

# Effectiveness of the Mindfulness-Based Diabetes Self- and Family Management Support Program among Adults with Uncontrolled Diabetes: A Randomized Controlled Trial

Nittaya Sukchaisong, Panan Pichayapinyo, \* Sunee Lagampan, Laura R. Saslow, James E. Aikens

**Abstract:** Adults with type 2 diabetes need to master illness self-management to meaningfully sustain behavior change and mindfulness practice may facilitate this process. This study investigated the effectiveness of the Mindfulness-Based Diabetes Self- and Family Management Support Program to improve glycated hemoglobin among Thai adults with uncontrolled diabetes. This program was developed from a literature review, and in-depth interviews with 15 participants who had poorly controlled diabetes and their family members. The Information-Motivation-Behavioral Skills Model and mindfulness approach was used as a framework to develop study intervention. We conducted a randomized controlled trial from September 2018 to March 2019. Eighty adults with uncontrolled type 2 diabetes were randomized to 12 weeks of either the control group who received only usual care (n = 40) or the experimental group (n = 40) who received an intervention in addition to usual care. Glycated hemoglobin, fasting blood glucose, mindful-eating, self-efficacy, dietary consumption, physical activity, and medication adherence were assessed at baseline, week 12 and week 16. Data were analyzed using descriptive statistics, ANCOVA, Repeated Measures ANOVA, and Independent *t*-test.

The findings showed that participants receiving the intervention improved more between baseline and both weeks 12 and 16 in fasting blood glucose and HbA<sub>1c</sub>, appropriate dietary consumption, amount of physical activity, medication adherence, mindful eating, and self-efficacy than those in the control group. Nurses can be trained to implement this intervention program in adults with uncontrolled diabetes. However, more studies with a larger number of community participants are recommended with the application of advanced technology such as mobile health.

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## Introduction

Type 2 diabetes (T2DM) is a chronic disease representing a major cause of death and disabilities worldwide. Glycemic control with improving glycated hemoglobin (HbA<sub>1c</sub>) to less than 7% is the target and can reduce long-term complications.<sup>1</sup> Evidence shows

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that improvement of HbA<sub>1c</sub> is associated with successful behavior changes including eating a healthy diet, and increasing physical activity.<sup>2-3</sup> Cradock et al. in a meta-analysis of behavior change techniques (BCT) found 13 studies demonstrating that combined diet and regular physical activity interventions and lead to a significantly reduction in HbA<sub>1c</sub> (> 0.3%).<sup>4</sup> Noticeably, low carbohydrate intake such as vegetables, and whole grain, non-starchy foods, as well as foods higher in fiber and lower in glycemic load has demonstrated HbA<sub>1c</sub> reductions of 0.3-2%.<sup>1,5</sup> Likewise, aerobic exercise showed a significant reduction of HbA<sub>1c</sub> at 0.30%,<sup>6</sup> and low-to-moderate intensity, and high-intensity resistance exercise can reduce HbA<sub>1c</sub> at 0.23% to 0.61% respectively.<sup>7</sup> These suggested diabetes interventions to promote physical activity and a greater emphasis on dietary habit improvements.

Diabetes self-management education and support (DSME/S) has been recognized as an intervention for behavior changes. A meta-analysis of 20 published randomized control trials (RCTs) with a total of 2,833 participants conducted from 2010 to 2019 concluded that DSME/S intervention showed a significantly mean reduced HbA<sub>1c</sub> by 0.60% among the participants of experimental groups compared with a control group.<sup>8</sup> Mostly, DSME/S interventions include sessions covering disease signs and symptoms, its complications (neuropathy, nephropathy and retinopathy), nutrition, physical activity, medication adherence and glucose monitoring.<sup>9</sup> Strategies capable of improving diabetes management include individual or group education, sharing experiences, increasing skills in problem-solving, self-reinforcement and monitoring, increased self-efficacy, motivation, demonstration and modeling.<sup>4,10-11</sup> Often, modes of delivery are online or by telephone.<sup>12</sup>

Thailand is a middle-income country where the population has undergone significant socio-economic, environmental and lifestyle changes, including the adoption of a more Westernized diet and reduced physical activity. The Thai Ministry of Public Health has launched health promotion programs with the aim of manipulating

behavior changes by enhancing diabetes knowledge and skills to perform health activities.<sup>8,13</sup> Despite available programs on diet and physical activity training, according to the National Survey Medication Research Network of the Consortium of the Thai Medical Schools (MedResNet) in 2018, 86.3% of adults with type 2 diabetes had access to the HbA<sub>1c</sub> test and only 36.5% of adults with diabetes achieved an HbA<sub>1c</sub> level of < 7%.<sup>14</sup> Noticeably, existing programs focus on providing knowledge about the disease and behavioral skill practice. A previous study suggested the need for an intervention focusing on motivation for healthy dietary habits in adults with diabetes to take control over their desired behaviors.<sup>15</sup>

## **Literature Review and Conceptual Framework**

To adopt behavior changes, people need information related to motivation and skill practice.<sup>16</sup> The Information Motivation Behavior Skills (IMB) Model developed by Fisher and Fisher is widely used to identify determinants of behavioral changes among people with chronic conditions.<sup>17-18</sup> The model is composed of three constructs, namely, information, motivation, and behavioral skills. First is the information construct, which includes precise information about specific knowledge, correct use of information, and critical knowledge, to adequately perform management behaviors. Second, the motivation construct, is composed of two components, personal and social motivation. Personal motivation involves attitudes toward a health behavior, which is the feeling that behavior change would be a beneficial to perform and the belief that such changes would be helpful. Social motivation involves people's perceptions regarding support from friends and family members to encourage them to believe in their ability in performing skills that are necessary for behavior changes.<sup>19-20</sup> Third is behavioral skills, which requires well-informed and motivated

people to believe in their own abilities to accomplish the desired behavior.

