Impact Of A Thai Holistic Well-Being Program In Medical Outcomes In Type 2 Diabetes: A Community-Based Trial

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Abstract

This study evaluated the effectiveness of the Thai Holistic Well-Being Program (THWP) in improving medical outcomes among patients with Type 2 Diabetes Mellitus (T2DM) in a community setting. With the rising prevalence of T2DM in Thailand, integrating traditional practices into conventional care may offer additional benefits. This study assessed whether a culturally relevant, holistic intervention could enhance health outcomes.

Methods: A randomized controlled trial was conducted with 70 T2DM patients at a community health-promoting hospital in Samutprakarn province, Thailand. Participants were randomly assigned to either the intervention group (n = 35) or the control group (n = 35). The 7-day intervention focused on lifestyle modifications including Ruesi DatTon (Thai physical activity), meditation, dietary adjustments, self-massage, outdoor walking for vitamin D, group sharing, and self-care workshops. Follow-up involved 12 weeks of monitoring through in-person meetings and digital platforms.

Results: The intervention group showed significant improvements in key medical parameters compared to the control group: HbA1c (-0.8%, $p < 0.001$), fasting blood glucose (-20.5 mg/dL, $p < 0.01$), cortisol (-2.5 µg/dL, $p < 0.05$), 25-hydroxyvitamin D (+5.2 ng/mL, $p < 0.01$), and BMI (-0.6 kg/m², $p < 0.05$). These findings highlight the positive impact of the THWP on both metabolic and physical health.

Conclusion: The THWP demonstrated significant improvements in medical outcomes among T2DM patients. This culturally tailored holistic program may be a valuable addition to diabetes management in community settings and has potential for wider application in clinical practice.

Introduction

Type 2 Diabetes Mellitus (T2DM) is a chronic metabolic disorder marked by insulin resistance and hyperglycemia, leading to complications such as cardiovascular disease, neuropathy, and nephropathy (1, 2). Globally, diabetes affects around 537 million adults (2021), projected to rise to 643 million by 2030 and 783 million by 2045 (3, 4).

In Thailand, approximately 11.6% of adults (6.1 million people) had diabetes in 2021 (5, 6). Contributing factors include urbanization, lifestyle changes, and aging. Despite available treatments, glycemic control is often inadequate due to poor adherence to diet and lifestyle

recommendations (7, 8). The economic impact of diabetes underscores the need for accessible and culturally appropriate interventions (9, 10).

Holistic programs targeting physical, mental, and behavioral health—through exercise, stress management, and dietary changes—have shown benefits in glycemic control and quality of life (11, 12). Thai traditional medicine aligns with this model, incorporating Ruesi DatTon, Thai massage, meditation, and herbal diets (13, 14).

The Thai Holistic Well-being Program (THWP) combines traditional practices with health promotion strategies, including Ruesi DatTon, self-massage, walking for vitamin D, mindfulness meditation, herbal dietary changes, and self-care workshops. These address physiological and psychological aspects of T2DM. For example, meditation reduces cortisol, improving glycemic control (15, 16), while vitamin D supports glucose metabolism and immune function (17). Improved sleep quality from mindfulness and physical activity may also support glycemic regulation (18, 19).

Despite growing interest in Thai traditional medicine, few studies have assessed their combined effects in structured diabetes care. This study evaluates the effectiveness of the THWP in improving health outcomes and behaviors among T2DM patients, supporting culturally tailored holistic approaches in diabetes management.

