Original

Effectiveness of Medical Nutrition Therapy with Technology-Assisted Intervention on Cardiometabolic Parameters in Thai Participants with Prediabetes and Obesity

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ABSTRACT: Prior studies proved that intensive behavioral lifestyle intervention can prevent or delay development of type 2 diabetes mellitus (T2DM). However, few studies regarding diabetes prevention were as effective programs for Thai participants. The objective of this study was to investigate the effects of developed behavioral lifestyle intervention program compared with usual care on cardiometabolic parameters in Thai participants with prediabetes and obesity after 12 weeks. The study design was randomized controlled trial and block allocation according to gender and age. Experimental group received individual Medical nutrition therapy (MNT) counseling and developed technology-assisted intervention. The technology-assisted intervention had 3 activities via LINE application including sending message 3 days/week according to their stages of change, asking question and self-report. Control group was the usual care at check-up center that received general health advice. Per-protocol analysis was performed in participants who completed 12-week intervention; experimental group (n=22) and control group (n=21). Experimental group had a greater percentage of weight loss -3.1% with median difference -4.4% compared control group. Twenty-seven percent of experimental group return prediabetes status to normoglycemia after 12 weeks without T2DM development. Moreover, waist circumference, percentage of body fat, fasting plasma glucose, blood pressure, Thai CVD risk and DM risk score were significantly changed to better outcomes over control group. In conclusion, the results demonstrated that this program is effective in weight reduction, remission of prediabetes status and improving other cardiometabolic parameters. Change of better outcomes was according to healthier diet pattern and more active physical activity.
Keywords: Medical nutrition therapy (MNT), prediabetes, obesity, diabetes prevention

INTRODUCTION

Type 2 diabetes mellitus (T2DM) is a common health problem effected disability and global health expenditure. International Diabetes Federation (IDF) 2019 reported the global prevalence of diabetes was approximately 9.3% or 463 million adults (20-79 years) with more than half undiagnosed (1). In Thailand, there were 8.9% of Thai people with diabetes, 14.2% with impaired fasting glucose (IFG) and 37.5% with obesity (2). Therefore, early detection and prevention in high risk of diabetes such as prediabetes and obesity are important for reducing the incidence of disease, other NCDs and consequent disability. The American Diabetes Association (ADA) 2019, the standards of medical care in diabetes recommends that people with prediabetes or high risk for T2DM should be referred to intensive behavioral lifestyle intervention for diabetes prevention. The lifestyle intervention should be composed of individual approach and goal setting to highly effective in T2DM prevention and also improve other cardiometabolic parameters such as blood pressure, lipid profile and inflammation. Combined technology-assisted intervention based on patient preference also could increase effectiveness of outcome. Long-term management should promote diabetes self-management education and support to maintain behaviours (3).

The Diabetes Prevention Program (DPP) recommended by the ADA demonstrated that intensive lifestyle intervention by initial weight loss and active physical activity can reduce the incidence of type 2 diabetes by 58% over 3 years (4). Moreover, a randomized controlled trial study in prediabetes with overweight or obesity who received individualized medical nutrition therapy by a registered dietitian was confirmed that HbA1C and diabetes risk score in 3 months were significant after this intervention compared with usual care group who received brief advice from a physician (5).

However, few lifestyle intervention program and study regarding diabetes prevention were as effective program for Thai participants with prediabetes. The usual care of prediabetes setting usually provides brief advice from a physician and no role of dietitian obviously. So the researcher wanted to develop diabetes prevention program that suitable for Thai people with high risk as prediabetes and obesity, and evaluate the effectiveness of the program for 12 weeks.

METHODS

The study design was a randomized controlled trial and block allocation. Recruited participants were randomly allocated according to gender and age (30-44, 45-60 years old) then divided into experimental or control group. This study was proceeded at check-up center of private hospital in Bangkok, Thailand. Participants were selected after blood test within 3 months. Inclusion criteria was Thai adults aged between 30-60 years old with IFG (100-125 mg/dL) and obesity (BMI $\geq$25 kg/m^2) diagnosed who could daily use of LINE application. Exclusion criteria was people with chronic disease such as related metabolism disturbance (chronic kidney disease,

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cancer, thyroid disease), eating disorder, who taking medication effected on weight, or ongoing other weight loss program within 3 months.

