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THE EFFECT OF SKT3 MEDITATION EXERCISE TO CONTROL HbA1c LEVEL OF TYPE2 DIABETES MELLITUS PATIENTS

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ABSTRACT

Background: Medical treatment of Type 2 Diabetes Mellitus is not always sufficient to achieve HbA1c control. Despite the previous studies on supplementary therapies, we investigated the effects of SKT3 interventions on HbA1c level in type 2 diabetic patients.

Materials and Methods: This is a three - arm randomized controlled trial aimed to evaluate the effect of SKT3 meditation exercise on the change of HbA1c level among type 2 diabetic patients. The 105 voluntary patients were randomly assigned into 2 experiment groups and one control group with equal number of 35. All patients in each group still received standard medical treatment during the study for 16 weeks. In the trial, the experimental group 1 was assigned to practice SKT3 meditation exercise for 30 minutes once a day, group 2 practiced charm meditation exercise SKT1 for 30 minutes once a day and the control group received only standard medical treatment. The HbA1c level of each group was measured 3 times; at the baseline, the 8th and the 16th week of implementation. The mixed linear regression was used to analyse the change of HbA1c.

Result: The results showed that the HbA1c level among SK3 was found lower than SK1 and standard treatment group with statistical significance ($p < .001$).

Conclusion: The study showed that the practice of SKT3 meditation exercise continuously for 16 weeks had the reduction effect of the HbA1c level among the Thai type 2 diabetic patients. Hence, SKT3 should be recommended as an effective supplementary method for controlling the HbA1c.

Keywords: Three-arms RCT, Type 2 Diabetes Mellitus, HbA1c, SKT3 meditation exercise

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1.0 Introduction

Diabetes mellitus is a metabolic disorder which the body is unable to bring blood sugar into cells resulting to hyperglycaemia, which, if prolong persistence could lead to complication of arterial blood vessels such as chronic wound at foot, and gastro-intestinal disorders. These complications and disorders have direct effect not only to the patient's quality of life but also to their families and societies to have big economic burden in caring the patients (World Health Organization [WHO], 2016).

A global number of diabetes mellitus patients have continually increased every year. In 1980 the prevalence of the disease was 4.7 per cent and increase to 8.5 in 2014 with economic value of 458 billion US dollars (WHO, 2015). The number is expected to reach 592 million globally in 2035. (Guariguata et al., 2014). The disease is the fourth leading cause of death which a person dies from diabetes-related causes among every ten deaths. (Kowluru & Chan, 2007)

Diabetes cannot be definitely cured. The goal of treatment must focus on the appropriate measure for controlling optimum level of blood sugar. The goal for controlling blood sugar is fasting plasma glucose (FPG) level should be 90-130mg/dl, or the level of HbA1c less than 7 percent (ADA, 2016). However, the level of HbA1c is much preference for it could reflect how success of blood sugar level has been controlled (The Diabetes Association of Thailand, 2014). The evidence has showed that if the HbA1C level decreased 1 percent could lead to minimize arterial blood vessel complication for 37 percent, foot amputation for 43 per cent, cerebra-vascular complication for 12 per cent, cardio-vascular complication for 14 per cent and DM-related mortality rate for 21 percent (Diabetes Prevention Program Research Group, 2002).

Guideline for caring the patient should begin with the use of medication together with behavioural modifications in food consumption, stress management, and appropriate exercise. There is evidence to supports that behavioural modification is 2-12 times better than using medication in controlling glycemic sugar but most patients has failed to control the blood sugar at standard level mainly due to the improper behavioural modification, which came from the non-responsive advice to patient's psycho-spiritual context. Therefore it is necessary to seek for supplementary medicine to integrate with current therapeutic care to increases efficiency in controlling the glycemic blood sugar (Bonora & Tuomilehto, 2011). The complementary medicine for DM patients can be classified into 2 groups; Biologically Based Therapies and Mind-Body Interventions. Commonly and currently used included Meditation Prayer, herbs and supplements, relaxation techniques, yoka ,Chinese Boxing Dance, etch (Mars & Abbey, 2010; Yeh, Eisenberg, Kaptchuk, & Phillips, 2003; Aljasir, Bryson, & Al-shehri, 2010; Freire & Alves, 2013; Dham, Shah, Hirsch, & Banerji, 2006).However these techniques should be under physician's guides and need further empirical evidence to confirm the effectiveness for the patient's safety and benefit (Sripa, 2005; Naewbood, Sorajjakool, & Triamchaisri, 2012).