Material and Methods

Study Design

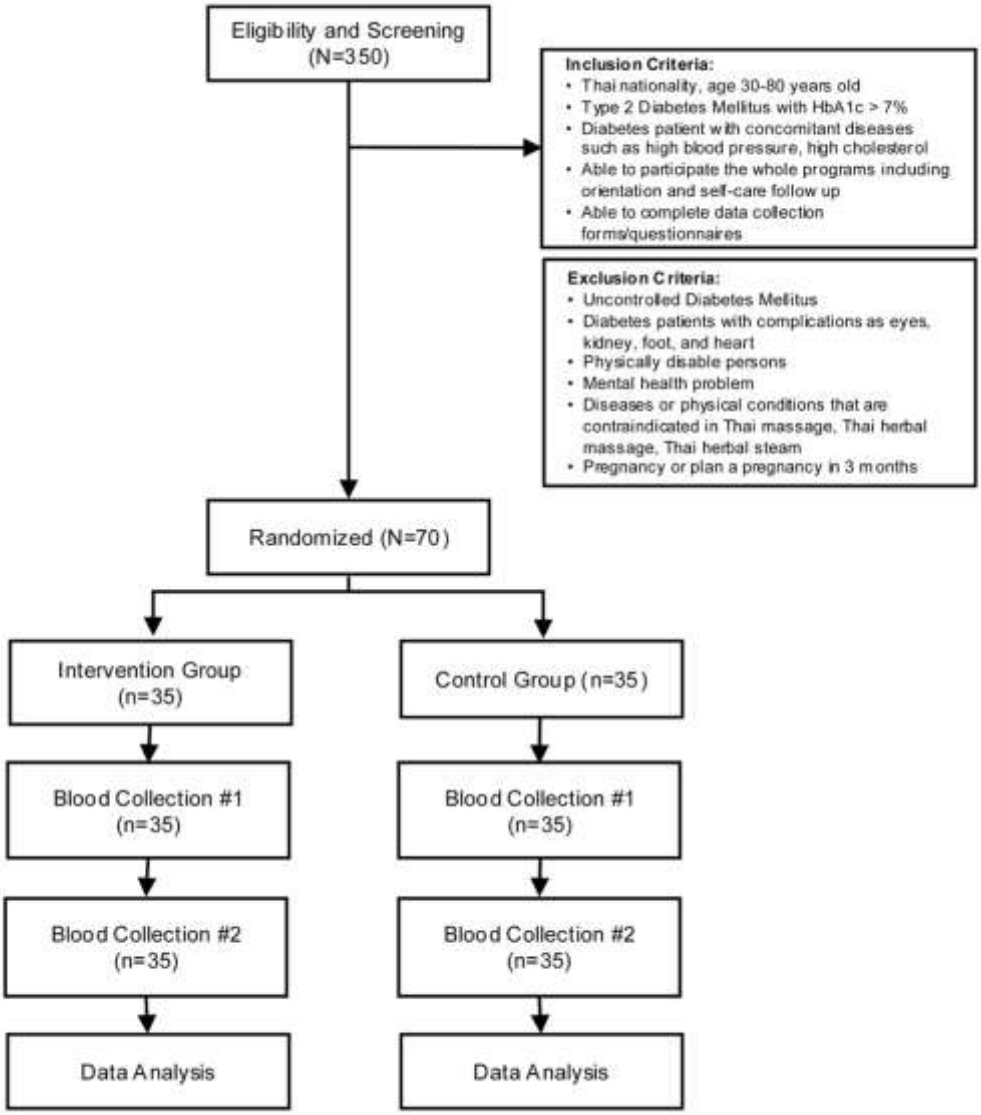
This randomized controlled trial (RCT) investigated the effects of the Thai Holistic Well-being Program on patients with Type 2 Diabetes Mellitus (T2DM). Conducted from June to September 2023 at Bang Pheung Subdistrict Health Promoting Hospital, Samutprakan province, Thailand, the study aimed to assess the intervention's impact on medical outcomes in individuals managing T2DM.

Selection and Recruitment

Participants were recruited from Bang Pheung Subdistrict Health Promoting Hospital. Eligibility screening (30–40 minutes) was conducted by healthcare professionals. Inclusion criteria were Thai nationals aged ≥30 years with T2DM (HbA1c >7%) and comorbidities (e.g., hypertension, hyperlipidemia), able to attend all sessions, complete questionnaires, and use the LINE app. Exclusion criteria included uncontrolled diabetes, complications (e.g., retinopathy, nephropathy), contraindications to massage/herbal therapy, or pregnancy. Recruitment was led by nurses and volunteers. Participants were randomized using a computer-generated sequence with allocation concealment. Group assignment was unblinded due to intervention nature. Independent professionals conducted outcome assessments. To prevent contamination, groups had separate recruitment, data collection, and LINE access.

Figure 1 shows that 350 individuals were screened for eligibility. After applying inclusion and exclusion criteria, 70 participants were randomly assigned to the intervention (n=35) and control (n=35) groups. Due to relocation, 2 participants in the intervention group and 4 in the control group were lost to follow-up. In total, 33 participants in the intervention group and 31 in the control group completed the study and were included in the final analysis. Detailed eligibility criteria are provided in Figure 1.

