

Effects of a mobile health diabetes self-management program on HbA1C, self-management and patient satisfaction in adults with uncontrolled type 2 diabetes: a randomized controlled trial

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Abstract

Purpose – This study aimed to examine the effects of a three-month mobile health diabetes self-management program (MHDSMP) on glycemic control, diabetes self-management (DSM) behaviors and patient satisfaction in adults with uncontrolled type 2 diabetes (T2DM) in Thailand.

Design/methodology/approach – This was a three-arm, parallel-group, randomized controlled trial among 129 adults with uncontrolled T2DM who attended the medical outpatient department in a medical center. The participants were randomly assigned to the three study groups ($n = 43$ per group), including MHDSMP, telephone follow-up (TF) and usual care (UC). MHDSMP encompassed four components, including DSM engagement, DSM mobile application, motivational text messages and telephone coaching. Outcomes were evaluated at three-month end-of-study by using HbA1C and response to the Summary of Diabetes Self-Care Activities (SDSCA) and the Client Satisfaction Questionnaire (CSQ-8). Data were analyzed by using descriptive statistics and multivariate analysis of covariance (MANCOVA).

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Conflict of interest: The authors declare that they have no conflict of interest regarding the publication of this paper.



Findings – The findings revealed that at the end-of-study, HbA1C decreased from 7.80 to 7.17% ($p < 0.001$) in MHDSMP group, from 7.72 to 7.65% ($p = 0.468$) in TF group, and from 7.89 to 7.72% ($p = 0.074$) in UC group. Significantly higher SDSCA and CSQ-8 scores were also observed in MHDSMP compared to TF and UC groups ($F = 12.283$, $F = 19.541$, $F = 8.552$, $p < 0.001$, respectively).

Originality/value – This study demonstrated that MHDSMP adjunct with usual care is beneficial for patient outcomes in adults with uncontrolled T2DM in Thailand, compared to TF and UC groups.

Keywords Adults, Glycemic control, Mobile health, Self-management, Type 2 diabetes, Thailand

Paper type Research paper

Introduction

Type 2 diabetes (T2DM) is a non-communicable disease which is a serious global public health problem among adults. Diabetes causes many burdensome complications and is the 7th leading cause of death worldwide [1]. It is anticipated that the global prevalence of diabetes will increase from 425 m people in 2017 to 629 m by 2045. T2DM accounts for approximately 90% of all cases of diabetes. In Thailand, diabetes prevalence is rising in parallel to the global trend. Two-thirds of T2DM cases have uncontrolled diabetes (HbA1C > 7%) [2]. According to the literature, glycemic control prevents diabetes-related complications and that helps reduce the burden in the healthcare system and healthcare expenditures [1, 3].

Diabetes self-management (DSM) is acknowledged as an effective method for improving diabetes control [3]. Adults with T2DM have to modify their everyday lifestyle to perform proper DSM for diabetes control. DSM comprises a complex set of behaviors, including dietary, physical activity and medication adherence [3, 4]. However, multinational studies have reported that DSM among adults with T2DM was deficient, resulting in poor glycemic control [4, 5]. The causes of suboptimal DSM include insufficient diabetes knowledge, inadequate patient-healthcare provider communication, lack of motivation, unavailable decision-making resources and competing day-to-day responsibilities [4, 5].

Numerous DSM programs have been implemented to enhance diabetes-related outcomes. Those programs generally used traditional teaching styles, including face-to-face instruction in lengthy sessions [6]. Traditional DSM programs have limitations in attracting adults due to transportation problems, schedule conflicts and the stigma of diabetes [6, 7]. Limited access to diabetes education and support during hospital visits has been reported as barriers to achieve the recommended DSM behaviors and glycemic control [7, 8]. Additionally, print educational material is difficult to carry as a guide for daily decision-making DSM. Although many DSM programs have been conducted [6], uncontrolled diabetes remains prevalent. As such, innovative interventions are needed to improve DSM behavior and diabetes outcomes, especially in cases of uncontrolled diabetes.