Somporn Kantaradusdi-Triamchaisri Technique (SKT) is an alternative medicine of mind-body interventions. It is the product of the integration of knowledge in both meditation and stretch exercise together with the breath in - out. There are now 7 SKT meditation technics for

selecting as complimentary methods for treating patient with some chronic illness including diabetes mellitus (Triamchaisri, Sresumatchai, Amnartsatsue, & Rawiworakul, 2012). Previous studies on the effectiveness of the SKT practice showed that the SKT7 practice for 8 continuous weeks could help controlling glycemic control and HbA1c level among type 2 diabetic patients (Achara, Linchong, & Paradee, 2011; Nawaporn, 2011).

The practice of SKT 1, 2, and 4 for 8 weeks continuously resulted in the lower glycemic level which was found lower in the experiment group than that of the control group with statistical significance. It is also found that the 2 weeks of practicing SKT1 could help in reducing the Postprandial Plasma Glucose (PPG) of the patients by 30 per cent (Chaiopanont, 2009).

However, there is still no reliable evidence to support the effectiveness of the SKT3 practice which is considered the easiest SKT practice and no instrument is needed for the type 2 diabetic patients. This study is therefore, aimed to confirm the effectiveness of the SKT3 practice among type 2 diabetic patients by using randomized controlled trial to evaluate the change of HbA1c level before and after the practice.

2.0 Materials and Methods

2.1. Universe and Sample of the Study

The study was designed as a 16 weeks, three-armed, single blinded randomized controlled trials comprising of two intervention groups and a control group aimed to determine the effect of meditation exercise (SKT3) on HbA1c level among type 2 diabetic patients at Sakon Nakhon Hospital Thailand. The detail of study with final observation was fully explained and all participants gave written informed consent before joining the trial. It was under taken between November 2016 and March, 2017. HbA1c measurement and other tests were carried out at baseline, after 8 weeks and 16 weeks of intervention.

2.2. Participants

The eligible participants were type II diabetes patient obtained from the out -patient clinic of the hospital .They were recruited by purposive sampling according to the following inclusion criteria: male and female, aged 35-65 years, being diagnosed as type II diabetes for 1- 10 years , had HbA1c level exceeding 7 mg/dl , no complications or disorder that could cause trouble or hinder meditation practice program i.e., end stage renal failure, myocardial infarction, heart disease, disability or paralysis, chronic depression, asthma, anaemia or short lived red blood cells disorders, such as thalassemia, and iron deficiency anaemia, pregnancy, physical disability i.e., bent spine retractable leash body that cannot lie down ,sit and stand, psychiatric disorders. The exclusion also covered those who received medication adjustment for managing the increase of blood sugar level, did not comply with the experiment procedure, and unwilling to participate during the intervention at any time.

2.3. Intervention

SKT3 exercise meditation was an innovative meditation practice developed by Somporn Kantharadussadee Triamchaisrin. It composes of 3 steps of body movement with concentrating likewise on respiration. Step 1: The trainee is in sitting position, stretching the legs fully with foots separated slightly, close one's eyes, long and soft inhale. Step 2: Slowly bend head forward, palm hands touch knees, and then gently and slowly move the palms from the knee to the foot ankles with comfortable extension. The arms are stretch fully but in relax extension. Inhale softly and deeply 1 time during moving the hand palms slowly and rhythmically until the end of central finger touches the foot ankles. Stop breathing for 2-3 seconds in lower back stretching position. Step 3: Slowly bend the back backward. The legs are stretched fully and slid palms from the foot ankles passing the lower legs upward to upper legs, bending the head upward in comfortable extent and exhale one time for a round. At this time the body is in upper back stretching position (Somporn, 2009, 2014).

Sham exercise meditation practice uses principle of SKT1 which was also invented by Somporn Kantharadussadee Triamchaisri. The practice of SKT 1 is in a sitting position, by deeply inhale slowly while counting 1, 2, 3, 4 and 5 in their mind, then holding their breath for a moment together with counting 1, 2, and 3 in ones' mind, followed by a slow long exhale while counting 1, 2, 3, 4, and 5 in ones' mind until the end of the respiratory cycle (Somporn, 2009, 2014).

