

Diabetes Mellitus Treated with Medical Nutritional Therapy and Self Blood Glucose Monitoring: A Randomized Controlled Trial

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Objective: To assess the effect of Medical Nutritional Therapy (MNT) combined with self blood glucose monitoring (SBGM) in the clinical outcomes of patients with type 2 diabetes.

Material and Method: A randomized controlled trial was conducted on patients with uncontrolled, not-using insulin type 2 diabetes at Her Royal Highness Princess Maha Chakri Sirindhorn Medical Center. Sixty patients were recruited and randomized equally into intervention group (MNT with SBGM) and control group (usual care). The primary endpoint was improvement of hemoglobin A_{1c} (HbA_{1c}) at 12 and 24 weeks.

Results: At 12 and 24 weeks the intervention group had significantly improved their glycemic control in comparison to control group (median decrement of HbA_{1c} at 12 weeks 0.72% vs. 0.15%; $p < 0.001$ and at 24 weeks 0.85% vs. 0.20%; $p < 0.001$). Oral hypoglycemic agents were reduced or discontinued in 7 patients in the intervention group and 1 patient in control group who achieved HbA_{1c} goal after 24 weeks ($p = 0.037$). After 24 weeks, body weight was significantly decreased from baseline (2.3 kg, $p < 0.001$) in the intervention group while only non-significant decrease was observed in control group (0.1 kg, $p = 0.632$).

Conclusion: MNT combined with SBGM is an effective non-pharmacological intervention for patients with uncontrolled type 2 diabetes.

Keywords: Lifestyle modification, Diet control, Capillary blood glucose monitoring

J Med Assoc Thai 2015; 98 (Suppl. 10): S66-S73

Full text. e-Journal: <http://www.jmatonline.com>

Type 2 diabetes mellitus (T2DM) is a chronic debilitating disease with a rapidly increasing incidence in developing countries such as Thailand⁽¹⁾. It was estimated that up to 10% of the Thai population suffers from this disease yet there is no known cure⁽²⁾. The goal of treatment for these patients is to maintain a good glycemic control in order to prevent microvascular and macrovascular complications. Oral hypoglycemic agents play a central role in maintaining appropriate blood glucose level in most T2DM patients. However, most of these medications will eventually result in

weight gain and worsening of insulin resistance in a long run⁽³⁾. Diet intervention such as medical nutritional therapy (MNT) and weight reduction are compelling tools to help patients achieve their glycemic goals in both short and long term⁽⁴⁻⁶⁾. Nonetheless, their implementation has proved to be challenging in real life, particularly in countries such as Thailand where there are vast varieties of cuisine, inadequate food labeling, and limited availability of certified dietitian.

The effectiveness of self-blood glucose monitoring (SBGM) in T2DM patients not treated with insulin still remains unclear. Additionally, Cochrane Reviews concluded that the effect was minimal and not statistically significant⁽⁷⁾. However, it is speculated that the effectiveness of SBGM was limited by patient's knowledge and application of the readings⁽⁸⁾.

The aim of the present study was to assess the effectiveness of individualized MNT combined with SBGM in reducing hemoglobin A_{1c} (HbA_{1c}) in patients with T2DM not treated with insulin

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Material and Method

Study design

This is a single-center, parallel-group, randomized controlled trial. Written informed consent was obtained before initial enrollment into the study. The protocol was approved by Srinakharinwirot University's Ethical Committee in accordance to the Declaration of Helsinki (serial number SWUEC-046/57E). The study was registered with Thai Clinical Trial Registry and given an identification number of TCTR20141208001.

Participants

Eligible participants were patients with age above 18 who have been diagnosed with T2DM with HbA_{1c} between 6.5 to 9%. Participants were excluded if they suffered from psychiatric disorder, received insulin or Glucagon-like Peptide-1 agonist, has been diagnosed with cirrhosis, were pregnant or planned to be pregnant within a year, received parenteral nutrition, or has an estimated glomerular filtration rate less than 60 mL/min/1.73 m². The study was conducted at HRH Princess Maha Chakri Sirindhorn Medical Center of Srinakharinwirot University Nakhon Nayok Thailand from July 2014 to March 2015. Participants were randomly assigned to either an intervention group receiving MNT and SBGM or a control group receiving usual medical care with allocation ratio of 1:1 by using block of 4 randomization.