Given the widespread access to the Internet and smartphones, a mobile health service has the potential to deliver DSM programs in new ways. The advantage of using modern communication technology is based on a mobile phone's functions and applications, such as providing distance learning, telemonitoring blood glucose, medication reminders, text messages and phone conversation [9]. Many benefits of a mobile health approach for diabetes-related outcomes have been published [9, 10]. However, those approaches have not been adapted to Thailand.

According to the self-management theory [11], six self-management skills, including problem-solving (problem identification, goal-setting and action-planning), decision-making, resource utilization, forming a patient-healthcare provider partnership, taking action and self-tailoring are required for people with chronic conditions. The authors developed a three-month mobile health diabetes self-management program (MHDSMP) based on the self-management theory [11] and the motivation concept [12].

The MHDSMP aimed to provide essential diabetes-related knowledge (e.g. diet, exercise, medications, stress management, hypo-hyperglycemic management, foot care), the six self-management skills and motivation. The authors hypothesized that the MHDSMP could

significantly improve the desired outcomes (HbA1C, DSM behaviors and patient satisfaction) in adults with uncontrolled T2DM compared with telephone follow-up (TF) and usual care (UC) groups over a three-month period.

Methods

Research design

This study is a three-arm, parallel-group, randomized controlled trial. Participants were randomly assigned to MHDSMP, TF or UC group. Study outcomes were measured twice, at baseline and at the three-month end-of-study.

Setting

The study took place from August 2018 to March 2019 at the medical outpatient department in a medical center located in the central region of Thailand. As part of usual care, group-based diabetes education is provided by a multidisciplinary team, and this is offered for persons with poorly-controlled diabetes (HbA1C > 7.0–8.9%). Cases with HbA1C \geq 9% receive an individual DSM consultation.

Study sample

A sample of 129 participants was recruited by the following criteria: age 18–60 years; diagnosed with T2DM; HbA1C 7.1–8.9% \leq 6 months; on a stable diabetes treatment since last visit; had a smartphone with Internet access and were Thai-language literate. The exclusion criteria include prior participation in a DSM program; had a serious illness or undergoing any treatment which would affect diabetes control. The discontinuation criteria include having received individual DSM consultation; or had acute complications, severe disease, surgery or hospitalization.

The required sample size was calculated for multivariate analysis of covariance (MANCOVA) analysis with a power of (β) 0.80, a significance level (α) = 0.05, and an effect size (f) = 0.3 [13], yielding a prescribed sample of 110 subjects. The attrition rate of 18% was added [13]. As a result, the total number of required participants was 129 (43 participants per group).

Ethical considerations

This study was approved by the Institutional Review Board of the university hospital, Thailand (COA. No. Si 237/2018).

Recruitment and randomization procedures

A registered nurse at the study clinic identified cases who met the inclusion criteria. Then the principal investigator (PI) informed them about the study objectives, study protocol, benefits, risks, privacy and confidentiality. Cases then provided signed consent and completed the baseline assessment. Then, they were randomly assigned to one of the three study groups.

In this study, randomization was achieved by using a computer-generated program. The unpredictable, sequenced random numbers were computer-generated by a statistician to randomly allocate participants to one of the three study groups. Allocation concealment was accomplished by placing the allocation assignment in a sealed, opaque envelope prepared by a clinical staff who was not part of the main study.

Data collection procedures

The study protocol

The three study groups include the two intervention (MHDSMP and TF) groups, and the UC group which served as the pure control group. All participants in this study received usual care throughout the three-month program.

UC group

Participants in the UC group received usual care of the study clinic. Usual care includes physician visit, clinical examination, laboratory testing, treatment, health-related advice as needed, and group-based diabetes education.

MHDSMP group

The researchers developed the MHDSMP, which includes four components: DSM engagement, DSM mobile application, motivational text messages and telephone coaching. This program was reviewed by five experts and then implemented by PI. The program was tested for feasibility and practicality with five participants who met the inclusion criteria but did not participate in the main study.

Component 1: DSM engagement. This component aimed to identify participant's DSM problems, and encouraged them to set achievable goals and action plans regarding diabetes control by using the MI approach and problem-solving skills. This was an individual, face-to-face session conducted by PI on the recruitment day.

