Effect of Diabetes Self-Management Education (DSME) with and without Motivational Interviewing (MI) on Glycemic Control among Children and Adolescents with Type 1 Diabetes Mellitus: A Randomized Controlled Trial

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ABSTRACT

Objective: Type 1 diabetes mellitus (T1DM) is a chronic disease that is difficult to control. Motivational interviewing (MI) is a collaborative style of communication that was designed to strengthen a person's motivation and commitment to change and improve. We hypothesized that applying MI to diabetes care would lead to improved glycemic control and improved diabetes self-care behavior.

Materials and Methods: Subjects were T1DM patients aged 10-18 years with HbA_{1C} ≥8% that were recruited from the Outpatient Diabetes Clinic during October 2016 - March 2017. Subjects were randomized into the diabetes self-management education (DSME) or DSME plus MI groups. HbA_{1C} levels, diabetes knowledge test, and diabetes self-care behavioral questionnaire were performed.

Results: Thirty-five patients (17 DSME, 18 DSME + MI) completed the study. Baseline HbA_{1C} was not significantly different between groups. At the end of the study, HbA_{1C} levels were not significantly different within or between groups. From pre-intervention to post-intervention, diabetes knowledge scores were significantly increased, and self-care behavioral scores were significantly increased for dietary control and medical taking. Transition to the stages of change *action* stage was increased from 0 to 12 persons.

Conclusion: The effectiveness of MI on glycemic control was not found to be statistically significant at 6 months. However, continuation of DSME in T1DM patients is necessary for improving diabetes knowledge and care. Further study in a larger sample size with longer duration of MI and follow-up is needed to conclusively establish the value of MI on glycemic control in pediatric T1DM.

Keywords: T1DM; motivational interviewing diabetes; self-management education; glycemic control (Siriraj Med J 2021; 73: 635-643)

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INTRODUCTION

Type 1 diabetes mellitus (T1DM) is a complex and chronic disease that requires lifelong insulin injections, psychological support, and lifestyle changes. To optimize glycemic control, regular and frequent self- monitoring of blood glucose (SMBG) is required. Ziegler R, et al. found one additional SMBG per day to be associated with a decrease in HbA_{1c} of 0.20%.[1] Miller KM, el al. also found a higher number of SMBGs per day to be strongly associated with a lower HbA_{1c} level.[2] The numbers of SMBGs per day in the patients at our outpatient clinic[3] was 2.7-3.3 times per day, which are less than the four to six times per day recommended by ISPAD clinical practice consensus guidelines.[4] A possible reason for the inadequate number of SBMGs per day among our patients may be due to the high cost of the glucose test strips. For this reason, in 2015 our hospital organized "The Universal Coverage (UC) provided free glucose strips project for patients with T1DM". However, fifteen months after initiation of this program, HbA_{1C} was improved only in some patients in our clinic.

Another factor in addition to SMBG that contributes to good glycemic control is motivation. Motivational interviewing (MI), which was developed by Miller WR. and Rollnick S., is a proven approach for working through ambivalence and facilitating change of behavior.[5] MI has been widely used in adults to improve control of addictive behaviors, such as reducing illicit drug use[6] and promoting smoking cessation.[7,8] During the last decade, MI has been used in pediatric practice to promote adherence to recommended treatment, including diabetes management with variable results in reducing HbA_{1C}.[9-12]

MI is a brief, goal-directed, patient-centered counseling approach that was designed to help patients increase intrinsic motivation and strengthen commitment to change and improve via the exploration and resolution of ambivalence. Patients are encouraged to develop and recite their own self-motivational statement (SMS) by facilitators. The six stages of change in MI are described, as follows. The initial stage, which is labeled *pre-contemplation*, is when the person is not yet considering change. The next stage is the period of *contemplation*, during which the person evaluates the reasons for and against change. The third stage is when the person reaches a state of *determination* where plans for change are formulated. The person then takes *action* in the fourth stage to effectuate the identified change in behavior. If the change in behavior is successful, the person then moves into the fifth stage, which is a state of *maintenance* to sustain the change in behavior for the long term. The last of the six stages occurs if and when the patient *relapse*, which is defined as a return to any of the previous behavior stages[12]

Thus we conducted a 6-month randomized controlled trial to evaluate the effectiveness of MI on glycemic control, as measured by HbA_{1C}. The primary outcome was HbA_{1C} at the 6-month follow-up. The secondary objective was to evaluate diabetes knowledge and self-care behavior. The secondary outcomes were the scores of the diabetes knowledge test and the self-care behavior questionnaire. We hypothesized that MI would improve glycemic control, diabetes knowledge, and self-care behavior in T1DM patients.