Experimental group received behavioural lifestyle intervention composed of individual MNT counselling and technology-assisted intervention via LINE application. Individual MNT counselling was provided by face-to-face at week 1 around 15-20 minutes, then via LINE call follow-up 5-10 minutes at week 3, 6, and 9. At the end of each MNT session, participants were specified "goal setting" (ex. weight, waist circumference or other health outcomes) and "action planning" (diet and exercise) together with the research and record in personal LINE Note. Technology-assisted intervention composed of motivational and educational text messages reviewed by 2 experts (diabetes with certified diabetes educator). There were four types of massages (diet, exercise, health problem and empowerment). Sending text messages depended on the stages of change, goal setting and action planning. Participants were received it via LINE chat 3 days/week. Moreover, they could send messages to asking questions related intervention or reporting behaviour change to the researcher anytime along 12 weeks.

Control group was similar to usual care in check-up center. Participants received general health advice from the researcher around 5 minutes. The advice followed by check-up report from the hospital and ADA recommendations. Contents of advice included lab result interpretation, diagnosis with IFG and obesity and generalize recommendations. The recommendations were long term losing weight 7% from baseline, diet control, regular exercise at least 150 minutes/week, monitoring and follow up with physician next 3 months.

Primary outcome was percentage of weight change between baseline and week 12. Secondary outcomes were cardiometabolic parameter changes including BMI, fat mass, blood glucose, blood pressure, Thai CVD and DM risk score. Other outcomes were observed diet pattern and active physical activities.

Statistical analysis was analysed with IBM SPSS Statistics for Windows version 19.0 (IBM Corp., Armonk, NY, USA). Analyses were performed using data available by per-protocol analysis from individuals who completed 12-week intervention. Independent T-test or Pearson Chi-square were used to compare intergroup differences of baseline characteristic in experimental and control group. Mann-Whitney U tests applied to skewed distribution data. Paired T-test was used to determine within group difference of outcome changes. P values < 0.05 considered statistically significant.

This study approved by the committee on human rights related to research involving human volunteers, Mahidol University.

RESULTS

Eligible 64 people enrolled between July and October 2019 from check-up center shown in Figure 1. Fourteen people were excluded before randomization. Total 50 participants were randomized and allocated into 4 categories by sex (female and male) and age (30-44 and 45-60 years old) then transferred to experimental group (n=25) or control group (n=25). There were 43 participants (84%) who completed 12-week intervention period; experimental group (n=22) and control group (n=21). Seven participants lost to follow-up or could not meet appointment. Per-protocol analysis was performed to determine the difference of outcomes after 12 weeks.

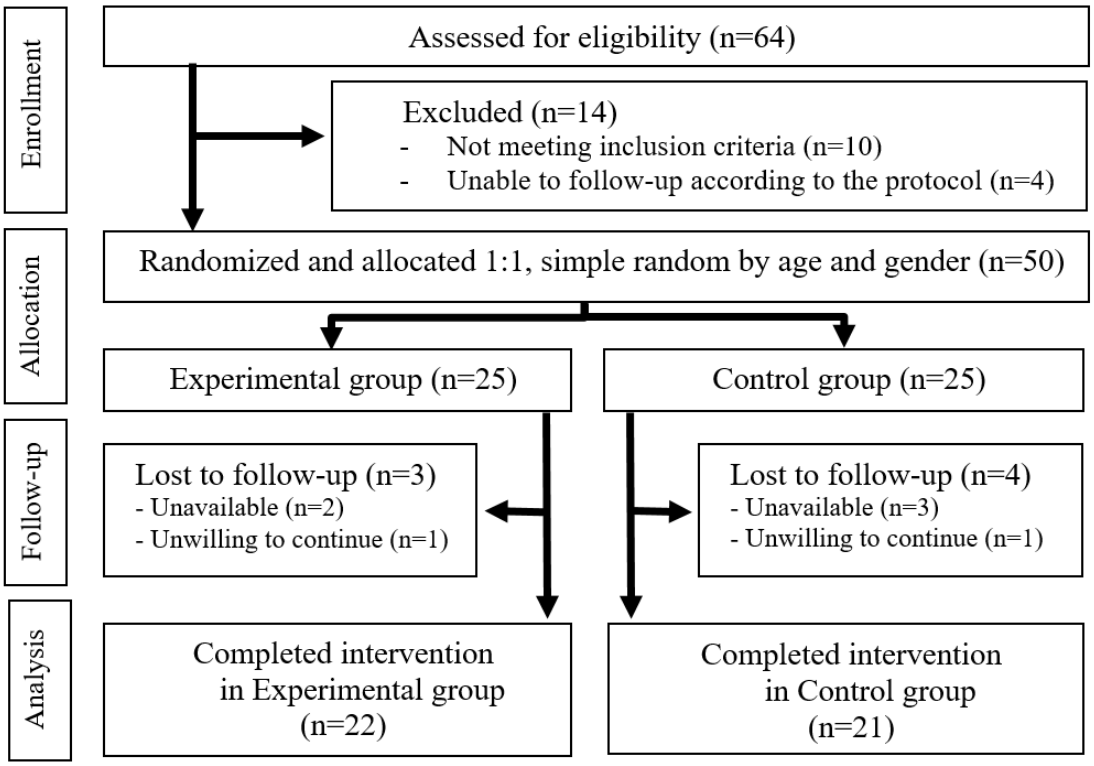

Fig 1. Participant flow diagram from screening to final analysis

Table 1 Baseline characteristic and cardiometabolic parameters in the experimental and control groups