Figure 1: Participant flow diagram based on the CONSORT guidelines, showing eligibility screening, randomization, and study completion.



Measurement Tools and Medical Parameters

Blood samples were collected at baseline and three months post-intervention to assess HbA1c, fasting blood glucose (FBG), cortisol, Vitamin D (25(OH)D), and body composition. These parameters were monitored to evaluate the Thai Holistic Well-being Program's effects on key health indicators for T2DM management.

The HbA1c levels were analyzed using the V5600 by Ortho-Clinical Diagnostics, with reference ranges of <5.7% considered normal, 5.7–6.4% indicating prediabetes, and ≥6.5% confirming diabetes (2, 20). To estimate the average blood glucose (eAG) levels, the following formula was applied: eAG=(28.7×HbA1c)−46.7. This calculation aids in the clinical interpretation of glycemic control. Fasting blood glucose (FBG) was measured using the Accu-Chek Instant by Roche Diagnostics, with reference ranges of <100 mg/dL as normal, 100–125 mg/dL indicating prediabetes, and ≥126 mg/dL indicating diabetes (2, 21). Cortisol was measured using the V5600 by Ortho-Clinical Diagnostics, with normal morning values ranging from 123–626 nmol/L. Levels <123 nmol/L suggested adrenal insufficiency (22). Vitamin D (25(OH)D) was analyzed using the V5600 by Ortho-Clinical Diagnostics, with values of 30–100 ng/mL considered sufficient, 20–29 ng/mL indicating insufficiency, and <20 ng/mL classified as deficient (23, 24). Body composition was assessed using the OMRON KaradaScan 375, which provided measurements of weight, body fat percentage, visceral fat level, BMI,

skeletal muscle mass, and body age (25, 26). All equipment was calibrated regularly per standard protocols to ensure accuracy.

Intervention

The intervention group participated in a 7-day Thai Holistic Well-being Program aimed at improving health through physical, dietary, and psychological practices. The 7-day duration provided a practical introduction to holistic methods. Key components included:

- **Physical Exercise (Ruesi DatTon)**: Daily Ruesi DatTon, a traditional Thai exercise involving movements and breathing techniques, improved flexibility, reduced stress, and enhanced glycemic control. Ruesi DatTon has been shown to lower blood glucose and improve heart rate variability in diabetes and prediabetes patients (27, 28). Each session lasted 1 hour, led by a licensed Thai Traditional Medicine practitioner with support from health volunteers.
- **Traditional Thai Massage (Self-massage)**: Daily self-massage sessions promoted relaxation, improved circulation, and alleviated muscle tension. Thai massage has been shown to reduce stress and improve well-being in individuals with chronic diseases, including diabetes(29). Participants were trained in self-massage techniques for home practice, with 1-hour sessions.
- **Meditation**: Daily mindfulness meditation, including breathing exercises and postures, aimed at balancing the body and mind, reducing stress, and improving glycemic control. Meditation has been shown to reduce cortisol and improve glycemic control in T2DM patients (30). Each session lasted 1 hour, led by a meditation expert.
- **Dietary Practices**: Participants followed a nutrient-dense Thai dietary plan featuring herbal foods and low-calorie traditional meals shown to support glycemic control and diabetes remission in obese T2DM patients (31). They received education on food choices, benefits, and recipes to promote long-term adoption. Rather than a strict meal plan, they were encouraged to adapt principles daily. Meal diaries and personalized feedback were used during the three-month follow-up. This session lasted 1 hour.
- **Vitamin D Exposure**: Participants engaged in 5–10 minutes of daily sun exposure, tailored to skin type and time of day, to support Vitamin D synthesis, which aids glucose regulation, immune function, and bone health (32, 33).
- **Workshops and Group Activities**: One-hour sessions focused on self-Thai massage, Thai herbal cooking, and traditional health practices to enhance self-care and build motivation through shared learning and community support (34).
- **Group Activities**: Group activities were included to build community support and promote group motivation. Activities fostered peer interaction and shared learning experiences, supporting participants' journey throughout the program. These sessions also lasted 1 hour.