MATERIALS AND METHODS

Design and participants

Following randomization, participants received either diabetes self-management education (DSME) or DSME plus MI. Clinical staff and participants were both aware of the group assignment. Participants were recruited from the Outpatient Diabetes Clinic of the Division of Endocrinology and Metabolism, Department of Pediatrics, Siriraj Hospital during October 2016 to March 2017. Subjects were T1DM patients aged 10-18 years with HbA_{1C} ≥8% that were receiving free glucose strips for at least 3 months. Patients who were receiving medications that effect glycemic control, such as steroids and switching of insulin regimen during this study, were excluded.

Randomization was generated by random permuted blocks with mixed block size. Group allocation results were sealed in sequentially numbered opaque envelopes. The person generated the allocation scheme had no additional role in the study. The protocol for this randomized controlled trial was approved by the Siriraj Institutional Review Board (SIRB) of the Faculty of Medicine Siriraj Hospital, Mahidol University, Bangkok, Thailand (COA no. Si 538/2016). Assent and written informed consent was obtained from patients and their parents/guardians, respectively.

The frequency of SMBG was assessed by downloading glucometer data using accu-check 360º software. The information received were total numbers of SMBG in the past 3 months and average numbers of SMBG per day. Baseline characteristics and diabetes-related data including age, gender, insulin regimen, carbohydrate counting method, diabetes chronic complication, hypertension and dyslipidemia were collected. HbA_{1C} levels were measured prior to entering the study and then at 3 and 6 months after entering the study.

Motivational interviewing (MI)

MI sessions were conducted by 3 interventionists, including 2 pediatric endocrinologists and a pediatric endocrinology fellow) and a diabetes education nurse. All interventionists were trained by experienced pediatric and adult psychiatrists from Department of Pediatrics and Department of Psychiatry, Faculty of Medicine Siriraj Hospital, Mahidol University. The initial training in MI includes hours of lecture, role play, case scenarios, and practicing with actual patients in individual and group sessions. Monthly discussion and supervision among interventionists and a psychiatrist was continued throughout the study.

MI in group session was performed at the beginning of the study, and at 3 months after entering the study. The length of the two MI sessions was 45-60 minutes each. MI by telephone call was performed individually at 1, 2, 4, and 5 months. Session dialogue included awareness building, making choices, alternatives, goal-setting, problem solving, and avoidance of confrontation. During MI sessions, interventionists encouraged patients to express self-motivational statements. The interventionists would respond to patients according to their stage of change. Interventionist responses included giving information and feedback for the *pre-contemplation* stage, discussion about pros and cons of undesired behavior for the *contemplation* stage, giving menu and promoting patient self-efficacy for the *determination* phase, encouraging compliance and adherence for the action stage, relapse prevention for the *maintenance* stage, and recovery process for the *relapse* stage. The MI manual was created by a pediatric psychologist. All MI sessions were documented, and all documentation was reviewed with a psychologist experienced in MI.

Diabetes self-management education (DSME)

DSME in group session was performed at the beginning of the study, and 3 months later in both the DSME and DSME plus MI groups. The session was designed as an interactive lecture and workshop, with a length of 60-90 minutes, and there were 8-10 patients in each class session. DSME consists of a diabetes knowledge component that was performed by physicians and a nurse, and a nutritional component that was performed by a nutritionist. Diabetes knowledge content included basic knowledge about diabetes, self-monitoring blood glucose, exercise with diabetes, hypo/hyperglycemia management, insulin action, sick-day management, and diabetes complications. Nutritional knowledge content included healthy food, carbohydrate-containing food, carbohydrate counting, food-exchange, and nutrition facts. Food models were used for food exchange and nutrition fact practice. Patients were encouraged to participate in class by asking questions, giving examples, and using case scenarios. We also focused on individual problem-solving skills and insulin self-adjustment at home.

Diabetes knowledge test

Diabetes knowledge test was performed at the beginning and end of the study. We modified a multiple choice test using 30 questions from the diabetes knowledge test administered at the Siriraj Diabetes Camp.[13] Questions covered 7 topics, including basic diabetes knowledge, nutritional management and carbohydrate counting, self-monitoring blood glucose, exercise with diabetes, hypo/hyperglycemia management, insulin treatment, and sick-day management.