Component 2: DSM mobile application. The application was installed on participant's mobile phone to deliver diabetes-related knowledge and promoted DSM behaviors. Participants were trained to use it. DSM mobile application consists of the following functions: diabetes-related knowledge through texted content, quizzes and video links, self-monitoring blood glucose, medication reminders and emergency call.

Component 3: Motivational text messages. This component aimed to motivate the participants to keep performing DSM behaviors. Text message was sent twice a week to the participant's mobile phone.

Component 4: Telephone coaching. This component aimed to motivate and follow-up the participant's DSM related to their goals and used the DSM mobile application. The monthly telephone coaching length of 15–20 minutes was provided by PI.

TF group

The researcher developed this competing intervention to compare its effects with the MHDSMP. Monthly telephone follow-up of 15–20 minutes duration was provided by PI, and focused on providing general health information and DSM, if required, throughout the three-month program. Study protocol is summarized in [Table 1](#).

Assessments

The Summary of Diabetes Self-Care Activities (SDSCA) is a self-administered questionnaire developed by Toobert *et al.* [14] to measure DSM behaviors. The SDSCA was translated into Thai and modified to suit the Thai culture by Keeratiyutawong *et al.* [15]. The SDSCA Thai version consists of 19 items encompassing five domains: diet, exercise, self-monitoring, foot care and medication adherence. The SDSCA uses a seven-point Likert scale, where a score of 0–7 refers to the number of days that the participant performed DSM behaviors; potential scores range from 0–133 points. A higher score indicates greater DSM behaviors. Cronbach's alpha coefficient for this study was .729.

The Client Satisfaction Questionnaire (CSQ-8) is a self-administered questionnaire developed by Attkisson and Zwick [16] to measure patient satisfaction. It was translated into Thai by Kongsakon and Jareonsettasin [17]. The CSQ-8 consists of eight items. It uses a four-point Likert scale; potential scores range from 8–32 points. A higher score indicates greater satisfaction. Cronbach's alpha coefficient for this study was .793.

A personal information form was used to obtain participant's demographic and clinical characteristics such as age, educational level, HbA1C and fasting plasma glucose (FPG).

Table 1.
Study protocol

Time	MHDSMP	Study groups TF	UC
Day 1 (Recruitment day)	<i>Component 1: DSM engagement</i> (1) MI approach (2) DSM problem identification (3) Goal-setting and action-planning (4) DSM mobile application installation and training	<i>Baseline assessment</i> <i>Randomly assigned to one of the three study groups</i> Making an appointment in the next four weeks for the telephone follow-up	Making an appointment in the next 11 weeks for the telephone reminder
Throughout the three-month program	<i>Component 2: DSM mobile application</i> (1) DSM mobile application utilization <i>Component 3: Motivational text messages</i> (1) Sent twice a week	–	–
Weeks 4, 8, 11	<i>Component 4: Telephone coaching</i> (1) Monthly telephone call using the MI approach	<i>Telephone follow-up</i> Monthly telephone call	<i>Reminder telephone call</i> only week 11
Week 12		<i>Study outcome evaluation</i>	

Data collection

Participants completed the baseline assessment using the three self-administered questionnaires, including the personal information form, the SDSCA and the CSQ-8.

At the three-month end-of-study, the trained research assistants (who were blinded to the study groups) collected the study outcome data using the SDSCA and the CSQ-8.

HbA1C at the baseline and the end-of-study was collected from the participant’s electronic profile.

Data analysis

The Statistical Product and Service Solutions (SPSS) statistical package version 18.0 (SPSS Inc., Chicago, IL, USA) was used for data analysis. Descriptive statistics (e.g. frequency, percentage, mean, standard deviation) were performed to describe the participants’ demographic and clinical characteristics. Baseline characteristics and the study outcomes among the three study groups were compared using one-way analysis of variance (ANOVA) or the Kruskal-Wallis test. MANCOVA was conducted to examine the difference in mean scores of the three study outcomes among groups. DSM behavior score and receiving group-based diabetes education at baseline were set as covariates. Intention-to-treat analysis was applied in the analysis.