	Experimental group (n=22)	**Control group (n=21)**	**P value**
Age (year)	45.1 ± 7.2	44.3 ± 8.05	0.75 [a]
Gender: Male, n (%)	8 (36.4%)	6 (28.6%)	0.59 [b]
Education level: Low/ High, n (%)	9 (40.9%) / 13 (59.1%)	10 (47.6%) / 11 (52.4%)	0.66 [b]
Smoking: Yes, n (%)	2 (9.1%)	0 (0.0%)	0.16 [b]
Alcohol drinking: Yes, n (%)	7 (31.8%)	5 (23.8%)	0.56 [b]
Hypertension: Yes, n (%)	4 (18.2%)	5 (23.8%)	0.65 [b]
Dyslipidemia: Yes, n (%)	17 (77.3%)	17 (81.0%)	0.77 [b]
Weight (kg)	77.2 ± 11.2	76.2 ± 10.8	0.76 [a]
BMI (kg/cm^2)	29.2 ± 3.3	30.1 ± 3.1	0.38 [a]
Waist (cm)	97.0 ± 6.1	99.9 ± 7.2	0.15 [a]
Lean mass (%)	60.0 ± 8.4	58.4 ± 7.6	0.52 [a]
Body fat mass (%)	36.4 ± 8.65	38.2 ± 7.71	0.49 [a]
Fasting plasma glucose (mg/dL)	112 ± 8	109 ± 6	0.16 [a]
Systolic blood pressure (mmHg)	128 ± 19	128 ± 11	0.97 [a]
Diastolic blood pressure (mmHg)	81 ± 11	82 ± 10	0.82 [a]
Thai CVD risk (%)	3.57 [-1.47, -5.71]	2.88 [-1.7, -5.57]	0.83 [c]
Thai DM risk score	10.3 ± 2.6	10.8 ± 2.7	0.54 [a]
Energy (kcal/day)	1713 [1561, 2148]	1724 [1516, 1940]	0.63 [c]
% Carbohydrate	55.0 ± 4.7	57.6 ± 6.9	0.22 [a]
% Protein	15.6 ± 3.0	15.2 ± 2.7	0.69 [a]
% Fat	29.4 ± 3.7	27.1 ± 5.5	0.13 [a]
Fiber (g/day)	10.0 [7.5, 14.5]	10.0 [7.0, 12.0]	0.49 [c]
Sugar (g/day)	50.5 [40.3, 63.0]	63.0 [46.5, 87.5]	0.08 [c]
Saturated fat (g/day)	16.0 [9.8, 20.0]	14.0 [9.5, 16.5]	0.62 [c]
Sodium (mg/day)	3106 [2090, 3649]	2587 [2316, 4928]	0.66 [c]
Water (ml/day)	1500 [1150, 2000]	1500 [1100, 2000]	0.56 [c]
Vegetable (serving/day)	1.75 [0.69, 2.25]	1.50 [1.00, 1.50]	0.20 [c]
Fruit (serving/day)	0.93 [0.29, 1.5]	1.43 [0.50, 2.00]	0.36 [c]
Whole gain (serving/day)	0.43 [0.07, 1.78]	0.29 [0.03, 0.50]	0.14 [c]
Legume (serving/day)	0.36 [0.15, 0.93]	0.13 [0.00, 0.75]	0.15 [c]
MVPA (minutes/week)	55.0 [0.0, 76.3]	40.0 [0.0, 90.0]	0.96 [c]

Data are presented as the frequency, mean ± sd (normally distributed data) and median [P25, P75] (non-normally distributed data). [a] Independent T-test, [b] Pearson Chi-Square, [c] Mann-Whitney U-test.
Low = high school or below, High = bachelor Degrees/ diploma or above; BMI, body index mass; Thai CVD risk, Thai cardiovascular risk; Thai DM risk score, Thai diabetic risk score.

There was no statistically significant difference in baseline characteristics among 43 participants in experimental group (n=22) and control group (n=21) that shown in Table 1. Participants in experimental group significantly lost a greater percentage of body weight (median [P25, P75]) with -3.11% [-4.16%, -0.95%] whereas those in the control group significantly gained their weight +1.30% [-0.45%, +3.05%].