Diabetes self-care behavior questionnaire

Diabetes self-care behavior questionnaire was given at the beginning and the end of the study. A 38-question standardized questionnaire that was developed by Tachanivate P.[14] was used. The questionnaire covers 8 topics, including personal hygiene care, dietary control, medical taking, physical activity, self-monitoring blood glucose, problem solving, stress management, and reducing risk of diabetes complications. The score was reported as percentage of the mean, which was calculated using the following equation: % of mean = (actual sore/maximum score) x 100. A higher score indicates better diabetes self-care behavior.

Statistical analysis

All data analyses were performed using SPSS Statistics (SPSS, Inc., Chicago, IL, USA). Patient characteristics were summarized using descriptive statistics. Categorical data were compared using chi-square test, and the results are presented as frequency or percentage. Normally distributed continuous data was compared using independent *t*-test, and the results were presented as mean ± standard deviation (SD). Non-normally distributed continuous data were compared using Mann-Whitney U-test, and the results were given as median and range (min, max). A *p*-value of less than 0.05 was considered statistically significant for all tests.

RESULTS

A flow diagram of the study protocol is shown in Fig 1. Of the 94 patients who received free glucose strips from the UC program, 39 were eligible for this study. Those patients were randomized into either the DSME

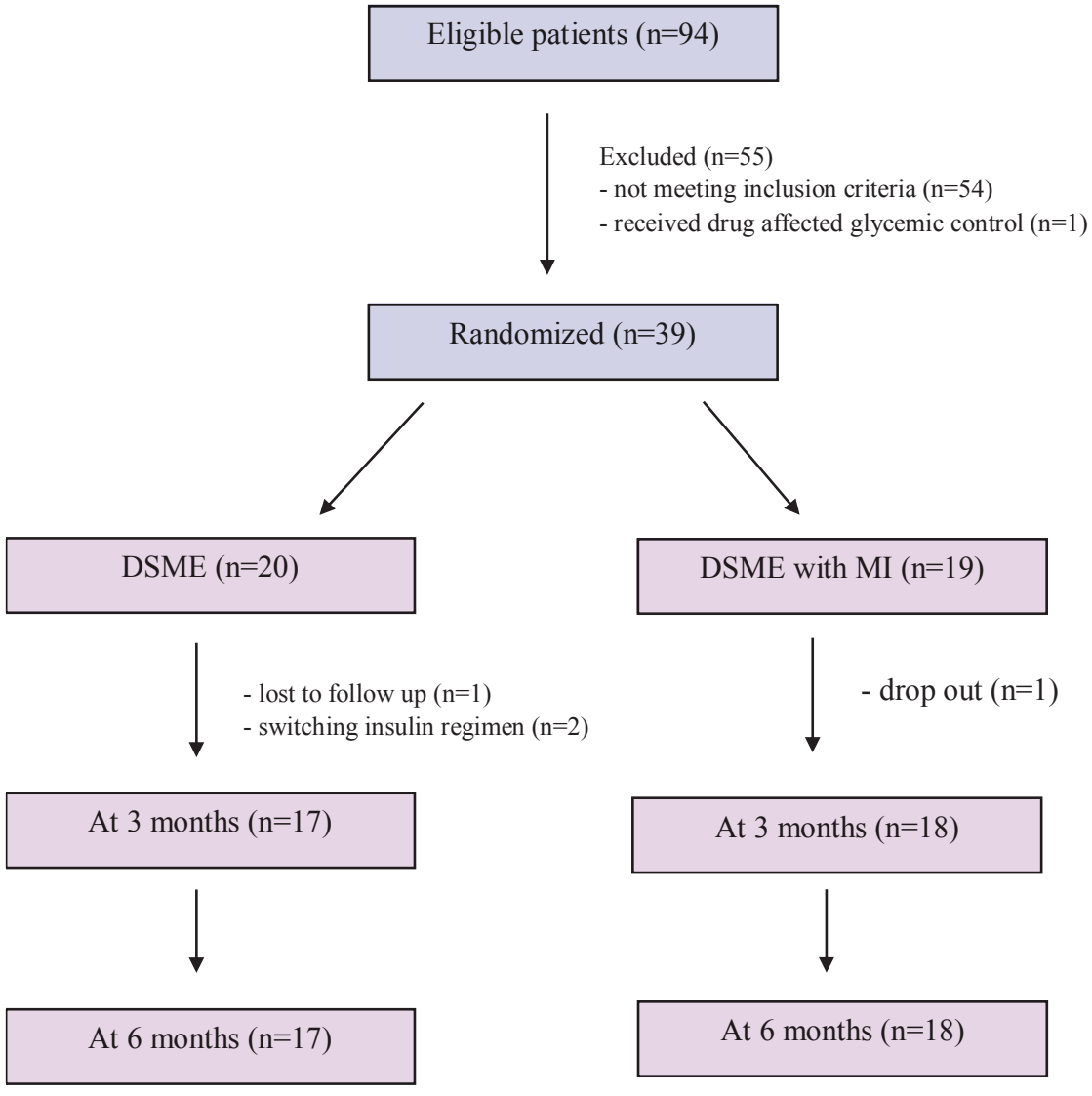

Fig 1. Flow diagram of the study protocol.

group (n=20) or the DSME plus MI group (n=19). One patient in DSME group was lost to follow-up. One patient in the DSME plus MI group declined to participate after randomization, before the first visit. Two patients in the DSME group were excluded due to the fact that they switched insulin regimen during the study. The remaining 35 patients (17 DSME, and 18 DSME plus MI) completed the study.

Demographic characteristics