Results

Over the recruitment period, 136 adults with T2DM were assessed for eligibility; seven persons declined to participate due to lack of available time. Of the balance of 129 enrollees in

the study, 122 (94.6%) finished the three-month program, with 41 in MHDSMP, 41 in TF and 40 in UC groups. Three participants (2.3%) (MHDSMP = 2, TF = 1) were removed from the study according to the discontinuation criteria, and four participants (3.1%) (TF = 1, UC = 3) were lost to follow-up. Details of enrollment and retention are shown in Figure 1.

Of 129 participants, 53.5% were male. The mean age was 51.95 (SD 6.22) years old, and 80.6% were married. More than half (57.4%) held at least a bachelor's degree, and 87.6% were employed. The mean duration of diabetes was 7.35 (SD 5.81) years, and 83.7% received oral hypoglycemic agents (OHAs). Over half (54.7%) did not receive group-based diabetes education, and the mean score of diabetes-related knowledge was 8.0 out of 10 (SD 1.46). The mean level of FPG was 161.57 (SD 29.63) mg/dL. The average HbA1C level was 7.78% (SD

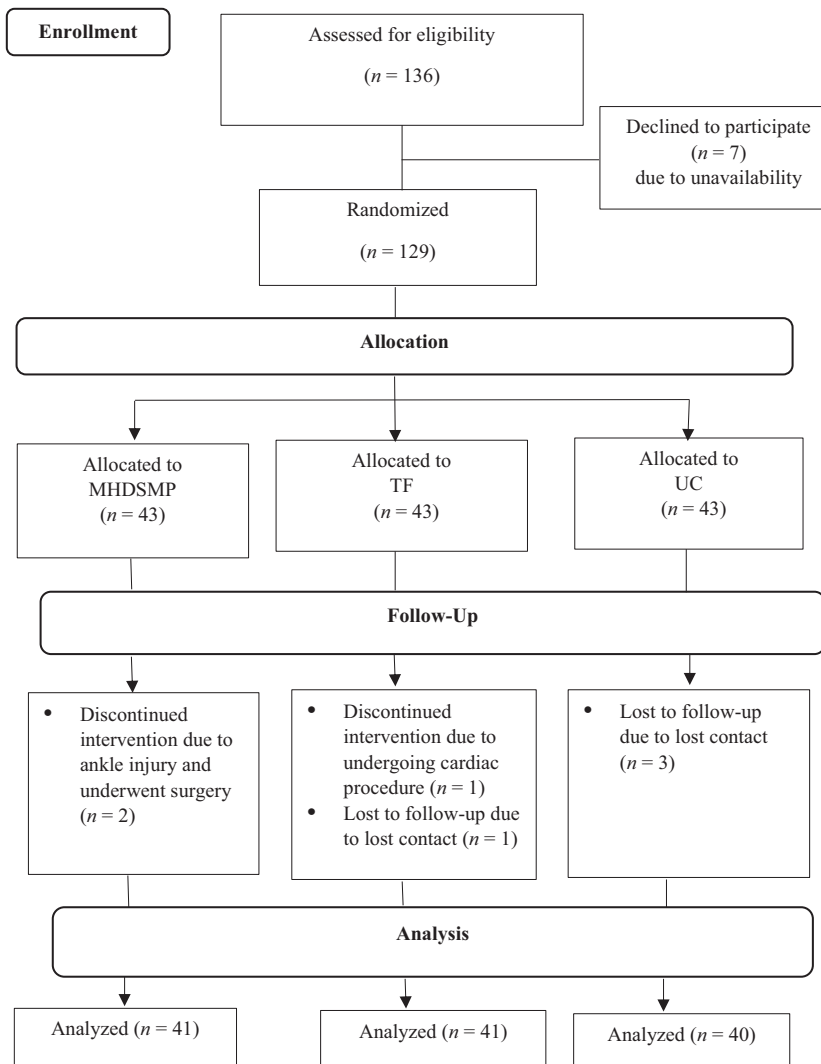


Figure 1. Flow diagram of participant enrollment and intervention

0.51), the mean score of DSM behaviors (SDSCA) and patient satisfaction (CSQ-8) were 83.57 (SD 10.43) and 27.19 (SD 2.63), respectively.