The program ran daily from 9:00 AM to 4:00 PM, with 5–6 hours of active participation, including breaks and lunch. This schedule balanced engagement and sustainability. It was delivered by the research team alongside local healthcare providers, including a Thai Traditional Medicine practitioner and community health volunteers. The control group received standard care, including medical advice and routine appointments.

Follow-up Support (Three-Month Period)

Following the 7-day program, participants entered a three-month self-practice phase, continuing Ruesi DatTon, self-Thai massage, meditation, dietary adjustments, and sun exposure. Support strategies included:

- **LINE App Engagement:** Participants shared daily updates to foster peer support and motivation.
- **Self-Monitoring:** Participants tracked their practice through logs, reviewed during follow-up calls.
- **Expert Support:** The research team offered ongoing guidance via calls and LINE chat to address challenges.

- **Scheduled Check-ins:** Follow-ups were conducted in the 7th and 12th weeks via phone or home visits to assess progress and reinforce participation (only 12th-week data were analyzed).
- **Trained Staff:** All activities were led by trained healthcare professionals and local providers.

Statistics

Data were analyzed using descriptive and inferential statistics. Descriptive statistics summarized categorical data as counts and percentages, and continuous data as means and standard deviations. Chi-square tests compared categorical variables, and independent t-tests compared continuous variables between groups. An intent-to-treat approach was used, including all randomized participants. Changes in primary outcomes (HbA1c, FBG, cortisol, Vitamin D, and body composition) were assessed with non-parametric tests and t-tests for within-group and between-group comparisons, depending on data distribution.

Results and Discussion

Baseline Characteristics

Baseline characteristics were generally comparable between the intervention and control groups, with most variables showing no statistically significant differences (Table 1). However, significant differences were observed in age distribution ($p = 0.017$), cardiovascular disease ($p = 0.027$), and retinopathy ($p = 0.038$), with the intervention group having a higher proportion of older participants and more cases of cardiovascular disease and retinopathy. These differences should be considered when interpreting the intervention outcomes.

Table 1 Baseline Characteristics of Intervention and Control Group in DM patients at Bang Pheung Subdistrict Health Promoting Hospital (N=70)

Characteristic	Intervention (n=35)	Control (n=35)	p-value
Age (years)			
< 50	1 (2.86%)	6 (17.14%)	
50-59	11 (31.43%)	14 (40.00%)	
60-69	14 (40.00%)	11 (31.43%)	
≥ 70	9 (25.71%)	4 (11.43%)	0.017*
Gender			
Male	8 (22.86%)	8 (22.86%)	1.000
Female	27 (77.14%)	27 (77.14%)	
Marital Status			
Married	22 (62.86%)	23 (65.71%)	0.956
Widow/Divorce	8 (22.86%)	7 (20.00%)	
Single	5 (14.29%)	5 (14.29%)	
Religion			
Buddhism	29 (82.86%)	31 (88.57%)	0.733

Characteristic	Intervention (n=35)	Control (n=35)	p-value
Islam	6 (17.14%)	4 (11.43%)	
Education			
Secondary or lower	25 (71.43%)	26 (74.29%)	0.430
High school or higher	10 (28.57%)	9 (25.71%)	
Income			
Enough income	19 (54.29%)	18 (51.43%)	1.000
Not enough income	16 (45.71%)	17 (48.57%)	
Occupation			
Housewife/husband	20 (57.14%)	18 (51.43%)	0.630
Self-employed	8 (22.86%)	6 (17.14%)	
Government officer	3 (8.57%)	5 (14.29%)	
Private company	2 (5.71%)	4 (11.43%)	
Others	2 (5.71%)	2 (5.71%)	
Duration of DM			
Mean (years)	11.43	10.57	0.353
Comorbidities			
Hypertension	27 (77.14%)	25 (71.43%)	0.393
Dyslipidemia	23 (65.71%)	28 (80.00%)	0.141
Cardiovascular	7 (20.00%)	1 (2.86%)	0.027*
Retinopathy	16 (45.71%)	8 (22.86%)	0.038*
Kidney	4 (11.43%)	5 (14.29%)	0.500
Osteoarthritis	13 (37.14%)	7 (20.00%)	0.093
Exercise			
Never	5 (14.29%)	10 (28.57%)	0.474
Rarely (1-2 days/week)	13 (37.14%)	12 (34.29%)	
3 days/week	5 (14.29%)	5 (14.29%)	
4-5 days/week	12 (34.29%)	8 (22.86%)	
Smoking			
Never	33 (94.29%)	32 (91.43%)	0.365
Rarely (1-2 days/week)	1 (2.86%)	0 (0.00%)	