Patients in the DSME and DSME plus MI groups were well matched for age (14.18±2.02 *vs.* 14.06±2.88 years, respectively), age at diagnosis (8.25±2.86 *vs.* 8.53±3.83 years), duration of diabetes [5.25 (0.83, 13.33) vs. 5.08 (1, 14) years], and HbA_{1c} [10.3% (8.4, 14) *vs.* 9.45% (8, 14.6)]. There were no significant differences between groups for age, age at diagnosis, duration of diabetes, or HbA_{1c}, as shown in Table 1. Counting carbohydrate in grams was 30% and 22%; using basal bolus regimen was 58% and 38% in the DSME and DSME plus MI groups respectively.

Primary outcome: HbA_{1C}

Baseline HbA_{1C} in the DSME and DSME plus MI groups was 10.3 (8.4, 14) and 9.45 (8, 14.6), respectively (p=0.204). At the end of the study, HbA_{1C} in the DSME and DSME plus MI groups was 9.8 (7.4, 16.8) and 9.35 (7.8, 13.2), respectively (p=0.234). No significant difference was observed for HbA_{1C} in each group compared between pre-intervention and post-intervention (Table 2).

Diabetes knowledge score

Diabetes knowledge score compared between baseline and 6 months increased significantly in both the DSME and DSME plus MI groups [19 (7, 24) to 21 (6, 25); p=0.012, and 18.5 (13, 24) to 21 (15, 28); p=0.001 respectively] (Table 3).

TABLE 1. Baseline characteristics.

	DSME (n=17)	DSME + MI (n=18)	*p*-value
Age* (years)	14.18 ± 2.02	14.06 ± 2.88	0.892
Age at diagnosis* (years)	8.25 ± 2.86	8.53 ± 3.83	0.810
BMI * (kg/m^2)	20.70 ± 3.70	20.66 ± 3.04	0.971
Total daily dose* (units/day)	1.26 ± 0.33	1.25 ± 0.35	0.934
Duration of DM**(years)	5.25 (0.83, 13.33)	5.08 (1, 14)	0.766
SMBG** (times/day)	2.00 (0.1, 4)	3.2 (0.07, 4.9)	0.013
HbA1C** (%)	10.3 (8.4, 14)	9.45 (8, 14.6)	0.204
Gender# male/female	10/7	9/9	0.600
Insulin regimen# basal bolus/non-basal bolus	10/7	7/11	0.472
Carbohydrate counting# grams/portion	5/12	4/14	0.627
Lipohypertrophy# yes/no	6/11	6/12	0.903
Diabetic nephropathy# yes/no	1/16	1/17	0.967
Diabetic retinopathy# yes/no	17/0	17/1	0.324
Hypertension# yes/no	0/17	0/18	-
Dyslipidemia# yes/no	8/9	13/5	0.129

* Independent *t*-test; mean ± SD, ** Mann-Whitney U-test; median (min, max), # Chi-square test

Abbreviations: DSME, diabetes self-management education; MI, motivational interviewing; BMI, body mass index.

TABLE 2. HbA_{1c} levels compared between groups at baseline, 3 months, and 6 months.