There were no statistically significant differences between the participants' demographic, clinical characteristics and the three study outcome variables among the three study groups at baseline ($p > 0.05$) (Table 2).

Effects of the MHDSMP

The MANCOVA found a statistically significant difference in HbA1C levels, SDSCA and CSQ-8 scores ($F = 12.283$, $F = 19.541$, $F = 8.552$, $p < 0.001$, respectively) among the three study groups (Table 3).

Comparisons of the three outcome variables at the end-of-study

There was a statistically significant difference observed in HbA1C and SDSCA score between MHDSMP and TF groups (MD = -0.49, SE = 0.12 and MD = 10.26, SE = 2.09; $p < 0.001$) and between MHDSMP and UC groups (MD = -0.53, SE = 0.12; and MD = 12.34, SE = 2.13; $p < 0.001$).

Characteristics	Min-max	MHDSMP Mean \pm SD <i>n</i> (%)	TF Mean \pm SD <i>n</i> (%)	UC Mean \pm SD <i>n</i> (%)	F/χ^2	<i>p</i>
<i>Demographic characteristics</i>						
Age (yrs.)	30–60	50.30 \pm 1.11	52.91 \pm 0.79	52.65 \pm 0.88	3.01 ^a	0.222
Gender					5.19 ^b	0.074
Male		25 (58.1)	17 (39.5)	27 (62.8)		
Female		18 (41.9)	26 (60.5)	16 (37.2)		
Marital status					2.27 ^b	0.321
Single		7 (16.3)	3 (7.0)	6 (14.0)		
Married		34 (79.1)	36 (83.7)	34 (79.1)		
Widowed/Divorced		2 (4.7)	4 (9.3)	3 (9.7.0)		
Educational level					0.48 ^b	0.787
High school		16 (37.2)	20 (46.5)	19 (44.2)		
Bachelor's degree		17 (39.5)	13 (30.2)	15 (34.9)		
Master's degree		10 (23.3)	10 (23.3)	9 (20.9)		
Employment					5.24 ^b	.073
Unemployed		2 (4.7)	9 (20.9)	5 (11.6)		
Employed		41 (95.3)	34 (79.1)	38 (88.4)		
<i>Clinical characteristics</i>						
Duration of diabetes (yrs.)	1–30	7.1 \pm 5.64	7.8 \pm 6.43	7.1 \pm 5.44	0.23 ^a	0.892
Diabetes medications					0.34 ^b	0.844
Oral		35 (81.4)	36 (82.7)	37 (86.0)		
Oral and injection		8 (18.6)	7 (16.3)	6 (14.0)		
Received group-based education		21 (48.8)	20 (46.5)	18 (41.9)	0.43 ^b	0.805
Diabetes knowledge	4–10	8.0 \pm 1.41	7.8 \pm 1.63	8.3 \pm 1.31	2.26 ^a	0.323
FPG (mg/dL)	81–257	160.0 \pm 29.41	160.9 \pm 30.83	163.8 \pm 29.19	0.84 ^a	0.660
<i>Study outcome variables</i>						
HbA1C (%)	7.1–8.9	7.8 \pm 0.50	7.7 \pm 0.52	7.9 \pm 0.53	2.33 ^a	0.312
SDSCA	43–107	84.9 \pm 8.24	84.7 \pm 10.72	81.6 \pm 10.52	1.60 ^a	0.449
CSQ-8	23–32	29.2 \pm 2.37	28.4 \pm 2.76	29.6 \pm 2.57	0.93 ^a	0.628
Note(s): ^a = One-way ANOVA (F test); ^b = Kruskal-Wallis test (χ^2 test)						

Table 2. Homogeneity analysis of participant demographic, clinical characteristics and the study outcomes variables at baseline ($n = 43$ /group)

Additionally, there was a statistically significant difference observed in CSQ-8 scores between MHDSMP and TF groups, and between MHDSMP and UC groups (MD = 1.22, SE = 0.46; $p < 0.01$ and MD = 1.89, SE = 0.46; $p < 0.001$). By contrast, there were no statistically significant differences in HbA1C, SDSCA and CSQ-8 scores between TF and UC groups ($p = 0.748$, $p = 0.328$ and $p = 0.153$, respectively). Details are shown in Table 4.