Eligible participants were randomly assigned to receive either one of two interventions or to be in a control group by block randomized allocation process. Eligible participants were randomly assigned to one of the three groups:

Groups 1: SKT3 meditation exercise with standard treatment recommendations once daily for 30 minute continuously for 4 months.

Groups 2: Sham exercise meditation (SKT1) with standard treatment recommendations once daily for 30 minute continuously for 4 months.

Groups 3: Standard treatment as a control group by following standard medication prescription, diet control and exercise, continuously for 4 months.

The follow up was done in three groups by 1) The patients recorded their daily activities under advice and support from the village health volunteer at the community they lived through a home visit every 2 weeks; 2) The assistant researcher made a call to check and monitor the practice once a week to assure the patients continue practicing exercise daily and continuously throughout the study period as being trained.

2.4. Recruitment and attrition

Figure 1 displays the participants' flowchart. Of the total 1,052 diabetic patients who were assessed and met the eligibility criteria, 198 were patients directly invited to participate the intervention program by the researcher and diabetes nurses at the out-patient diabetes clinic during the scheduled appointment .A number of 105 patients accepted the invitation. The

common reasons for declination were; too busy to follow the intervention, felt unsure to complete the practice, unsure to attend the meetings.

In the group1: SKT3, 2 patients (5.7%) dropped out before the 8 weeks of the intervention, two cases had medical treatment adjustment from oral medication to injection, making the remaining 33 patients.

In the group 2: Sham exercise meditation (SKT1), there were also 3 patients (8.5%) dropped out before the 8 week of the intervention, one was hospitalized for managing complication, one had medical treatment adjustment, and one moved to other province, making the total remaining of 32 patients.

In the groups 3 : Standard treatment, there were 3 patients dropped out before the 8 weeks of the intervention, two had complication and being hospitalized, one had to undergo medical adjustment and one had changed the hospital making the total remaining of 32. Therefore there were 97 participants throughout the intervention program; 33 in SKT3 group, 32 in Sham exercise meditation group and 32 in control group.

The main outcome was haemoglobin A1C (HbA1c) measurement at the end of the program and its consequent changes, before, during and after interventions. The HbA1c level was measured by medical laboratory of the hospital and expressed as mg/dl.

The protocol description of this study follows the CONSORT checklist for randomized controlled trials (Schulz, Altman, Moher, & Group, 2010).

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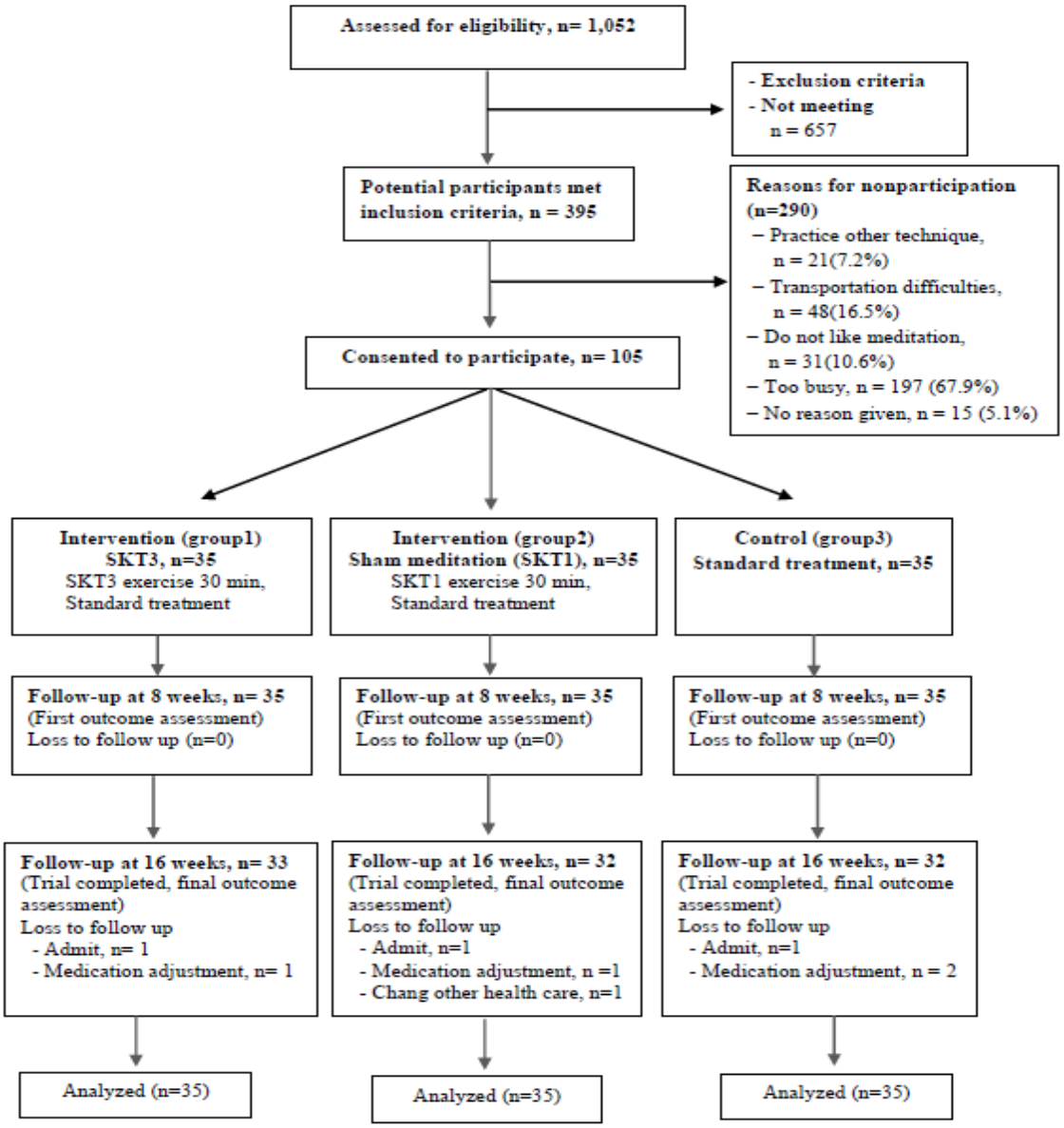