	DSME (n=17)	DSME + MI (n=18)	*p*-value*
HbA_{1c} at baseline	10.3 (8.4, 14)	9.45 (8, 14.6)	0.204
HbA_{1c} at 3 months	10.1 (7.4, 17.6)	9.35 (7.8, 14.5)	0.095
HbA_{1c} at 6 months	9.8 (7.4, 16.8)	9.35 (7.8, 13.2)	0.234
p-value**	0.813	0.459	

*Compared between DSME and DSME + MI, **Compared between pre-intervention and post-intervention

Data expressed as median (min, max)

Abbreviations: DSME, diabetes self-management education; MI, motivational interviewing

TABLE 3. Pretest and post-test diabetic knowledge test results compared between groups.

	DSME (N=17)	DSME + MI (N=18)	*p*-value*
Pretest score	19 (7, 24)	18.5 (13, 24)	0.816
Post-test score	21 (6, 25)	21 (15, 28)	0.326
p-value**	0.012	0.001	

*Compared between DSME and DSME + MI, **Compared between pre-intervention and post-intervention
Data expressed as median (min, max)
Abbreviations: DSME, diabetes self-management education; MI, motivational interviewing

Self-care behavioral score

The self-care behavioral score was significantly different at 6 months compared between the DSME and DSME plus MI groups for the dietary control domain [48.97 (32.65, 73.47) *vs.* 60.20 (30.61, 77.55); p=0.024], and the medicine taking domain [52.38 (28.57, 78.57) *vs.* 67.86 (47.62, 80.95); p=0.016] (Table 4). There was no significant difference between groups at 6 months for the personal hygiene care, physical activity, self-monitoring, problem solving, stress management, or reducing risk of diabetes complications domains.

Stage of MI

In DSME plus MI group, at the beginning of the study, there was 1 patient in pre-contemplation, 8 in contemplation, 9 in determination, and 0 in the action, maintenance, and relapse stages. At the end of the study, there were 12 patients in the action stage. (Table 5)

TABLE 4. Self-care behavioral score compared between groups post intervention.

Topics	DSME (% of mean)	DSME + MI (% of mean)	*p*-value
Personal hygiene care	71.43 (28.57, 100)	69.04 (33.33, 100)	0.765
Dietary control	48.97 (32.65, 73.47)	60.20 (30.61, 77.55)	0.024
Medication taking	52.38 (28.57, 78.57)	67.86 (47.62, 80.95)	0.016
Physical activity	57.14 (19.05, 90.48)	64.29 (9.52, 85.71)	0.337
Self-monitoring	39.29 (17.86 , 78.57)	51.79 (28.57 , 67.86)	0.068
Problem solving	48.21 (23.21, 78.57)	50.89 (30.36, 71.43)	0.895
Stress management	47.62 (0, 71.43)	40.47 (0, 71.43)	0.640
Reducing risk of diabetes complications	57.14 (35.71, 71.43)	55.36 (35.71, 71.43)	0.973

Data expressed as median (min, max)
Abbreviations: DSME, diabetes self-management education; MI, motivational interviewing

TABLE 5. Stages of change in the motivational interviewing group (n=18).

Stage of Change	Sessions (months)					
	0	1	2	3	4	5
Pre-contemplation	1	1	1	-	-	-
Contemplation	8	6	5	2	-	3
Determination	9	6	3	15	6	3
Action	-	5	9	1	12	12
Maintenance & relapse prevention	-	-	-	-	-	-

SMBG

Baseline SMBG frequency in the DSME and DSME plus MI groups was 2 (0.1, 4) and 3.2 (0.07, 4.9) times/day, respectively (p=0.013). At the end of the study, SMBG frequency in the DSME group and the DSME plus MI group was 2 (0, 4) and 3 (0, 4.7) times/day, respectively (p=0.053). SMBG frequency data was downloaded from the glucometer at baseline, 3- and 6-month time points.

DISCUSSION

We found no significant different in HbA_{1C} between the DSME and DSME plus MI groups at the end of the study, as well as between pre- and post-intervention. Diabetes knowledge score in both groups was significantly increased at the end of study. Self-care behavioral score showed significant improvement in 2 domains (dietary control and medicine taking) in the DSME plus MI group. Transition to the *action* stage increased from 0 to 12 patients, and the transition occurred at approximately 4 months.