Comparison of the outcome variables between the baseline and at end-of-study among the three study groups

At the three-month end-of-study, for MHDSMP, HbA1C level decreased significantly from 7.80% to 7.17% ($p < 0.001$). SDSCA and CSQ-8 scores were significantly higher, increasing from 84.90 to 97.39 ($p < 0.001$) and 29.22 to 30.41 ($p < 0.01$), respectively.

For TF, only CSQ-8 score was significantly higher at end-of-study than at baseline ($p < 0.001$). For UC, there were no statistically significant differences among all three outcome variables between end-of-study and baseline ($p = 0.074$, $p = 0.417$ and $p = 0.062$, respectively). Details are shown in Table 5.

The analysis shows that the cases who received MHDSMP had lower HbA1C levels, better DSM behaviors and higher patient satisfaction scores than those who received TF and UC regimens, and those differences were statistically significant ($p < 0.01$). Additionally, those who received MHDSMP had lower HbA1C levels, higher DSM behaviors and higher patient satisfaction scores at the end-of-study than at baseline.

Discussion

The results show the effects of MHDSMP on improving HbA1C, DSM behaviors and patient satisfaction. These findings might be explained by the fact that UC and TF groups may lack continuous support to promote DSM behaviors for cases with poor T2DM control. The findings suggest that MHDSMP, through its four components, enabled participants to enhance DSM skill and continuously perform DSM behaviors in their daily life to improve glycemic control.

Table 3. Results of MANCOVA after controlling for the covariates

Outcome variables	Study groups			$F(2, 117)$	p -value	η^2
	MHDSMP ($n = 41$) Mean (SD)	TF ($n = 41$) Mean (SD)	UC ($n = 40$) Mean (SD)			
HbA1C	7.2 (0.45)	7.6 (0.54)	7.7 (0.61)	12.283	<0.001	0.17
SDSCA	97.4 (12.08)	87.0 (11.29)	82.8 (11.54)	19.541	<0.001	0.25
CSQ-8	30.4 (1.25)	29.9 (1.72)	30.2 (2.02)	8.552	<0.001	0.13

Table 4. Comparisons of the three outcome variables at the end-of-study

Outcome variables	Group comparison	Mean difference (MD)	Standard error (SE)	p -value
HbA1C	MHDSMP vs TF	-0.49	0.12	<0.001
	MHDSMP vs UC	-0.53	0.12	<0.001
	TF vs UC	-0.04	0.12	0.748
SDSCA	MHDSMP vs TF	10.26	2.09	<0.001
	MHDSMP vs UC	12.34	2.13	<0.001
	TF vs UC	2.09	2.13	0.328
CSQ-8	MHDSMP vs TF	1.22	0.45	<0.01
	MHDSMP vs UC	1.89	0.46	<0.001
	TF vs UC	0.67	0.46	0.153

Table 5.
Comparison of the three outcome variables between baseline and end-of-study

Characteristics	Baseline (T1) Mean (SD)	End-of-study (T2) Mean (SD)	<i>t</i>	<i>p</i> -value
<i>HbA1C</i>				
MHDSMP	7.80 (0.50)	7.17 (0.45)	6.43	<0.001
TF	7.72 (0.52)	7.65 (0.54)	0.73	0.468
UC	7.89 (0.53)	7.72 (0.61)	1.83	0.074
<i>SDSCA</i>				
MHDSMP	84.90 (8.24)	97.39 (12.08)	-7.00	<0.001
TF	84.71 (10.72)	87.02 (11.29)	-1.73	0.091
UC	81.60 (10.52)	82.83 (11.54)	-0.82	0.417
<i>CSQ-8</i>				
MHDSMP	29.22 (2.37)	30.41 (1.25)	-3.23	0.002
TF	28.44 (2.76)	29.88 (1.72)	-4.82	<0.001
UC	29.58 (2.57)	30.20 (2.02)	-1.92	0.062