Related studies have shown that these IMB model constructs provide a successful framework to develop interventions to improve weight loss,<sup>21</sup> medication adherence,<sup>19,22</sup> physical activity,<sup>21</sup> eating behaviors, and HbA<sub>1c</sub> level among adults with type 2 diabetes.<sup>23</sup> Critical knowledge and correct use of information have been associated with health behaviors by enhancing people's understanding of the information that is acquired for change.<sup>24-25</sup> Additionally, most prior diabetes management interventions enhanced personal motivation by more narrowly assisting patients in developing diabetes management skills with confidence.<sup>8,26</sup> Furthermore, strong evidence supports that family members play a crucial role in social motivation, helping adults to control their blood glucose levels, become and remain motivated and generally maintain diabetes management skills to perform healthy behaviors.<sup>27-28</sup> Despite the promising findings from interventions developed based on the IMB model and family support, lasting glycemic control in Thai diabetes populations remains largely unsustainable.<sup>14</sup>

A mindfulness approach has been recognized as a potential practice increasing an individual's awareness as well as skills for behavior changes.<sup>29</sup> This is formally defined as paying close attention to one's current thoughts, feelings, bodily sensations and surrounding environment without judging its value or considering past and future events.<sup>30</sup> Intervention based on mindfulness practices has been effective in lowering people's stress levels, influencing engagement in emotional eating, diabetes self-management and HbA<sub>1c</sub> improvement in adults with diabetes.<sup>31-32</sup> Despite the availability of specific-disease information and source of motivation in the literature, interventions focusing on mindfulness-based skills assisting in behavioral change should be explored according to individual's perception and context. To date, interventions with intensified mindfulness practice with a greater focus on dietary habits among Thai adults with uncontrolled diabetes are limited, with

a growing interest in such practices for behavior changes worldwide.

## Study Aim

This study aimed to develop an intervention using the IMB Model as the basis to identify adults' needs for information and skills as well as perceptions of mindfulness for behavior changes and evaluate whether the Mindfulness-Based Diabetes Self-and Family Management Support Program (MDSFM) could improve behaviors and glycemic level. We investigated the effectiveness of the MDSFM program on mindful eating, self-efficacy for diabetes management, health behaviors, fasting blood glucose, and HbA<sub>1c</sub> among Thai adults with uncontrolled diabetes.

## Methods

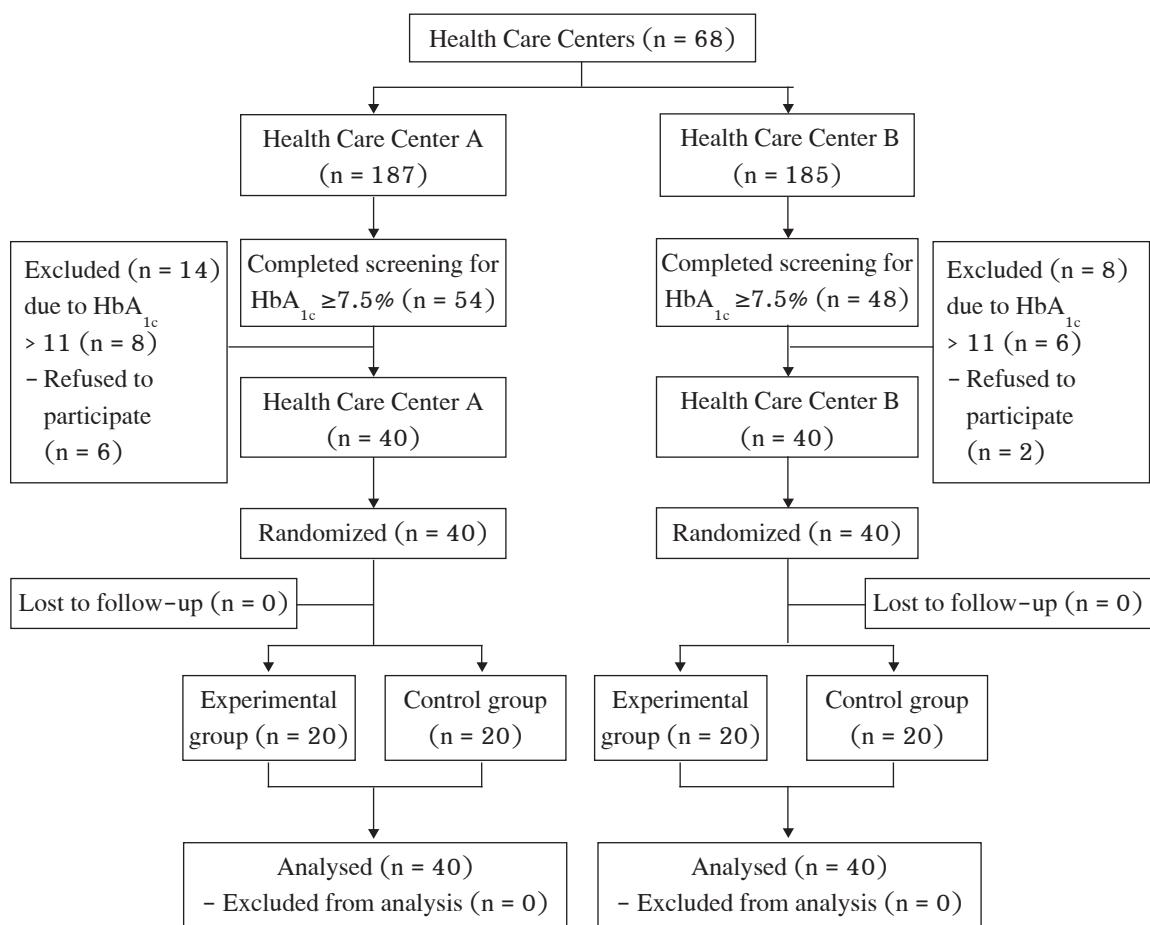
**Design:** This study employed a two-armed, 16-week, randomized controlled trial with baseline and post-intervention, and follow-up assessments. This research report followed the CONSORT 2010 checklist of information to include when reporting a randomized trial.