Characteristic	Intervention (n=35)	Control (n=35)	p-value
4-5 days/week	1 (2.86%)	3 (8.57%)	
Alcohol			
Never	27 (77.14%)	31 (88.57%)	0.391
Rarely (1-2 days/week)	7 (20.00%)	3 (8.57%)	
4-5 days/week	1 (2.86%)	1 (2.86%)	

Notes: Values are presented as n (%). p-values were calculated using chi-square tests for categorical variables and t-tests for continuous variables. The chi-square test was used to compare baseline characteristics between the intervention and control groups to ensure comparability at baseline. Indicates statistical significance ($p < 0.05$).

Changes in Health Behaviors

After three months of intervention, the intervention group showed significant improvements in several health behaviors compared to baseline (Table 2). Key improvements included increased vegetable and fruit consumption (mean change = +0.60, p = 0.041), non-salty food choices (+0.89, p = 0.033), and low-fat food choices (+1.23, p = 0.005).

Between-group comparisons highlighted a significantly greater improvement in vegetable/fruit consumption and low-fat food choices in the intervention group compared to the control group. Other behaviors, including coping with stress, smoking cessation, and alcohol cessation, did not show significant differences within or between groups.

Table 2 Differences in Health Behavior from Baseline to 3 Months Post-Intervention

Health Behavior	Intervention		Control		Intervention	Control
	Baseline	3 Months	Baseline	3 Months	p-value	p-value
Exercise/Physical Activities	1.40 (1.52)	1.94 (1.51)	1.11 (1.16)	0.86 (1.14)	0.134	0.331
Vegetable/Fruit Consumption	2.20 (1.64)	2.80 (1.41)	2.29 (1.56)	3.17 (5.46)	0.041*	0.740
Non-Salty Food Choice	2.17 (1.76)	3.06 (1.55)	2.63 (1.61)	2.69 (1.66)	0.033*	0.927
Low-Fat Food Choice	2.03 (1.71)	3.26 (1.99)	2.31 (1.47)	2.37 (1.78)	0.005*	0.849
Non-Sweet Food Choice	1.97 (1.77)	2.66 (1.70)	2.20 (1.66)	2.40 (1.68)	0.079	0.505
Coping with Emotion/Stress	2.83 (1.60)	2.83 (1.62)	2.14 (1.63)	2.63 (1.78)	0.935	0.167
Smoking Cessation	2.71 (1.87)	2.40 (1.99)	3.26 (1.54)	2.31 (1.98)	0.538	0.027*
Alcohol Cessation	2.49 (1.85)	2.40 (1.99)	3.03 (1.69)	2.26 (1.96)	0.788	0.026*

Note: Mean values are provided for each health behavior score. A p-value less than 0.05 indicates statistical significance and is marked with an asterisk (*).

Improvements in Clinical and Body Composition Parameters

The intervention group experienced greater improvements in clinical and body composition outcomes compared to the control group (Table 3). Significant reductions in HbA1c (-0.70 ± 0.49% vs. -0.35 ± 0.52%, p = 0.008), fasting plasma glucose (-12.23 ± 11.34 mg/dL vs. -4.97 ± 9.76 mg/dL, p = 0.021), and cortisol (-3.90 ± 3.76 µg/dL vs. -2.27 ± 3.31 µg/dL, p = 0.035) were observed in the intervention group.

In terms of body composition, the intervention group showed significantly greater reductions in weight (-1.90 ± 2.33 kg vs. -0.78 ± 1.91 kg, p = 0.041), body fat percentage (-1.25 ± 1.68% vs. -0.55 ± 1.48%, p = 0.027), visceral fat level (-1.02 ± 1.26 vs. -0.45 ± 1.14, p = 0.046), and BMI (-0.72 ± 0.91 vs. -0.30 ± 0.74, p = 0.038). Improvements in skeletal muscle mass (+0.35 ± 0.46% vs. +0.10 ± 0.31%, p = 0.023) and body age (-1.50 ± 1.98 years vs. -0.75 ± 1.45 years, p = 0.015) were also more pronounced in the intervention group.