Interventions

The intervention group received 4 sessions of individualized MNT by the authors at 0, 6, 12 and 18 weeks. During the first visit, patients received dietary advice and instructions to correctly self-administer SBGM. The dietary advice was based on American Diabetes Association and Thai diabetes recommendation guidelines^(9,10). These recommendations were tailored according to each patient's regular eating habits. They were also instructed to measure their capillary blood glucose (CBG) 8 times per week. These measurements were carried out twice per day: right before and two hours after the largest meal of the day (2 weekdays and both weekend days). Participants also received food diaries to record all their dietary intakes in juxtaposition to CBG for the next 6 weeks. Compliance was defined by frequency of SBGM at least 95%. Individualized goals were also set for target

body weight, waist circumference, pre-meal and post-meal CBG. The estimated length of the first visit and subsequent visits were 20-30 minutes and 10-15 minutes per patient, respectively. Upon subsequent visits, their food diaries were analyzed and individualized advice was given accordingly. Hypoglycemic symptoms were recorded in each visit. Weekly phone calls were implemented to ensure good compliance by reminding them to perform their SBGM.

The control group received usual care. They were followed-up at 0, 12, 24 weeks and received dietary advice from doctor or practitioner nurse when rising HbA_{1c} were identified. Both groups were prescribed unchanged hypoglycemic agents unless severe or frequent hypoglycemia (>2 times per week) was detected. Severe hypoglycemia was defined as any hypoglycemia with the need for assistance by another person or blood glucose level below 40 mg/dL. Clinical and laboratory data were collected from all participants at baseline 12 and 24 weeks.

Study outcomes

The primary outcome of the present study was the reduction in HbA_{1c} level at 12 and 24 weeks after enrollment. Additional analyses include change of body weight, fasting plasma glucose, and lipid profile consisting of low-density lipoprotein-cholesterol (LDL-c), high-density lipoprotein-cholesterol (HDL-c), and triglyceride.

Statistical methods

Sample size estimation of the present study was based on data from Marion et al⁽¹¹⁾. To detect a reduction in HbA_{1c} of 1% with SD of 1.28% at 24 weeks with a two-tailed significance level of 5% and a power of 90%, a sample of 30 participants per group was needed, given an anticipated dropout rate of 10%.

Descriptive statistics were used to compare baseline characteristics between the groups. Mean and standard deviation (SD) for normal distribution data or Median and interquartile range (IQR) for non-normal distribution data were used for continuous data. Percentages were calculated for discrete data. All outcome measurements were compared between intervention and control group using independent t-test for normal distribution data or Wilcoxon rank-sum test for non-normal distribution data. Other outcome measurements within intervention and control group were analyzed using dependent t-test for normal distribution data or Wilcoxon signed-rank test for non-normal distribution data. Percentage of patients who

achieved HbA_{1c} target (HbA_{1c} <6.5%) were compared by Pearson Chi-square. The analyses were performed using intention-to-treat analysis. A *p*-value <0.05 was deemed as statistically significant.

Funding

The present study was funded by Srinakharinwirot University. The sponsors had no influence over the study design, data collection, data analysis, data interpretation or writing of the report.

Results

Of the 65 participants, 60 were included in the study (Intervention group, *n* = 30; Control group, *n* = 30). No participant was dropped out from the present study (Fig. 1). Characteristics of the patients in both groups were shown in Table 1. They were relatively older age, long duration of diabetes, and low HbA_{1c} in the control group. Diabetes related complications and comorbidities were shown in Table 2. All the patients in the intervention group completed 4 sessions of individualized nutritional advice and each patients have taken at least 95% of their total capillary blood glucose

readings.