Figure 1: Study flow diagram of patient enrolment, allocation, and attrition.

2.5. Statistical Analysis

Data were analysed using the STATA version 12. The baseline characteristics were described as mean (SD) for continuous variables and percentage for categorical variables. The primary endpoint and secondary endpoints were compared using Chi-square test and one-way ANOVA. The primary endpoint and secondary endpoints were compared between before and after 16 week intervention period in each group, mean differences between groups on HAb1c were calculated using multilevel mixed-effect modelling for repeated measures, adjusting for

baseline values by entering intervention groups, time, and baseline values as covariates. This matches the standard intention-to-treat analytic approach of clinical trials with missing data. Mix linear regression was used for improved/declined in the outcome measures. The level of statistical significance was set at 0.05. Results are presented as mean difference, 95 % Confidence interval (95%CI) and p-value.

Trial registration: Trials Identification Number (TCTR 20141024002).

3.0 Result

The demographic characteristics of the patients among the three groups are shown on table 1, which shows similarities in mean of age, sex composition and other base-line characteristics; BMI, FBS,HbA1C, illness duration and blood pressure, which are considered as risk factors of diabetes.

Table 1: Baseline demographics measurements of 105 diabetes patients recruited in the studies.

Demographics	**Intervention SKT3(n=35)**	**Intervention SKT1(n=35)**	**Control Standard(n=35)**	**p-value**
	Mean(SD)	Mean(SD)	Mean(SD)	
sex				0.735[b]
% Male	28.6	22.9	20.0	
% Female	71.4	77.1	80.0	
Age (years)	54.74±7.18	54.94±7.91	51.74±7.59	0.214 [a]
Illness duration(years)	5.42±3.50	5.91±3.71	4.80±3.47	0.425 [a]
BMI (Kg/m^2)	26.08±3.94	26.08±3.59	24.46±4.44	0.743 [a]
FBS (mg/dl)	164.22 ± 38.52	153.17 ± 26.12	176.91 ± 52.25	0.567 [a]
HbA1c (%)	9.29 ± 1.59	8.50(1.20)	8.90(1.41)	0.068 [a]
SBP(mm/Hg)	133.37 ± 15.81	138.20 ± 21.64	132.14 ± 15.95	0.459 [a]
DBP(mm/Hg)	80.37 ± 10.39	81.88 ± 11.86	78.42 ± 10.84	0.762 [a]

[a] one-way ANOVA; [b]χ2 test; BMI: Body Mass Index; FBS : Fasting Blood Sugar; SBP : Systolic Blood Pressure; DBP: Diastolic Blood Pressure.