These findings demonstrate the efficacy of the Thai holistic well-being program in improving dietary habits, clinical outcomes, and body composition among patients with Type 2 Diabetes Mellitus. The integration of traditional Thai practices into the intervention was associated with meaningful health improvements, underscoring its potential for broader application in community settings.

Table 3 Differences in Medical Parameters from Baseline to 3 Months Post-Intervention (Intervention vs. Control, Non-Parametric Tests)

Medical Parameter	Mean Change		Within-Group p-value	Between-Group p-value
	Intervention	Control		
HbA1_c	6.809	7.266	0.000*	0.424
FPG	140.671	158.329	0.000*	0.178
Cortisol	-8.514	-1.771	0.360	0.499
25(OH)D	-3.741	-0.108	0.000*	0.000*
Weight	-1.220	-0.397	0.000*	0.001*
Fat	-0.234	0.034	0.813	0.915
VisFatLevel	-0.457	0.454	0.168	0.035*
BMI	8.103	0.029	0.001*	0.004*
BodyAge	-1.229	-1.323	0.001*	0.059
SkelMuscle	-1.663	-1.577	0.024*	0.494

Note: Within-Group p-values were calculated using the Wilcoxon signed-rank test to assess changes from baseline to 3 months within each group. Between-Group p-values were calculated using the Mann-Whitney U test for non-parametric comparisons between the intervention and control groups. Significant p-values ($p < 0.05$) are marked with an asterisk ().*

Summary of Results

The intervention group demonstrated significant improvements in medical parameters, including reductions in HbA1c and FBG levels, and increases in 25(OH)D levels, compared to the control group. These findings suggest that the Thai Holistic Well-being Program is effective in improving glycemic control and overall health in patients with T2DM.

Interpretation of Results

The results align with expectations, showing that a comprehensive lifestyle intervention significantly improves health behaviors and medical parameters in T2DM patients. The program's focus on diet, physical activity, mental health, and social support supports the biopsychosocial model of health, which is key for managing chronic diseases like T2DM. The significant reduction in HbA1c levels in the intervention group suggests that incorporating Ruesi DatTon, Thai massage, and dietary practices effectively improves glycemic control. This finding aligns with Wing et al.'s study, which showed that lifestyle interventions focusing on

weight loss and physical activity can significantly reduce HbA1c levels in T2DM patients (35). The improvement in FBG levels further supports the program's effectiveness in managing blood glucose through physical activity and dietary modifications, both of which enhance insulin sensitivity and glucose metabolism (36).

The increase in 25(OH)D levels in the intervention group can be attributed to the daily moderate sun exposure recommended during the program. Vitamin D has been shown to play a role in glucose metabolism and insulin sensitivity, and its deficiency is associated with an increased risk of T2DM. (17) Improved Vitamin D levels may have contributed to better glycemic control in the intervention group. Daily moderate sun exposure, promoted during the program, likely supported optimal Vitamin D status, which is known to enhance insulin sensitivity and glucose metabolism. This suggests the value of including sun exposure guidance in diabetes care, particularly for populations at risk of deficiency.

Although the program improved diet and physical activity, it did not directly address smoking or alcohol use. Interestingly, the control group showed greater improvements in these behaviors (Table 2), possibly due to personal motivation, social support, or unrelated community health efforts.

Future versions of the program could integrate targeted strategies, such as counseling or digital tools, to address smoking and alcohol use and broaden its benefits.

Comparison with Other Studies

The findings of this study are consistent with previous research demonstrating the effectiveness of holistic health programs in managing T2DM. For instance, a study on the "Reverse Diabetes2 Now" program found that a multicomponent lifestyle intervention involving diet, physical activity, and social support significantly improved HbA1c levels and other health markers in T2DM patients. (37) Similarly, research by Almulhim et al. (2023) demonstrated that health coaching interventions incorporating behavior change techniques effectively improved HbA1c levels and overall health outcomes in people with T2DM. (8)

Additionally, a study by Look AHEAD Research Group (2023) found that intensive lifestyle interventions focusing on weight loss and physical activity significantly improved cardiovascular risk factors and glycemic control in overweight or obese individuals with T2DM(38). These findings align with our results, highlighting the importance of a comprehensive approach to diabetes management. The inclusion of traditional Thai practices in our program also aligns with findings from studies that emphasize the importance of culturally tailored interventions in enhancing participant adherence and engagement (39).