**Sample:** The sample size was calculated using G\* power analysis software, with power set at 0.8 and an expected (delta) effect size of 0.7 as shown in prior research.<sup>32</sup> With these assumptions and statistical significance set at 0.05 ( $\alpha = 0.05$ ), we estimated that 34 participants were needed per group. After assuming an attrition rate of 20%, our intended sample size was 40 participants per group, or a total of 80 participants. For adults with diabetes, inclusion criteria were being at least 20 years old, poor glycemic control as indicated by the most recent HbA<sub>1c</sub> of 7.5% to 11.0%, and being prescribed only oral hypoglycemic medication. Potential participants were excluded if they were pregnant, on insulin or presented severe complications, such as blindness or stroke. In addition, we withdrew patients from the study if they participated

in < 2 of the intervention sessions. The inclusion criteria for the family members included persons who lived with and had primary responsibility for taking adults with diabetes to see the physician.

**Sampling and setting:** Two health care centers were purposively selected from a pool of 68 health care centers in Bangkok, Thailand. After consent and screening for  $\text{HbA}_{1c}$  eligibility, 54 potential participants out of 187 patients at Health Center A, and 48 potential participants out of 185 patients at Health Center B were identified. Within each health center, the primary

investigator (PI) recruited 40 participants on the day of their appointment and randomly assigned to either the experiment or control group, based upon the alternating weeks of their clinic appointment. At Health Center A, eight did not meet the inclusion criteria and six attended no classes. At Health Center B, six potential participants did not meet inclusion criteria and two attended no classes. No patients dropped out or were withdrawn from the study. A participant recruitment flow diagram is presented in **Figure 1**.



**Figure 1:** Study participant flowchart

**Ethical Considerations:** The study was approved by the Human Subjects Committee at Mahidol University (MUPH 2017-214), and the directors of each involved health care center, all located in Bangkok (U009h/61). Participants signed informed consent documents (read aloud to them) which clearly indicated they were free to decline participation, decline to answer any specific question or withdraw at any time from the study. Information collected through the course of this study was kept confidential and stored securely.

**Research Instruments:** There were two parts of research instruments: six questionnaires to obtain the data, and the intervention program. All questionnaires were initially evaluated by five experts including a physician, a nurse who specializes in the instrumental development, and a nutritionist regarding accuracy of item construct and appropriate wording. Content validity index (CVI) of instruments ranged from .76% to .84%, indicating the instruments measured the content of what was proposed to be measured.

The *Sociodemographic Information Form* was developed by the researchers to collect data from adults with diabetes. It consists of age, sex, marital status, occupation, education level, family income and family composition. Medication variables included illness history, weight, waist and hip circumference, fasting blood glucose (FBG) and HbA<sub>1c</sub> level. For family members, this included age, gender, family relationship, marital status, and occupation.

*Mindful Eating Questionnaire* adapted from Framson et al.<sup>33</sup> was used to evaluate participants' awareness of dietary consumption regarding noticing and attending to food taste and enjoyment. The questionnaire was back-translated into Thai by the research team and two experts in instrumental development, and used with the author's permission in this study. It consists of 14 items with 4-point Likert scales ranging from 1 to 4 (1 = none of the time, 2 = 1 to 2 times/week, 3 = 3 to 4 times/week, 4 = more than 4 times/week). Example of the item was "I notice when there are subtle flavors in the foods I eat." Total

scores range from 4 to 54, with higher scores indicating higher levels of mindful dietary consumption. CVI was .88, and Cronbach's alpha coefficient in the actual study was .78.

*The Diabetes Self-Efficacy Scale* was developed by Ritter, Lorig and Laurent<sup>34</sup> and used to evaluate participants' confidence in performing routine diabetes self-care tasks to control blood glucose levels including dietary consumption, taking medication and physical activity. This scale was used with the authors' permission and was previously translated into Thai by Pichayapinyo et al.<sup>35</sup> It comprises eight items with 10-point Likert-type scales ranging from 1 = not at all confident to 10 = totally confident, with higher scores indicating higher levels of self-efficacy. An item example is "How confident do you feel that you can choose the appropriate foods to eat when you are hungry." CVI was .97, and Cronbach's alpha coefficient in the actual study was .84.

*The Dietary Consumption Questionnaire*, developed by the researchers, was used to measure participants' diet over the past week, including carbohydrates, sugar, fiber, and fat. It contains 12 items with 8-point Likert-type scales. For example, "Over the past week, how much did you eat or drink each of the following types of food including rice, noodles, fried foods, green or non-starchy vegetables and so on." Possible responses ranged from 1 (none of the time) to 8 (more than 6 times/day), with higher scores indicating higher proper dietary habits. The CVI was .93, and Cronbach's alpha coefficient in the actual study was .76.

*The Stanford Leisure-Time Activity Categorical Item (L-CAT)*, developed by Kiernan et al.,<sup>36</sup> was used to evaluate participants' frequency of performing activities over the past week including walking, jogging, dancing and cycling for at least 30 minutes daily and 3 to 5 times weekly. This scale was used with the authors' permission and was translated into Thai by Pichayapinyo et al.<sup>35</sup> It contains a single item, with six descriptive categories ranging from 1 (inactive) to 6 (very active/almost daily physical activity).