HbA_{1c}

At week 24 the median HbA_{1c} decrement was 0.85 (IQR 0.18-1.33) in the intervention group and 0.20

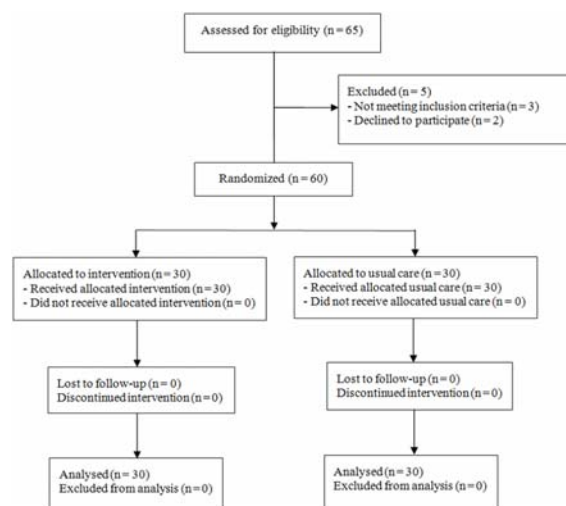


Fig. 1 Trial profile.

Table 1. Baseline characteristics of participants

	Intervention (n = 30)	Control (n = 30)	Total (n = 60)
Male sex (%)	10 (33)	10 (33)	20 (33)
Age (years)	52.1 (10.2)	59.1 (7.9)	55.6 (9.69)
Duration of diabetes (years) *	2.0 (1.0-5.8)	4.5 (1.8-8.0)	3.0 (1.0-7.75)
Body weight (kg)	72.5 (16.5)	67.7 (11.4)	70.1 (14.3)
BMI (kg/m ²)	28.3 (5.0)	26.1 (3.8)	27.4 (4.5)
Waist circumference (cm)	96.6 (11.5)	95.1 (9.9)	96.1 (10.7)
Systolic blood pressure (mmHg)	130 (18.0)	136 (14.1)	133 (16.3)
Diastolic blood pressure (mmHg)	77.8 (11.2)	76.8 (11.0)	77.3 (11.0)
Fasting plasma glucose (mg/dL)	151 (29.0)	147 (31.1)	149 (29.9)
HbA _{1c} (%)	7.56 (0.74)	7.14 (0.52)	7.35 (0.67)
Total cholesterol (mg/dL)	161.7 (35.4)	176.0 (41.2)	171.3 (39.3)
HDL-c (mg/dL)	47.5 (13.3)	53.2 (11.9)	50.3 (12.8)
LDL-c (mg/dL)	93.1 (24.5)	114.2 (37.0)	103.0 (32.9)
Triglycerides (mg/dL) *	145 (112-174)	125 (97-153)	136 (105-159)
Creatinine (mg/dL)	0.76 (0.21)	0.80 (0.18)	0.78 (0.20)
Oral hypoglycemic agent usage (%)			
Metformin	29 (96.7)	25 (83.3)	54 (84.4)
Sulfonylurea	20 (66.7)	15 (50.0)	35 (54.7)
Thiazolidinedione	4 (13.3)	5 (16.7)	9 (14.1)
Dipeptidyl peptidase-4 inhibitor	0 (0)	1 (3.3)	1 (1.6)
Alpha-glucosidase inhibitors	0 (0)	0 (0)	0 (0)
Total oral hypoglycemic agent usage	29 (96.7)	26 (86.7)	55 (91.7)

Data are reported as means (SD) or numbers (%)

* Data are reported as median (interquartile range)

Table 2. Co-morbidities and diabetes related complications

	Intervention (n = 30)	Control (n = 30)	Total (n = 60)
Comorbidities (%)			
Hypertension	19 (63.3)	25 (83.3)	44 (73.3)
Dyslipidemia	26 (86.7)	28 (93.3)	54 (90.0)
Non-alcoholic fatty liver disease	3 (10.0)	0 (0)	3 (5.0)
Complications (%)			
Diabetes retinopathy	2 (6.7)	3 (10.0)	5 (8.3)
Diabetes nephropathy	6 (20.0)	6 (20.0)	12 (20.0)
Diabetes neuropathy	1 (3.3)	1 (3.3)	2 (3.3)
Coronary artery disease	0 (0)	2 (6.7)	2 (3.3)
Cerebrovascular accident	2 (6.7)	4 (13.3)	6 (10.0)
Peripheral artery disease	0 (0)	2 (6.7)	2 (3.3)
Diabetes foot	0 (0)	1 (3.3)	1 (1.7)