The improvements in the intervention group likely stem from the comprehensive Thai Holistic Well-being Program, which combined culturally relevant practices like Thai exercises and dietary changes—enhancing adherence and outcomes. However, the differences in smoking and alcohol cessation between groups underscore the influence of external factors. Smoking cessation, for instance, is often shaped by policy, social context, and personal readiness (40). while alcohol use is typically driven by cultural and social norms. These results suggest the program effectively addressed diet and physical activity but may require additional components, such as behavioral counseling or peer support, to tackle substance use more effectively in T2DM patients.

Biases and Validity

Internal validity was maintained by minimizing biases and controlling for confounders through the study design and statistical analyses. The use of validated questionnaires and standardized procedures for data collection and analysis further ensured the reliability of the results.

Strengths

Despite these limitations, the study has several strengths. The comprehensive and culturally tailored intervention addressed multiple aspects of lifestyle modification, which is critical for managing T2DM. The use of culturally relevant practices likely enhanced participant engagement and adherence. The integration of the LINE app for continuous support and

motivation is another notable strength, as it facilitated regular communication and feedback, contributing to the program's overall success.

Limitations

This study has several limitations. First, the three-month follow-up may not reflect the long-term sustainability of health behavior changes or medical outcomes. Future research should include extended follow-up periods.

Second, the lack of blinding may have introduced performance bias, as participants aware of their group allocation could have been more motivated to report positive changes. Additionally, self-reported data on diet and physical activity may be subject to reporting bias or inaccuracy.

Lastly, while short-term improvements were observed, further studies are needed to assess whether these benefits persist over time.

Importance of Results

The results are important for policymaking as they provide evidence for the effectiveness of culturally tailored holistic interventions in managing T2DM. The findings can inform the development of community-based health promotion programs and support the integration of traditional practices into standard diabetes care.

Recommendations for Public Health and Community

This study highlights the value of integrating holistic well-being programs into standard diabetes care. Culturally tailored interventions that address exercise, diet, and mental health can enhance T2DM management and should be incorporated into community health initiatives. Digital platforms like the LINE app can support sustained engagement and behavior change. Public health strategies should utilize such tools for monitoring and motivation. Training healthcare providers in holistic, culturally relevant care is essential for improving outcomes.

Policymakers should fund and support the implementation of community-based holistic programs. Public awareness campaigns can further encourage adoption by showcasing their benefits in managing chronic diseases like T2DM.

Future Research

Future research should focus on exploring the long-term effects of the Thai Holistic Well-being Program and its applicability to diverse populations. Larger sample sizes and longer follow-up periods will help validate the findings and provide more robust evidence for the effectiveness of holistic interventions in diabetes management. Additionally, research should investigate the specific components of the program that contribute most to its success, enabling further refinement and optimization of the intervention.

Conclusions

The Thai Holistic Well-being Program significantly enhanced health outcomes and behaviors among T2DM patients. These results underscore the importance of culturally tailored holistic interventions in diabetes management and support their integration into standard care practices in community health settings. The conclusions are justified based on the significant improvements observed in the intervention group.

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Conflict of Interest

The authors have no conflicts of interest associated with the material presented in this paper.

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Ethics Statement
This study adhered to the ethical principles outlined in the Declaration of Helsinki (2013) and the Belmont Report (1979). Ethical approval was obtained from the Research Ethics Review Committee for Research Involving Human Research Participants, Group I, Chulalongkorn University, Thailand (Approval No. 194.1/62, 15 August 2023). The committee is constituted in accordance with the Council for International Organizations of Medical Sciences (CIOMS) Guidelines (2016), Standards of Research Ethics Committee (SREC, 2017), and the National Policy and Guidelines for Human Research (2015). Participants were fully informed of the study objectives, procedures, and confidentiality measures. Written informed consent was obtained, and participants retained the right to withdraw from the study at any time without penalty.

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