Scores range from 1 to 6, with higher scores indicating higher levels of physical activity.

*The Hill-Bone Compliance Scale* developed by Kim et al.<sup>37</sup> was used to evaluate participants' adherence to medication regimens and prescription refills. This scale was used with the authors' permission and was previously translated into Thai by Pichayapinyo et al.<sup>35</sup> It contains 8 items with 4-point Likert-type scales ranging from 1 to 4 (1 = none of the time, 2 = 1 to 2 times/week, 3 = 3 to 4 times/week, 4 = more than 4 times/week). For example, "Do you sometimes forget to take your pills?" Higher total scores indicated higher levels of medication adherence. In this study, CVI was .93, and Cronbach's alpha coefficient in the actual study was .77.

#### **Mindfulness-Based Diabetes Self-and Family Management Support Program**

The Mindfulness-Based Diabetes Self- and Family Management Support Program (MDSFM) was developed based on a literature review, the IMB model and qualitative data from an interviewed convenience sample of 15 adults with poorly controlled diabetes and their family members recruited as key informants. Four different focus group interviews were conducted by the PI in a private conference room with two groups of 7–8 patients each, plus two groups of their family members. The semi-structured interviews focused on participants' interest in diabetes self-management principles and motivation for behavior change, whereas their family members' interviews focused on how they could better support the patients' diabetes self-management. Participants' interviews also explored the role of mindfulness and behavior change. These group interviews tended to last about two hours. All were audio recorded and transcribed verbatim. Content analyses of responses was undertaken by two researchers.

Findings revealed that most participants considered diabetes to be a severe disease that potentially resulted in stroke, amputation or death given chronically high blood glucose levels. Overwhelmingly, they most often reported a perceived lack of sufficient information about diabetes self-management and expressed frustration

with their inabilitys to control their blood glucose. Many participants reported feeling unaware of their prescribed diabetes medication regimen. They sometimes self-adjusted their glycemic doses or did not follow medication prescriptions, depending on their intuition, eating patterns and currently detectable symptoms.

Interestingly, mindful eating was the main issue related to poor self-control among participants. Most related that they were consuming food that was available at home provided by their families, and they could not pay attention to eating when they felt hungry. Moreover, when they had food cravings, they would eat whatever was available without considering its taste or their enjoyment to address their physical hunger and urge to eat.

As expected, family members played roles in providing daily reminders for participants to adhere to their prescribed medication. They also reported trying to motivate them to control their blood glucose levels by convincing them to have more vegetables and engage in healthy physical activities.

From the interview findings, the content and activities of MDSFM program was developed along with literature review. The program comprises six sessions designed to provide knowledge and skill training for disease management including 1) program introduction with an overview of health behaviors, 2) strategies of dietary consumption improvement such as mindful eating techniques, food label, and menu creation, 3) how to adhere medication, 4) strategies for enhancing physical activity, 5) summary of desire health behaviors, and 6) telephone monitoring. At the first and fifth sessions, family members were invited and asked to learn about the disease and desired health behaviors, as well as discuss potential behavior changes with the participants.

Importantly, mindfulness practice with a relaxing breath exercise was performed at the beginning of each session. By emphasizing dietary habit changes, mindful eating was practiced by asking participants to take the time to check in with themselves before eating and learn to enjoy their food even more. Group discussion regarding barriers during the past weeks

was performed for enhancing positive changes in health attitudes and behaviors. The PI mainly facilitated all sessions, and a nutritionist provided nutrition-based knowledge and facilitated practice in reading food label, and menu creation. Participants in the experimental group received printed materials, including behavioral

logbooks to record their diets and physical activity, along with an educational booklet covering diabetes self-management behaviors and mindfulness practice. All materials were prepared by the researchers. The detailed of the program and activities are shown in **Table 1**.

**Table 1:** Program sessions and implementation

<b>Week 1</b>	
<b>Session 1: Program introduction and overview of health behaviors (2 hrs)</b>	
<b>Participants:</b> Adults with diabetes and their family members	
Objectives	Content/activities
1. To engage participants in the study	1. Provide objective and procedures of study
2. To enhance knowledge of type 2 diabetes, and information regarding health behaviors	2. Discuss diabetes and its complications, symptoms of hypoglycemia and hyperglycemia
3. To raise self-awareness	3. Discuss how to perform health behaviors dietary consumption, physical activity, medication adherence, sleep and foot care
4. To set goals for controlling blood glucose	4. Practice mindfulness technique: body scan and slow-paced breathing techniques
	5. Create goals of each behavior
<b>Week 3</b>	
<b>Session 2: Strategies of dietary consumption improvement (2 hrs)</b>	
<b>Participants:</b> Adults with diabetes	
Objectives	Content/activities
1. To remind of mindfulness techniques	1. Practice mindfulness technique: body scan, breathing technique
2. To review behavior changes during the past weeks	2. Assess behavior and discuss the problems of such changes
3. To learn and practice proper dietary consumption methods with dietitian	3. Discuss about type and portion of food intake
	4. Teach and discuss about MyPlate method
	5. Teach how to read food labels
	6. Practice creating healthy menus
4. To raise awareness of dietary consumption	7. Mindful eating techniques
5. To set goals for specific behaviors	8. Revise goal of each behavior if necessary
<b>Week 5</b>	
<b>Session 3: How to adhere to the medication (2 hrs)</b>	
<b>Participants:</b> Adults with diabetes	
Objectives	Content/activities
1. To remind of mindfulness techniques	1. Practice mindfulness techniques
2. To review behavior changes during the past weeks	2. Assess behavior and discuss the problems of such changes
3. To learn how to adhere to medication	3. Discuss tips and tools of management in side-effects, dosing strategies and use of tools (pillboxes)
	4. Discuss problems in behavior changes they have and find means to solve them
4. To set goals of specific behaviors	5. Revise goal of each behavior if necessary