All data are reported as numbers (%)

Table 3. Changes in HbA_{1c} after 12 and 24 weeks

	Intervention (n = 30)	Control (n = 30)	p-value
Total HbA _{1c} decrement in 0-24 weeks (%)	0.85 (0.18-1.33)	0.20 (-0.13-0.45)	<0.001
HbA _{1c} decrement in 0-12 weeks (%)	0.72 (0.40-1.13)	0.15 (-0.20-0.63)	<0.001
HbA _{1c} decrement in 12-24 weeks (%)	0.11 (-0.30-0.70)	-0.05 (-0.02-0.23)	0.509

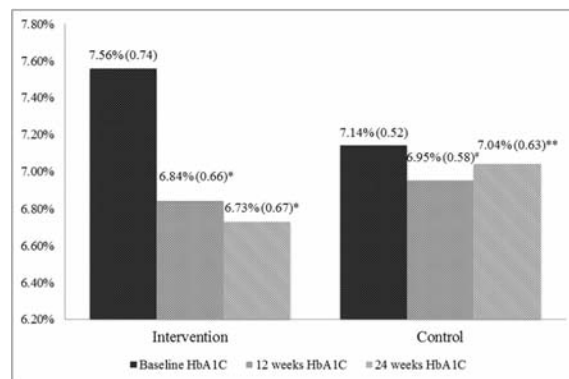
All data are reported in median (interquartile range). The *p*-values were calculated by Wilcoxon rank-sum test.

(IQR -0.13-0.45) in control group. The decrements were statistically significant between both groups (*p*<0.001) (Table 3).

The mean HbA_{1c} in the intervention group progressively decreased from 7.56% at baseline to 6.84% at 12 weeks (*p*<0.001) and 6.73% at 24 weeks (*p*<0.001). The mean HbA_{1c} in the control group was non-significant decreased (Fig. 2). At 24 weeks, there was significantly higher number of patients who achieved their targeted HbA_{1c} (HbA_{1c} <6.5%) in the intervention group compared with the control group (37% vs. 13%, *p* = 0.037).

Other outcomes

Body weight and waist circumference at 24 weeks were significantly decreased (2.3 kg; *p*<0.001 and 3.7 cm; *p*<0.001) in the intervention group whereas there was no significant anthropometric changes in the control group (0.1 kg; *p* = 0.632 and 0.8 cm; *p* = 0.144) (Table 4). Fasting plasma glucose was non-significantly decreased in both groups at 24 weeks. Triglyceride was significantly decreased in the



* *p*<0.001, #*p* = 0.014, ** *p* = 0.283

Fig. 2 Mean (SD) of Hemoglobin A_{1c} at baseline, 12 weeks, and 24 weeks.

Dependent t-test was used to calculate the difference between value at baseline and 12 weeks or at baseline and 24 weeks. Intervention group but non-significant increased in the control group. HDL-c was also significantly increased in the intervention group.

Table 4. HbA_{1c}, weight, waist circumference, total cholesterol, triglycerides, HDL-c and LDL-c at baseline, 12 weeks and 24 weeks

