ciardullo et al. reported that 63 patients with diabetes mellitus exhibited improvement in A1C from 8.2 ± 1.2% to  $7.8 \pm 1.4\%$  (P<0.001) at 3 months after 4 sessions of CM [5]. In a retrospective study, Dorland et al. reported that 21 T2DM patients had a 0.6% A1C reduction at 6 months after CM sessions [6]. In a comparative study, Penalba et al. demonstrated that T2DM patients who enrolled into the CM program exhibited better diabetes knowledge than regular care [7]. Recently, with the aid of CM, Zheng el al, reported that a modified American Association of Diabetes Educators curriculum could be helpful to Chinese T2DM patients [21]. In our study, we clearly demonstrated that the CM program resulted in improvement in T2DM patients who failed to respond to individual usual care. Of note, our study participants were characterized by long-standing diabetes, complex regimens and a lower educational level, which may strengthen the clinical value of CM. On the basis of the above points, our results supported that CM is an effective DSME program for T2DM patients.

Recently, the rigorous IDEA study reported conflicting results, which may diminish the value of

CM [8]; however, those results should be interpreted with care. In the IDEA study, patients who enrolled into the CM were required complete 4 different visual map sessions (each of 2 hours' duration) within a 4-week period. The process may be too time-consuming for most patients, and some contents of the visual map (e.g., The Nature Course of Diabetes) may distress the participants [22]. In association with the logical difficulty of CM (e.g., less flexibility in scheduling), there were high non-adherence (12.4%) and non-completion rates (28%) in

the CM group in the IDEA study [8], which could hinder the clinical value of CM.

It should be noted that there is no universally effective DSME program that meets all needs. Thus, the method of delivering DSME should take into consideration the resources of the healthcare system and personalized requirements. On the basis of the above statement, it should be noted that DSME trial results should not be used to reject any DSME approach, and healthcare providers should choose an appropriate DSME approach to fit a particular clinical scenario. In the real world of diabetes care, individual DSME remains the mainstream method of delivery of diabetes education, and its efficacy has been examined in detail [8, 10-13]. However, a different approach should be considered when patients with diabetes mellitus fail to achieve further improvement in response to individual DSME. In order to provide a promising solution to bridge the gap between reality and idealism, CM has the advantages of harnessing social norms and providing peer counseling in a more interactive fashion to help patients to develop individual goals [9, 23]. In light of our results, we suggest that CM could be a promising toolkit for T2DM patients who fail to respond to routine individual diabetes care.

The result of participants' higher interest in peer interaction (72%) rather than the program visual maps (7%) was interesting. One unique way in which CM differs from individual DSME is the involvement of peer counseling, based

on self-efficacy and social-learning theory, which inspires participants to identify what could be achieved to improve their daily diabetes care [23]. Thus, the result of only 7% participants chose the visual maps as their most interested material should not be viewed as a downside of CM. After all, it was this illuminated colorful visual maps started and focused all of the participants. Instead, our results demonstrated that it was indeed the atmosphere arising from interactive group discussion that enthused the participants, and indirectly supported our viewpoint that CM should be considered for patients who fail to respond to routine individual DSME. In addition, our results demonstrating that majority of patients benefited from discussion of healthy eating were consistent with the experience of the participants in the IDEA study [22]. This result suggested that the content of visual maps (i.e., "healthy eating and being active" and "starting insulin") was helpful in managing the participants' nutrition issues, even though they had already received education previously. Furthermore, our results also shed light on the fact that CM could motivate long-standing T2DM patients with complex regimens and increase their understanding of the associations between insulin, dietary intake and exercise, leading to higher rates of being active, self-monitoring of blood glucose and insulin injection, accompanied by improvements in the knowledge and behavior of healthy eating and insulin perception.

There were several limitations in our study. First, our results may be questioned owing to the non-randomized study design. However, it should be noted that a non-randomized study design is appropriate for an educational trial which largely depends on the participant's active partition [24, 25]. In addition, the aim of the present study was not to compare the differences between DSME methods, as they haveal ready been proved to be valuable [4, 12, 26, 27]. Instead, the present study was designed to clarify a clinical scenario for healthcare providers in delivering CM. We believe that our results made this viewpoint. Second, our results may be biased, because the CM group may have been more motivated than the usual care group. However, as compared with the history of unchanged glycemic control before the CM program and clinical inertia in the glycemic control and regimens of the usual care group, we believe that our results also demonstrated that CM could be an encouraging solution for these persistently poorly-controlled T2DM patients. Despite these limitations, our results-were underscored by a statistical power of over 95% according to post-hoc analysis. In addition, instead of complete all visual maps as other studies [5, 7, 8], our study demonstrated that selective delivery of visual maps is clinically applicable and time-saving for a specific target population and health providers. On the basis of the above, we believe that our study willfurther extend the current understanding of CM for use in diabetes care.

In conclusion, our results supported that CM is helpful for poorly-controlled T2DM patients in terms of improving their diabetes care. Moreover, CM could be considered as a promising DSME toolkit, particularly when T2DM patients fail to respond to routine individual care.

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#### Disclosure of conflict of interest

None.

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