**Table 1:** Program sessions and implementation (Cont.)

<b>Week 7</b>	
<b>Session 4: Strategies for enhancing physical activity (2 hrs)</b>	
<b>Participants:</b> Adults with diabetes	
<b>Objectives</b>	<b>Content/activities</b>
1. To practice concentration techniques	1. Practice mindfulness techniques
2. To review lifestyle changes during the past weeks	2. Assess behavior and discuss the problems of such changes
3. To learn and practice physical activity methods	3. Discuss physical activity type and duration
	4. Choice to enjoy physical activity
	5. Discuss problems in behavior changes they have and find means to solve them
4. To set goals of specific behaviors	6. Revise goals of each behavior if necessary
<b>Week 9</b>	
<b>Session 5: Summary of desire health behaviors (2 hrs)</b>	
<b>Participants:</b> Adults with diabetes and family members	
<b>Objectives</b>	<b>Content/activities</b>
1. To practice concentration techniques	1. Mindfulness practicing: Body scan, breathing technique
2. To raise awareness of lifestyle changes	2. Discuss problems of behavior changes
3. To remind of the intervention content	3. Summarize information of the disease and desired health behaviors (dietary consumption, physical activity, and medication adherence)
4. To motivate patients' performing behaviors	4. Share experience and group support for behavior changes
5. To set goals of specific behaviors	5. Revise goals of each behavior if necessary
<b>Week 10-11</b>	
<b>Session 6: Telephone monitoring (10-15 mins)</b>	
<b>Participants:</b> Adults with diabetes	
<b>Objectives</b>	<b>Content/activities</b>
1. To raise awareness of behavior changes	1. Assess dietary consumption, physical activity and medication adherence
	2. Discuss problems of behavior changes
3. To set goals of specific behaviors	3. Revise goals of each behavior if necessary

**Usual care:** All participants in this study were expected to have appointments to see their physicians every three months. During these appointments and before receiving their medication refills, participants received education from a nurse for approximately 15 minutes covering topics such as dietary consumption, medication adherence, physical activity, and mental health. For adults with poorly controlled diabetes or other high-risk indicators, the nurses provided individual counselling for approximately an extra 30 minutes.

**Data Collection:** The study was conducted between September 2018 to March 2019. After randomization

and informed consent, blood samples for glycated hemoglobin and fasting blood glucose were drawn by nurses at their clinics. If glycemic inclusion criteria were met, they then completed self-report questionnaires as baseline data, lasting approximately 30 minutes for each participant. Participants in the experimental group received instructional booklets with behavioral logbooks and participated in the six-session MDSFM program in a separate room at the clinics, in addition to receiving usual care, whereas the control group received only usual care at the clinics' outpatient section. At 12 and 16 weeks, they were asked to complete the same

self-report questionnaires. While fasting blood glucose was collected at baseline, 12 weeks and 16 weeks, HbA<sub>1c</sub> was only collected at baseline and 16 weeks. Eighty participants consented to and completed the study.

**Data analysis:** The Statistical Package for Social Science Program (SPSS) for Windows (Version 23) was used to analyze data. Descriptive statistics including percentage, mean, and standard deviation were used to describe the participants' characteristics, health information and study variables, and the Kolmogorov-Smirnov test was used to assess normal distribution. The Chi-square test was used to analyze differences between groups for categorical data, and Independent samples *t*-tests were used to compare means between the experimental and control groups at baseline, 12 weeks and 16 weeks. Analysis of covariance (ANCOVA) was used to determine intervention effects after

adjusting for baseline scores, with 12- and 16-week scores as dependent variables. Statistical significance was set at *p*-value < .05.

## Results

**General characteristics:** There were no significant differences of all sociodemographic variables between the experiment and the control groups. Most participants had comorbidities such as hypertension and dyslipidemia, and more than one half indicated that their spouses/children were main supportive resources in terms of food preparation and accompaniment to medication appointments. Also, family members were similar in age, gender, education, and family relationship. Most of them were spouse and their children. The details are shown in **Table 2**.

**Table 2** General characteristics of adults with diabetes and family members

Characteristics	Experimental Group (n = 40)	Control Group (n = 40)	<i>p</i> -value
	n (%)	n (%)	
<b>Adults with diabetes</b>			
Gender			
Female	32 (80.0)	31 (77.5)	.79 <sup>a</sup>
Age (years)			
50-65	23 (57.5)	24 (60.0)	
> 65	17 (32.5)	16 (40.0)	
min-max; mean ± SD	51-70; 63.8 ± 5.1	52-70; 63.4 ± 5.2	.73 <sup>c</sup>
Marital Status			
Married	37 (92.5)	31 (77.5)	.08 <sup>b</sup>
Education Level			
Primary School	26 (65.0)	25 (62.5)	.82 <sup>a</sup>
Secondary School	14 (35.0)	15 (37.5)	
Occupation			
Unemployed	27 (67.5)	25 (62.5)	.35 <sup>a</sup>
Family Income (monthly)			
10,000-20,000 Baht (298-597 USD)	33 (82.5)	22 (55.0)	.76 <sup>a</sup>
> 20,000 Baht (> 597 USD)	7 (17.5)	18 (45.0)	
Underlying Diseases/Conditions			
DM with HT	25 (62.5)	28 (70.0)	.63 <sup>a</sup>
DM with HT and Dyslipidemia	15 (37.5)	12 (30.0)	