	Intervention (n = 30)	<i>p</i> -values	Control (n = 30)	<i>p</i> -values
Baseline weight (kg)	72.5 (16.5)		67.7 (11.4)	
Weight at 12 weeks (kg) *	70.3 (15.7)	<0.001	67.2 (11.1)	0.092
Weight at 24 weeks (kg) **	70.2 (15.6)	<0.001	67.6 (11.9)	0.632
Baseline waist circumference (cm)	96.6 (11.5)		95.6 (10.0)	
Waist circumference at 12 weeks (cm) *	93.8 (10.4)	<0.001	95.3 (9.9)	0.305
Waist circumference at 24 weeks (cm) **	92.9 (11.2)	<0.001	94.8 (10.3)	0.144
Baseline fasting plasma glucose (mg/dL)	150.6 (29.0)		145.6 (31.1)	
Fasting plasma glucose at 12 weeks (mg/dL) *	139.1 (24.7)	0.013	134.1 (27.9)	0.001
Fasting plasma glucose at 24 weeks (mg/dL) **	141.2 (37.6)	0.175	140.2 (33.5)	0.247
Baseline total cholesterol (mg/dL)	161.7 (35.4)		176.0 (41.2)	
Total cholesterol at 12 weeks (mg/dL) *	156.6 (31.7)	0.193	165.6 (35.3)	0.096
Total cholesterol at 24 weeks (mg/dL) **	162.3 (33.1)	0.916	169.8 (31.6)	0.187
Baseline triglyceride (mg/dL)	145 (112-174)		125 (97-153)	
Triglyceride at 12 weeks (mg/dL) *	116 (87-186)	0.009	123 (80-169)	0.624
Triglycerides at 24 weeks (mg/dL) **	112 (77-187)	0.007	128 (93-175)	0.688
Baseline LDL-c (mg/dL)	93.1 (24.5)		114.2 (37.0)	
LDL-c at 12 weeks (mg/dL) *	93.1 (26.2)	1.000	98.8 (35.1)	0.076
LDL-c at 24 weeks (mg/dL) **	99.3 (26.9)	0.212	104.8 (30.0)	0.219
Baseline HDL-c (mg/dL)	47.5 (13.3)		53.2 (11.9)	
HDL-c at 12 weeks (mg/dL)*	48.4 (14.0)	0.505	53.3 (11.7)	0.939
HDL-c at 24 weeks (mg/dL)**	53.5 (15.4)	0.001	54.9 (10.1)	0.365

All data are reported as means (SD) except triglycerides where data are reported as median (interquartile range).

All data are analyzed by Dependent t-test except triglycerides where data are analyzed by Wilcoxon signed-rank test.

* Dependent t-test or Wilcoxon signed-rank test was used to calculate the difference between value at baseline and 12 weeks.

** Dependent t-test or Wilcoxon signed-rank test was used to calculate the difference between value at baseline and 24 weeks.

However, there were non-significant changes in total cholesterol and LDL-c between both groups (Table 4). Oral hypoglycemic agents were discontinued or reduced in dosage in 7 patients in the intervention group and in one patient in the control group due to frequent hypoglycemia. None of the patient had severe hypoglycemia. The 3.2% (2.3 kg) weight reduction was positively correlated with 0.88% of HbA_{1c} decrement at 24 weeks in all patients ($r = 0.46, p < 0.001$).

Discussion

The present study exemplified the benefits of MNT and SBGM in glycemic control in patients with T2DM. MNT is known as a safe and effective tool for glycemic control in diabetes. Most studies on MNT were done in Western countries with very different dietary style from Asian countries. To the best of our knowledge, this is the first study in Thailand that proved the benefit of MNT and SBGM. There are a diverse range of cuisine in Thailand with multiple food additives

and inadequate food labels. This provides a great challenge for clinicians when giving dietary advice to T2DM patients, not to mention the lack of registered dietitians and Diabetic nurses. The magnitude of HbA_{1c} decrement in the present study was comparable with the Western countries studies^(5,12,13).

Regarding the given intervention, each visit took approximately 10 to 15 minutes, which is comparable to routine diabetes clinic visit. During each session, great emphasize was placed on eating a balanced diet using the food pyramid. Patients were encouraged to replace simple carbohydrates with complex carbohydrate, minimize fat and sugar consumption. Calories' counting was only recommended to certain participants. This was due to the complexity of the process, the diversity of Thai cuisine and the limited availability and quality of food labeling. In addition, calories' counting would be difficult to integrate into the clinical practice of T2DM

where most patients are elderly. Food diary is valuable in guiding physician to giving concise and individualized dietary advices. Additionally, pre-meal and post-meal SBGM provide patients with instant feedback upon their food consumptions. This is a powerful self-educating tool which patients' can rapidly apply the CBG readings and adjusts their meal plan accordingly.