According to MHDSMP, the MI approach and problem-solving skills include identifying the participant's DSM problems, setting achievable goals and formulating action plans. This program seemed to provide extra stimulus to motivate cases to perform DSM. The DSM mobile application allowed the participants to use it as a diabetes-related knowledge resource for proper decision-making regarding DSM while they were at home. DSM mobile application also included self-monitoring blood glucose function to monitor participant's blood sugar levels and medication reminder function for improving medication adherence. Motivational text messages and telephone coaching continuously motivated the participants to improve and maintain their DSM behaviors during the three-month program. Together, these four components of MHDSMP worked to promote DSM behaviors and improve glycemic control, resulting in increased participant satisfaction with the health service.

This study's results are congruent with previous studies which found that improved DSM behaviors are associated with enhanced HbA1C levels [6, 8]. This study's results are also consistent with previous studies which found that using MI approach and problem-solving skills can help adults with diabetes to change DSM and achieve glycemic control [8]. Adults with T2DM have to control their behaviors and diabetes, while dealing with their daily chores and obligations. Motivation is accepted as an essential part of DSM program to support people with diabetes in changing and maintaining their DSM. Previous studies have found that motivational approaches via mobile health (e.g. the MI approach and motivational text messages) positively affect DSM and glycemic control. In addition, telephone coaching can provide motivation and useful strategies for enhancing DSM [10, 18].

Furthermore, previous studies have found that mobile health interventions which provide diabetes-related knowledge, medication reminders and self-monitoring blood glucose help adults with diabetes to improve DSM in many ways [7, 10]. Diabetes-related knowledge supports better understanding of diabetes, more confidence to deal with diabetes and better decision-making for daily DSM. Medication reminders prompt cases to take medication on time and that increases medication adherence. Self-monitoring of blood glucose helps cases understand the impact of their lifestyle on blood sugar level and motivates them to improve DSM. These changes lead to improved glycemic control [7, 10].

Additionally, the present study's findings are consistent with a 12-week trial which examined the effect of a diabetes mobile application for T2DM participants and coaching program [9]. In that study, participants used a mobile application containing diabetes education, and they were also encouraged via live coaching. That study found a significant improvement in HbA1C level ($p < 0.001$).

By contrast, this study's findings are inconsistent with another diabetes mobile health study, which used diabetes education and motivational text messaging to participants twice a day for six months. That study found no statistically significant improvement in HbA1C. A possible explanation is that using text messages as one-way communication from healthcare providers without interaction with the participant may not be motivational enough to improve outcomes [19].

In the current study, the patient satisfaction score was statistically significantly higher in both intervention groups (MHDSMP and TF). However, MHDSMP had the highest patient satisfaction score. This finding may be explained by the fact that the participants in this group received the comprehensive intervention of MHDSMP, which supported and motivated them to manage day-to-day DSM and improve glycaemic control. Previous studies have found that patient engagement with mobile health interventions helps them understand disease-related content, improve self-management, increase patient-healthcare provider communication, enhance continuity of care and perceive mobile health's usefulness [10, 20]. However, the result revealed that the participants used the DSM mobile application at a low to moderate level. Some participants reported having difficulty logging-in to the application. Improvement of mobile application accessibility should be explored in further studies.

The current study has a few limitations. First, the MHDSMP was conducted in the tertiary-level hospital to evaluate short-term outcomes. Participants were adults with T2DM who had an HbA1C level ranging from 7.1–8.9%. Those factors might limit the generalizability of the study findings to persons who have different characteristics. Additionally, this study provides evidence that MHDSMP is an effective program to improve HbA1C, DSM behavior and patient satisfaction in adults with uncontrolled T2DM in Thailand. Healthcare providers should deliver the MHDSMP to improve diabetes-related outcomes in the Thai population. Further studies which use a longer time period of implementation, at a larger scale, across diverse healthcare levels, with cases at different HbA1C levels and age groups are required to more comprehensively assess the effectiveness of MHDSMP on diabetes outcomes.

Conflicts of Interest: None

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