**Table 2** General characteristics of adults with diabetes and family members (Cont.)

Characteristics	Experimental Group (n = 40)		Control Group (n = 40)	p-value	
	n	(%)	n	(%)	
<b>Duration of Disease (years)</b>					
10–15	35	(87.5)	37	(92.5)	
>15	5	(12.5)	3	(7.5)	
min–max; mean ± SD	10–18; 12.9 ± 2.3		10–20; 12.3 ± 2.3		.23 <sup>c</sup>
<b>Family Members</b>					
Gender					
Male	30	(75.0)	29	(72.5)	.76 <sup>a</sup>
<b>Family Relationship</b>					
Spouse	28	(70.0)	26	(65.0)	.55 <sup>a</sup>
Child	10	(25.0)	11	(27.5)	
Other Relative	2	(5.0)	3	(7.5)	
<b>Age (years)</b>					
35–65	28	(70.0)	25	(62.5)	
> 65	12	(30.0)	15	(37.5)	
min–max; mean ± SD	36–70; 60.8 ± 8.4		37–69; 58.2 ± 10.3		.22 <sup>c</sup>
<b>Marital Status</b>					
Married	36	(90.0)	33	(82.5)	.58 <sup>b</sup>
<b>Education Level</b>					
Primary School	22	(55.0)	25	(62.5)	.73 <sup>a</sup>
Secondary School	18	(45.0)	15	(37.5)	
<b>Occupation</b>					
Unemployed	24	(60.0)	22	(55.0)	.48 <sup>a</sup>

<sup>a</sup>Chi-square test, <sup>b</sup>Fisher's Exact test, <sup>c</sup>Independent *t*-test; SD = standard deviation

**The effectiveness of the program:** Analysis of covariance (ANCOVA) with baseline scores as the covariate was used to evaluate the intervention effects. **Table 3** shows the means and standard deviations of the study variables at baseline, at 12 and 16 weeks with univariate F values as well as *t*-statistics for all pairwise comparisons. ANCOVA score at 12 and 16

weeks revealed that the experimental group had significant improvement of mindful-eating, dietary consumption, perceived self-efficacy, physical activity, and medication adherence than those in the control group (all  $p < .001$ ). None of the study variables showed improvement in the control group.

**Table 3** Means, standard deviations, and intervention effects for study variables

Variable – Group	Baseline (T1)	12 weeks (T2)	16 weeks (T3)	2-Group ANCOVA (F)		t-statistics		
	M (SD)	M (SD)	M (SD)	12 weeks	16 weeks	T2 – T1 <sup>b</sup> M (SD)	T3 – T2 <sup>b</sup> M (SD)	T3 – T1 <sup>b</sup> M (SD)
<b>Mindful eating</b>								
Experiment	30.2(2.4)	36.9(1.8)	38.8(2.0)	32.2*	32.1*	6.6(0.4)*	1.9(0.1)*	8.5(0.4)*
Control	30.3(2.3)	30.9(1.9)	29.9(1.7)			0.6(0.3)	-1.0(0.1)*	-0.4(0.3)
Experiment vs Control <sup>a</sup>	-0.03(0.1)	5.6(1.2)*	8.9(1.2)*					
<b>Self-efficacy</b>								
Experiment	35.2(2.3)	42.6(2.5)	45.6(2.2)	30.1*	8.6*	7.4(0.4)*	3.1(0.3)*	10.5(0.5)*
Control	34.9(2.09)	32.8(1.9)	32.6(1.9)			-2.2(0.2)*	-0.2(0.9)	-2.4(0.2)*
Experiment vs Control <sup>a</sup>	0.2(0.2)	9.8(1.3)*	13.1(1.5)*					