At 12 weeks time, there was a slightly decrease in HbA_{1c} in the control group. This is likely due to the recognition in the importance of lifestyle modification in all patients during recruitment before randomization. However, upon follow-up from 12 weeks to 24 weeks, HbA_{1c} continued to decline in the intervention group but trended to increase in the control group. SBGM could be attributed to this effect by encouraging patients to adhere to their healthy-eating habits in order to continue the satisfactory CBG readings. Other benefits of SBGM include early detection of hypoglycemia. This greatly helps guiding physician decisions in the adjustment of oral hypoglycemic regimens and minimizes the adverse effects such as weight gain and reduces the cost of these medications.

Only 3.2% (2.3 kg) weight reduction was observed in the intervention group. This is less than the recommendation in multiple diabetes guidelines which encourage up to 5-7% weight reduction within 24 weeks for patients undergoing diet control^(10,14). However, the weight decrement observed was strongly correlated with the HbA_{1c} decrement. Nonetheless, further weight reduction could produce addition HbA_{1c} reduction and would likely lead to a better glycemic profile. Due to the reduction in simple carbohydrate intake and weight loss, better lipid changes were also seen in triglyceride and HDL-c as expected.

Prior studies about the benefit of SBGM in non-insulin using T2DM have shown either non-significant decrease in HbA_{1c} or significant decreases without clinical relevance (less than 0.3%)⁽⁷⁾. On the contrary, the present study reveals significant decrease in HbA_{1c} (0.65% compare with the control group). These differences can be explained by the difference in study design. In the present study, MNT was only offered to the intervention group and structured education on the usage and interpretation of CBG results were given to maximize the benefit of SBGM. Anti-diabetic agents were not adjusted throughout the trial. Most of the prior studies offered diet education to both the SBGM group and the control group⁽¹⁵⁻¹⁷⁾. In some of these studies, there were adjustments in oral hypoglycemic regimen and/or initiation of insulin^(15,17-20). In addition,

there were great differences in HbA_{1c} at baseline between these studies. Higher level of baseline HbA_{1c} usually leads to a greater reduction in HbA_{1c} after intervention. Prior studies with higher rate of compliant to the interventions also demonstrated more benefit from SBGM^(17,19,20).

The results of the present study should be interpreted with caution since the effect of HbA_{1c} changes can be attributed to either SBGM or MNT. While SBGM, as shown in the present study, may decrease the cost and time taken for each MNT session, it can also be expensive. Future studies should focus on comparing the cost-effectiveness of strict-caloric counting MNT with personalized MNT guided by SBGM. Because diabetic patients in Asia have a lower BMI than Western and only 3.2% weight reduction in the present study was associated with 0.85% HbA_{1c} reduction. Future studies on Thai T2DM should also focus on the magnitude of weight loss that can have a positive effect on glycemic control. Due to the nature of behavioral-modification studies, the long-term effectiveness of these interventions are difficult to assessed. In the present study, MNT was conducted by the authors, only one was an endocrinologist in one center over a short period of time. For generalizability, multicenter and long-term studies will be required.

Conclusion

The combination of medical nutritional therapy and self blood glucose monitoring is an effective add on intervention for reducing HbA_{1c}, improving lipid profiles and anthropometric measurements in patients with uncontrolled T2DM who are not using insulin at 12 and 24 weeks. Thus, SBGM, if properly implemented, could be another non-pharmacological tool for clinical to help patients reach and maintain their glycemic goal. This intervention also obviates over prescription of oral hypoglycemic agents.

What is already known on this topic ?

Medical nutritional therapy is a safe and effective tool for glycemic control in most Western country studies, which have adequate food labels and difference dietary style from Thailand. Self blood glucose monitoring has showed minimal or non-significant HbA_{1c} reduction in type 2 diabetes patients who are not using insulin.

What this study adds ?

Individualized medical nutritional therapy

guided with self blood glucose monitoring is effective and safe for Thai patients. The magnitude of HbA_{1c} reduction is comparable to the Western countries' studies, which also involved registered dietitians and well-training nurses. Self blood glucose monitoring can aid physicians in provide effective dietary advice to Thai patients using the same amount of consultation time as a regular visit to diabetes clinic.

Acknowledgement

This research was supported by research grant from Faculty of Medicine, Srinakarinwirot University (389/2558)..