The decrease in HbA1c level was found among the three groups, but with different rate. The comparative baseline measurements at the 8th week and 16th week showed highest rate in SKT3 meditation group 1, followed respectively by the sham meditation group (SKT1 group) and the control group, as shown on table 2.

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Table 2: Mean HbA1c (mg/dl) measured at baseline, 8th week, and 16th week of intervention

Variable groups	Mean	SD	95%CI	p-value
SKT3				<0.001*
Baseline (n= 35)	9.29	1.59	8.75 to 9.84	
At Week 8 (n= 35)	8.42	1.70	7.83 to 9.01	
At Week 16 (n= 33)	7.78	1.68	7.18 to 8.37	
SKT1				<0.001*
Baseline (n= 35)	8.50	1.20	8.09 to 8.91	
At Week 8 (n= 35)	8.22	1.27	7.78 to 8.66	
At Week 16 (n= 32)	8.23	1.34	7.75 to 8.72	
Control				<0.001*
Baseline (n= 35)	8.90	1.41	8.41 to 9.39	
At Week 8 (n= 35)	8.76	1.75	8.16 to 9.36	
At Week 16 (n= 32)	8.89	1.64	8.29 to 9.48	

** Significant (p<0.01)*

In addition, the mean difference of HbA1c after intervention among three groups was also different with statistical significance (p < 0.001), as shown on table 3.

Table 3 Mean difference of HbA1c adjusted for baseline after intervention at week 16 based on Mix linear regression**.**

Study Groups	Baseline Mean (SD)	At Week 16 Mean (SD)	Mean Difference		p-value
			Adjusted for baseline	95%CI	
HbA1C					< 0.001***
SKT3	9.29(1.59)	7.78(1.68)	-	-	
SKT1	8.50(1.20)	8.23(1.34)	-0.79*	-1.43 to -0.16	
Control	8.90(1.41)	8.89(1.64)	-0.54**	-1.21 to 0.33	

** SKT1 compare SKT3, **Control compare SKT3, *** significant (p<0.01)*

The changes in HbA1c level from the baseline were found in the three groups but the greatest reduction was showed in the SKT3 group, as illustrated on figure 2.

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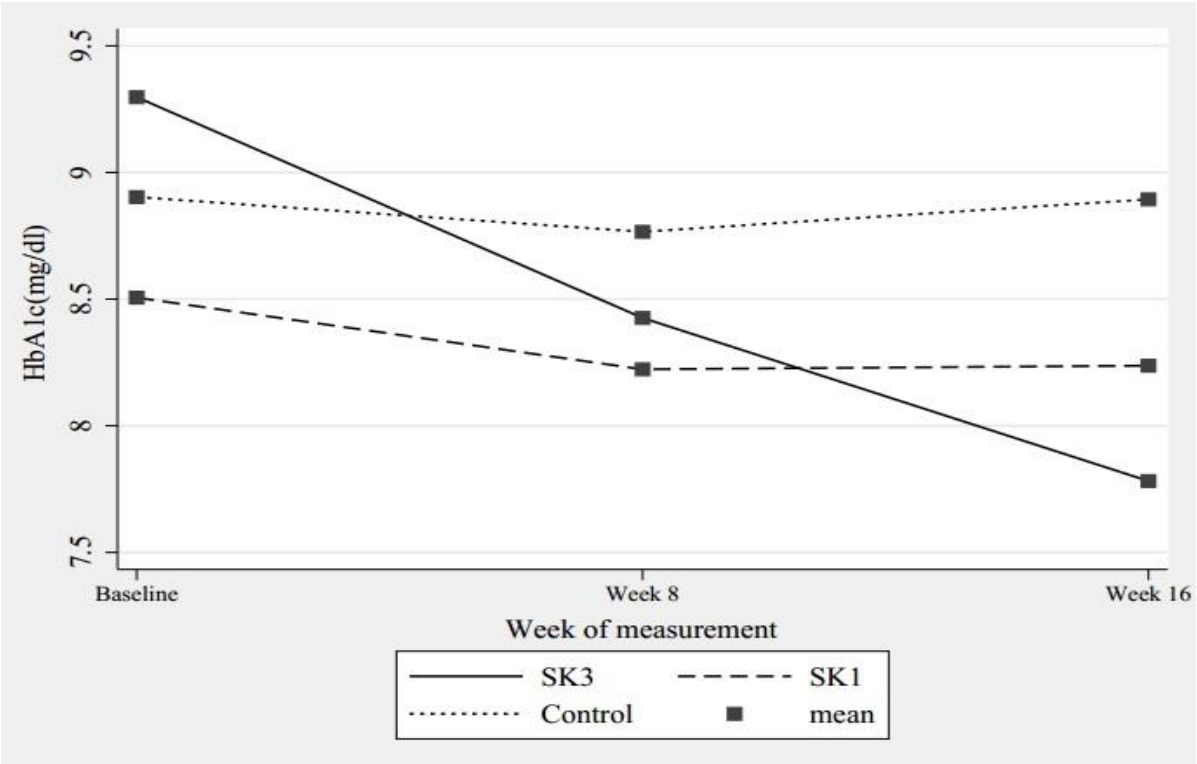