**Table 3** Means, standard deviations, and intervention effects for study variables (Cont.)

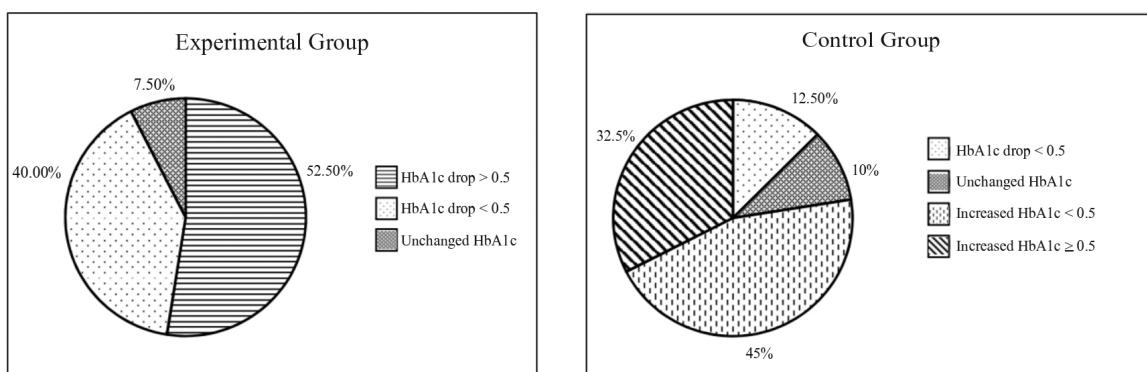
Variable - Group	Baseline	12 weeks	16 weeks	2-Group ANCOVA (F)		t-statistics		
	(T1) M (SD)	(T2) M (SD)	(T3) M (SD)	12 weeks	16 weeks	T2 - T1 <sup>b</sup> M (SD)	T3 - T2 <sup>b</sup> M (SD)	T3 - T1 <sup>b</sup> M (SD)
<b>Dietary consumption</b>								
Experiment	45.5(1.9)	51.3(2.4)	54.2(2.1)	63.2*	63.2*	5.8(0.2)*	2.9(0.3)*	8.7(0.2)*
Control	45.2(1.9)	44.7(2.4)	42.4(2.3)			-0.5(0.3)	-2.3(0.2)	-2.8(0.3)*
Experiment vs Control <sup>a</sup>	0.3(0.2)	6.7(0.8)*	11.8(2.8)*					
<b>Physical activity</b>								
Experiment	12.1(2.8)	17.8(3.7)	18.6(4.2)	40.6*	31.7*	5.6(0.6)*	0.8(0.6)*	6.5(0.7)*
Control	11.2(2.8)	11.0(2.6)	10.7(2.4)			-0.2(0.2)*	-0.3(0.1)*	-0.5(0.2)*
Experiment vs Control <sup>a</sup>	0.9(0.4)	6.8(1.0)*	7.9(1.4)*					
<b>Medication adherence</b>								
Experiment	24.1(1.6)	27.4(1.3)	28.4(1.3)	101.7*	56.6*	3.2(0.2)*	1.0(0.1)**	4.3(0.2)*
Control	23.6(1.8)	23.1(1.4)	22.8(1.3)			-0.6(0.1)*	-0.2(0.1)	-0.9(0.2)*
Experiment vs Control <sup>a</sup>	0.5(0.9)	4.3(0.7)*	5.6(1.3)*					
<b>Fasting blood glucose</b>								
Experiment	134.9(19.6)	132.3(19.3)	131.7(19.1)	689.7*	16293.6*	-2.7(0.6)*	-0.6(0.6)	-3.3(0.8)*
Control	137.6(13.6)	142.2(12.5)	144.2(12.1)			4.6(0.9)*	1.9(1.0)	6.5(1.4)*
Experiment vs Control <sup>a</sup>	-2.6(1.1)	-9.9(1.2)*	-12.5(3.8)*					
<b>HbA<sub>1c</sub></b>								
Experiment	8.4(0.6)		7.8(0.5)		46.3*			-0.7(0.6)*
Control	8.5(0.7)		8.9(0.8)					0.5(0.7)*
Experiment vs Control <sup>a</sup>	-0.1(0.8)		-1.1(0.8)*					

\* $p < .001$ ; ANCOVA = Analysis of Covariance; <sup>a</sup>Independent *t*-test; <sup>b</sup>paired *t*-test

When compared with baseline, the mean scores for fasting blood glucose in the experimental group significantly decreased by 2.7 mg/dL ( $SD = 0.64$ ) mg/dL at 12 weeks and 3.3 ( $SD = 0.8$ ) mg/dL at 16 weeks ( $p < .001$ ). Furthermore, HbA<sub>1c</sub> levels improved by 0.7 % at 16 weeks. At 16 weeks, the mean FBG and HbA<sub>1c</sub> in the experimental group had statistically significantly greater improvements than those in the comparison group ( $p < .001$ ). When compared to those in the control

group, the average glycated hemoglobin level in the experimental group was decreased by 1.1%, and fasting plasma glucose was decreased by 12.5 mg/dL.

As shown in **Figure 2**, approximately 92.5% of participants in the experimental group had decreased HbA<sub>1c</sub> and 52.5% of those reduced at least .5%, whereas 77.5% of those in the control group increased HbA<sub>1c</sub>. No participants in both groups showed a change in medication dosage during the study.

**Figure 2** Changes in HbA<sub>1c</sub> level in the experimental and control groups

## **Discussion**

The MDSFM program is considered an effective program for lowering the HbA<sub>1c</sub> level. The reason might be that the participants improved greater behavior changes such as dietary habits and active physical activity than those in the control group. In the study, participants were encouraged and set goal to consume high fiber, low carbohydrate diet, and low sugar as well as performed regular physical activity at the end of each session. Our findings are supported by the study of Furukawa et al,<sup>38</sup> who indicated that dietary changes and regular physical activity are effective in HbA<sub>1c</sub> improvement. Also, performance to overcome barriers was discussed with family members at the beginning and in the fifth session, and group support was provided throughout the session.

There was significant improvement in mindful eating, dietary consumption, self-efficacy, physical activity, and medication adherence among participants who received the MDSFM program. These findings are consistent with the study conducted by Meunier et al. supporting the IMB model in that information, motivation, and behavioral skills can promote behavior changes.<sup>39</sup> With the long-term treatment and multiple required behavior change, adults with uncontrolled diabetes should have both disease management information and self-awareness when performing such behaviors, as well as the skills to do so. In the present study, practicing the MyPlate method and reading food labels might make participants understand how to eat healthy food and could do it appropriately. Participants were taught and practiced simply to pay attention to what was occurring in their mind and bodies, to more quickly regain their balance and to bring themselves back to a calm state at the beginning of each session. Also, mindful eating was included as an intensified practice by enhancing self-observation of physical hunger and food cravings and we believed that this reduced stress/emotional eating, as suggested by Mason et al.,<sup>29</sup> Lattimore et al.,<sup>31</sup> and Stanszus et al.<sup>32</sup>

Perceived self-efficacy was significantly higher among the participants in the experimental group, which was in line with prior research findings and a meta-analysis of 739 cross-sectional research that increased self-efficacy is linked to improved diabetes education, competence in managing their illness condition and HbA<sub>1c</sub> improvement.<sup>40</sup> In this study, we initially started by assessing participants' knowledge and discussing their self-management behaviors before providing educational and skills practice sessions every week with the purpose of enhancing their confidence to perform desired behavior because the IMB model indicated that information was important in acquiring skills and ultimately resulting in behavior changes. According to Bandura,<sup>41</sup> perceived greater confidence to perform behavior impacts activity options and people's motivation to perform such behavior; that is, the greater the perceived self-efficacy, the higher the influences on people's motivation to pursue desired behaviors and adhere to such behaviors.