Potential conflicts of interest

None.

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การให้โภชนาบำบัดร่วมกับการตรวจระดับน้ำตาลในเลือดด้วยตนเองในผู้ป่วยเบาหวานโดยการศึกษาแบบสุ่มและมีกลุ่มควบคุม

กัญญา งามสุวรรณ, สรวิต โอสถาพันธุ์

วัตถุประสงค์: เพื่อประเมินประสิทธิภาพของการให้โภชนาบำบัดร่วมกับการตรวจระดับน้ำตาลในเลือดด้วยตนเองในการควบคุมโรคเบาหวานชนิดที่สอง
วัสดุและวิธีการ: ดำเนินการวิจัยแบบสุ่มและมีกลุ่มควบคุมในผู้ป่วยโรคเบาหวานชนิดที่สองที่ควบคุมระดับน้ำตาลในเลือดไม่ได้ และยังไม่ได้รับการฉีดอินซูลิน ณ โรงพยาบาลศูนย์การแพทย์สมเด็จพระเทพรัตนราชสุดาฯ สยามบรมราชกุมารี มหาวิทยาลัยศรีนครินทรวิโรฒ องค์กรฯ โดยมีผู้เข้าร่วมการวิจัยจำนวน 60 ราย แบ่งเป็นสองกลุ่มเท่าๆ กัน ได้แก่ กลุ่มที่ได้รับโภชนาบำบัดร่วมกับการตรวจระดับน้ำตาลในเลือดด้วยตนเอง และกลุ่มที่ได้รับการดูแลรักษาตามปกติ (กลุ่มควบคุม) โดยผลลัพธ์หลักของการศึกษาคือ ระดับน้ำตาลในเลือดสะสม HbA_{1c} ที่ลดลงใน 12 และ 24 สัปดาห์

ผลการศึกษา: ค่ามัธยฐานของระดับ HbA_{1c} ของกลุ่มที่ได้รับโภชนาบำบัดร่วมกับการตรวจระดับน้ำตาลในเลือดด้วยตนเองที่ระยะเวลา 12 สัปดาห์ลดลง 0.72% ในขณะที่กลุ่มควบคุมลดลง 0.15% โดยมีความแตกต่างอย่างมีนัยสำคัญทางสถิติ ($p < 0.001$) และที่ระยะเวลา 24 สัปดาห์ ค่ามัธยฐานของระดับ HbA_{1c} ของกลุ่มที่ได้รับโภชนาบำบัดร่วมกับการตรวจระดับน้ำตาลในเลือดด้วยตนเองลดลง 0.85% ในขณะที่กลุ่มควบคุมลดลง 0.20% โดยมีความแตกต่างอย่างมีนัยสำคัญทางสถิติ ($p < 0.001$) ผู้ป่วยในกลุ่มที่ได้รับโภชนาบำบัดร่วมกับการตรวจระดับน้ำตาลในเลือดด้วยตนเองจำนวน 7 ราย และในกลุ่มควบคุมจำนวน 1 ราย สามารถลดหรือหยุดยาลดระดับน้ำตาลในเลือดที่ 24 สัปดาห์ ทั้งสองกลุ่มแตกต่างอย่างมีนัยสำคัญทางสถิติ ($p = 0.037$) น้ำหนักตัวเฉลี่ยในกลุ่มที่ได้รับโภชนาบำบัดร่วมกับการตรวจระดับน้ำตาลในเลือดด้วยตนเองลดลงจากเดิม 2.3 กิโลกรัม ($p < 0.001$) และน้ำหนักตัวเฉลี่ยในกลุ่มควบคุมลดลงจากเดิม 0.1 กิโลกรัม ($p = 0.632$)

สรุป: การให้โภชนาบำบัดทางการแพทย์ร่วมกับการตรวจระดับน้ำตาลด้วยตนเอง เป็นการรักษาโรคเบาหวานโดยไม่ใช้ยาอย่างมีประสิทธิภาพในผู้ป่วยโรคเบาหวานชนิดที่สองที่ไม่สามารถควบคุมระดับน้ำตาลในเลือดได้