Figure 2: Illustration of the changes in HbA1c concentration of diabetes patients group1 (SKT3), group2 (SKT1) and group 3(standard treatments).

4.0 Discussion

Although this study revealed the decrement of HbA1c level in all groups which was possibly due to the effect of standard treatment received, the different rates of the changes were found. The greatest reduction was shown in the SKT3 group followed by the sham meditation group (SKT1) and the control group, respectively. Since the practice of SKT3 meditation could lead to proper respiratory control resulting in reducing the HbA1c at cellular level if one practices regularly and continuously. The desirable reduction effect was detected as early as at the 8th weeks of intervention and peaked at the 16th weeks. However, standard medication for the patients was still needed. The SKT3 meditation practice is benefit as supplementary sort for speeding up the rate of HbA1c reduction leading to minimize the possibility of developing complication. Therefore SKT3 should be encouraged to practice as a supplementary medical care of diabetes type2 patients.

The findings were similar to other studies. Rosenzweig et.al, for example, studied the effect of practicing mindfulness meditation for 20 -30 minutes per day for 6 days a week. They found that the level of HbA1c was decreased significantly in the 12th weeks (Rosenzweig et al., 2007). Likewise, Karunagari found that the random plasma glucose had decreased after practicing 3 yoga styles with mindfulness meditation for a period of 3 months continuously (Karunagari, 2007). Atchara found that the practice of Qigong (SKT17) for 8 weeks period

among the type 2 diabetic patients could decrease HbA1c with statistical significance (Atchara et al., 2010). In addition, Sompong found that after the type 2 diabetic patients had practiced the Somporn Kantaradusdi-Triamchaisri technique 1 (SKT1) of sitting breathing meditation exercise after breakfast once a week for two weeks, the patients' HbA1c was decreased with statistical significance (Chaiopanont, 2009).

In this study the observatory period of practicing exercise was designed for 16 weeks. The HbA1c level was shown decreased from 9.29 per cent to 7.33 percent or 1.96 percent reduction. Although the reduction did not meet the target of controlling blood sugar level which was set at 7 per cent or less, it showed much greater than other studies. In comparison with the study of Rosenzweig et al. (2007) found that the decrease of HbA1c level was averagely for only 0.48 per cent after the 12 weeks of practicing mindfulness meditation. Also Atchara et al. (2010) Found that the HbA1c reduction was only 0.68 per cent after a period of eight week of the practicing Thai Qigong. Dinardo. (2009) found that the HbA1c reduction was only 0.5 percent after a year period. The better result of this study may possibly result from the design of longer study period, the more frequency of measuring HbA1c level, and continue follow up the participants every week, done by the assistant researchers and the responsible village health volunteers.

The findings confirmed the evidence that the practice of SKT3 regularly and continuously among the type 2 diabetic patients could control blood sugar level better than those who did not practice. The SKT3 practice could help reduction of using medication, lessen risk from adverse effect of the drug to liver and kidney and also reduce patient care cost. Therefore nurses or other health personnel who give care to the type 2 diabetic patients should be trained practicing SKT3 correctly so that they can advise and teach the patients to practice the SKT3 as a supplementary method for more effective control of blood sugar.

5.0 Conclusion and recommendation

The SKT3 meditation practice is benefit as a supplementary sort for speeding up the rate of HbA1c reduction leading to minimization of the possibility of patient complication development. SKT3 should be encouraged for a supplementary health care of patients with type2 diabetes.

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Declaration

Authors declare that there are no conflicts of interest.

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