## **Limitations**

Although the MDSFM program was probably sufficiently simple for most people to understand, and the plate method and mindful eating practices were appropriate strategies for participants in the study, there are many limitations for generalization in this study. First was the participants' characteristics, that is they tended to be over 60 years of age with low education levels so the findings may be unsuitable for application to adults with diabetes who are younger or higher educated. Secondly, this study was conducted in urban Bangkok, the capital of Thailand. In light of the distinct differences in lifestyles between rural and urban/suburban areas, further study should be conducted in different contexts to confirm and extend the results.

## **Conclusion and Implications for Nursing Practices**

The IMB model and mindfulness practice benefit in guiding intervention development to promote

engagement in behavior changes. Engagement in care with understood symptoms and sets of behaviors needed for change and affective influences of disease management from family members should be persistently promoted. Also, findings indicated that self-management motivation with practicing mindfulness skill could facilitate the process of taking control over desired behaviors in adults with diabetes.

The MDSFM program may serve as a program for nurses' in diabetes clinics with special training in the mindfulness approach. Using the IMB model to identify problems of adults with diabetes and their family members in self-management would help nurses understand the unique needs of this group and how to support them in behavior changes and glycemic control. Also, our findings suggest that promoting mindful-eating skill practice can enhance their self-awareness of hunger, fullness, cravings and triggers for eating. Although mindfulness is rooted in Buddhist religious practices, all participants did not know how to apply mindfulness to change behaviors. Thus, nurses should be trained to practice and become familiar with the method before implementing the intervention in adults with diabetes. Future studies with a larger number of participants to confirm the findings are recommended, and extending this research with mobile health application is suggested.

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## ประสิทธิผลของโปรแกรมการจัดการตนเองด้วยสติและการสนับสนุนของครอบครัวในผู้ป่วยโรคเบาหวานที่ไม่สามารถควบคุมระดับน้ำตาลในเลือดได้: การวิจัยแบบสุ่มและมีกลุ่มควบคุม

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**บทคัดย่อ:** ผู้ป่วยโรคเบาหวานชนิดที่ 2 จำเป็นต้องจัดการกับภาวะโรคด้วยตนเองเพื่อให้เกิดการปรับเปลี่ยนพฤติกรรมสุขภาพอย่างยั่งยืนและการฝึกสติอาจเป็นวิธีที่เอื้อต่อกระบวนการจัดการโรคได้ การศึกษาที่มีวัดถูกประสงค์เพื่อทดสอบประสิทธิผลของโปรแกรมการจัดการตนเองของผู้ป่วยเบาหวานที่ไม่สามารถควบคุมระดับน้ำตาลในเลือดได้ ซึ่งโปรแกรมนี้พัฒนาจากการทบทวนวรรณกรรมร่วมกับการรับฟังความคิดเห็นของผู้ป่วยเบาหวานจำนวน 15 คนและสมาชิกครอบครัว การทดลองแบบสุ่มและมีกลุ่มควบคุมนี้ทำการศึกษาระหว่างเดือนกันยายน 2561 ถึง เดือนมีนาคม 2562 โดยใช้รูปแบบการให้ข้อมูล การสร้างแรงจูงใจและทักษะพฤติกรรมร่วมกับวิธีการฝึกสติเป็นกรอบแนวคิดในการพัฒนาจิกรรม กลุ่มตัวอย่างเป็นผู้ป่วยโรคเบาหวานที่ไม่สามารถควบคุมระดับน้ำตาลในเลือดได้และรับการรักษาด้วยยาจำนวน 80 คนและถูกสุ่มเข้าเป็นกลุ่มที่ได้รับการดูแลตามปกติ (40 คน) หรือเข้ากับกลุ่มทดลอง (40 คน) ที่ได้รับโปรแกรมที่มีจิกรรมการจัดการโรคเบาหวานด้วยตนเองและการฝึกสติขณะรับประทานอาหาร ทำการประเมินค่าน้ำตาลสะสมในเลือด ระดับน้ำตาลในเลือด การรับประทานอาหารด้วยสติ การรับรู้ความสามารถของตนเอง การรับประทานอาหาร การออกกำลังกายและ ความร่วมมือในการรับประทานยา ในสัปดาห์แรก สัปดาห์ที่ 12 และ สัปดาห์ที่ 16 และวิเคราะห์ข้อมูลด้วยสถิติเชิงพารณนา ANCOVA, Repeated Measures ANOVA และ Independent t-test ผลการศึกษาพบว่ากลุ่มทดลองที่ได้รับโปรแกรมมีระดับน้ำตาลในเลือด ค่าน้ำตาลสะสมในเลือดลดลง มีการรับประทานอาหารอย่างเหมาะสม เพิ่มการออกกำลังกาย เกิดความร่วมมือในการรับประทานยา การรับประทานอาหารอย่างมีสติ และการรับรู้ความสามารถของตนเอง ในสัปดาห์ที่ 12 และสัปดาห์ที่ 16 ดีกว่าเมื่อเปรียบเทียบกับสัปดาห์แรกและกลุ่มควบคุม พยาบาลควรได้รับการฝึกการดำเนินกิจกรรมในผู้ป่วยโรคเบาหวานที่ไม่สามารถควบคุมโรคเบาหวาน การศึกษาครั้งต่อไปควรเพิ่มจำนวนกลุ่มตัวอย่าง ที่สำคัญอุปกรณ์ชุดชั้นตัวยการประยุกต์ใช้เทคโนโลยีขั้นสูง เช่น อุปกรณ์สื่อสารเคลื่อนที่สำหรับการดูแลสุขภาพ

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