T1DM is a complex and chronic illness that requires consistent adherence to treatment, psychological support, and changes in lifestyle. Optimal glycemic control is not easy to achieve, requires commitment to change, and depends on multiple factors. Accurate carbohydrate counting is crucial for precise insulin calculation. The DAFNE Study Group reported significant improvement in HbA_{1C} at 6 months (p<0.0001) after training patients how to match their insulin dose to their food choice.[15] As demonstrated by Spiegel G, et al., T1DM patients overestimated and underestimated carbohydrate content, especially in mixed meals.[16] Moreover, less than half of our patients were counting carbohydrates as grams, not portions (Table 1). Calculating insulin dose according to carbohydrate portion size may yield a loser insulin dose than calculating according to gram weight. This may result in a suboptimal dose of insulin and poor glycemic control. Intensive patient education in carbohydrate counting and encouraging patients to count carbohydrates accurately may result in accurate insulin calculation and improving of glycemic control.

Non-intensive insulin regimen could be a barrier to achieving tight glycemic control. The American Diabetes Association (ADA) recommends that individuals with T1DM receive multiple daily insulin injections (three or more injections per day of prandial insulin, and one to two injections of basal insulin) or CSII.[17] Hathout EH, et al. reported improvement in glycemic control with intensive therapy as compared with conventional insulin regimens.[18] Only 58% and 38% of our patients in the DSME and DSME plus MI groups, respectively, used intensive insulin therapy, so tight glycemic control may be difficult to achieve. Likitmaskul S, et al. reported that Thai patients with T1DM had unsatisfactory glycemic control, with a mean HbA_{1C} of 9.3±2.5%.[19] Achieving good glycemic control in Thai patients may be challenging due to the fact that intensive diabetes treatment requires glucose test strips, and glucose strips are not available to all patients.

At the end of the intervention, the patients in the DSME plus MI group did better in the dietary control and medicine taking domains of self-care behavior than those in the DSME group, however, the HbA_{1C} levels in the DSME plus MI group did not improved. This may be explained by the complexity of diabetes self-care, which requires multiple tasks of management. Their self-care behavior scores in other domains e.g. self-monitoring, problem solving, stress management, etc. were relatively low. No increase in frequency of SMBG and the fact that majority of patients in DSME plus MI group were treated with non-intensive insulin regimen might partly explain the lack of improvement in glycemic control. Moreover,

psychological issue might be another factor. The burden of having type 1 diabetes and the demands in managing daily diabetes-related tasks can lead to negative emotions or diabetes distress and depressive symptoms[20] which can impact the glycemic control.

The duration of this study may have been too short to observe the effect of MI. In the present study, transition to the *action* stage of MI was observed at 4 months, so measurement of HbA_{1C} at 6 months may be too early to observe the effect of action that recently took place. Channon S, et al. conducted a randomized controlled trial that showed significant reduction of HbA_{1C} in the MI group compared to the control group at 12 months and 24 months, but not at 6 months.[21] In our study, HbA_{1C} was not significantly decreased in any comparison. On the other hand, MI may not affect glycemic control. Walter G. suggested that verbal indices of MI to change do not necessarily translate to actual change in response to treatment if the patient does not also have the ability to change, and that patient declarations should be regarded as reflecting the patient's intent to change at that moment as opposed to being considered a predictor of real change in behavior.[22]

Diabetes knowledge score was significantly improved in both groups, which is similar to the finding reported by Santiprabhob, et al. at 6 months post-DSME at diabetes camp.[23] Despite improving of diabetes knowledge score but the HbA_{1C} levels did not improved may be due to the patients know the theory but did not apply the knowledge gained to daily life problem solving. From International Society for Pediatric and Adolescent Diabetes (ISPAD) recommendation and guidelines, educational interventions in children and adolescents with diabetes have a beneficial effect on both glycemic control and psychosocial outcomes.[24] However, it is important to evaluate patients' ability to apply their knowledge to their daily self-care.

The limitations of this study are short duration of intervention, infrequency of motivation intervention sessions and small sample size. Increasing the duration, intensity, and frequency of MI sessions, as well as focusing on individual ambivalence, may have positive impact on MI stage progression and actual change. It should also be considered that our small sample size may have given our study insufficient statistical power to identify all significant differences in HbA_{1C}.

CONCLUSION

In conclusion, this study demonstrated that applying MI to diabetes care does not lead to improvement in glycemic control. However, diabetes knowledge was improved in both groups, and self-care behavior score was improved in some topics. The process and methods for instilling and integrating diabetes knowledge, daily diabetes management, and self-care behavior, as well increasing the patient's intrinsic motivation to change and improve, requires further study. Further study should also include a larger sample size, motivation that is focused on individualized specific issues, and a longer follow-up period.

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