There were 59% of participants who lost weight ≥ 3%, other cardiometabolic parameter changes were shown in Table 2. Percentage of lean mass in experimental group significantly increased and mean percentage of body fat significantly decreased, while those in control group did not. Fasting capillary blood glucose in experimental group significantly decreased (-5.0 mg/dL, P <0.01). Moreover, glycemic status after intervention was regressed from IFG to normoglycemia about 27% without newly diagnosed diabetes during 12-week intervention. Fasting plasma glucose in control group significantly increased and did not change in glycemic status. Thai DM risk score in experimental group was significantly decreased within and between groups. Statistically significant differences among both groups were observed in Thai CVD risk, systolic and diastolic blood pressure.

Nutrient data from 3-day food record and semi-FFQ were shown in Table 2. Experimental group reduced daily energy intake 334 kcal (p <0.001) while control group was little increasing. Significant food group and nutrient consumption difference between groups were found in protein distribution (p<0.05), saturated fat (p<0.05), water intake (p<0.05) and vegetable (p<0.01). Distribution of macronutrient (Carbohydrate: Protein: Fat %) at week 12 were (50: 20: 30 %) in experimental group and (57: 17: 26 %) in control group. Diet pattern within experimental group had a significant increasing in protein distribution, fiber, vegetable, and decreasing in carbohydrate distribution, sugar, saturated fat at 12-week compared baseline. Minute of weekly moderate to vigorous intensity physical activity (MVPA) at baseline and week 12 were shown in Table 2 Participants in experimental group significantly increased the minute of weekly MVPA at week 12 compared baseline above control group (p<0.05).

Table 2 Changes of cardiometabolic parameters, food groups, energy and nutrient intakes within the group and between the groups

Cardiometabolic parameters	Experimental group	Control group	P value [a]
Weight (kg)	-2.2 [-3.1, -0.9] ***	+1.0 [-0.4, +2.1] *	<0.001
BMI (kg/cm^2)	-0.8 [-1.2, -0.3] ***	+0.4 [-1.5, +0.85] *	<0.001
Waist (cm)	-2.3 [-5.0, -1.0] ***	+1.0 [-0.3, +2.0] **	<0.001
Lean mass (%)	+0.8 [-0.2, +1.8] *	-0.3 [-0.8, +0.3]	<0.01
Body fat mass (%)	-0.8 [-1.8, +0.2] *	+0.5 [-0.3, +0.8]	<0.01
Fasting plasma glucose (mg/dL)	-5.0 [-10.5, +1.0] *	+3.0 [-1.5, +12.0] *	<0.01
Systolic BP (mmHg)	-2.5 [-10.5, +1.0]	+3.0 [-2.5, +9.5]	0.04
Diastolic BP (mmHg)	-2.0 [-7.5, +1.8]	+4.0 [-0.5, +11.5] *	0.01
Thai CVD risk (%)	-0.25 [-0.43, +0.13]	+0.10 [-0.10, +0.70]	0.02
Thai DM risk score	0.0 [-2.0, 0.0] *	0.0 [0.0, 0.0]	0.02
Energy (kcal/day)	-334 [-574, -128] ***	+77 [-134, 288]	<0.001
% Carbohydrate	-4.0 [-9.3, +2.0] *	0.0 [-4.5, +2.5]	0.20
% Protein	5.0 [+3.0, +7.3] ***	1.0 [-1.0, +2.5] *	<0.01
% Fat	0.0 [-6.25, 5.5]	0.0 [-3.5, +2.5]	0.87
Fiber (g/day)	+2.0 [-1.3, +6.3] *	+2.0 [-1.0, +4.0]	0.53
Sugar (g/day)	-24.8 [-10.5, +0.5] *	+11.0 [-14.4, +22.0]	0.07
Saturated fat (g/day)	-4.5 [-12.3, +3.5] *	0.0 [-4.5, +6.5]	0.11
Sodium (mg/day)	+39 [-1197, +1027]	+492 [-796, +1529]	0.17
Water (ml/day)	+350 [0, +625] **	0 [0, 0]	<0.01
Vegetable (serving/day)	+0.47 [0.00, +1.31] **	0.00 [0.00, 0.00]	<0.01
Fruit (serving/day)	+0.07 [-0.27, +0.52]	0.00 [0.00, +0.13]	0.70
Whole gain (serving/day)	0.00 [-0.40, +0.34]	0.00 [0.00, +0.09]	0.98
Legume (serving/day)	0.00 [-1.7, +0.28]	0.00 [-0.2, 0.00]	0.60
MVPA (minutes/week)	+55 [+8, +90] *	0 [0, 0]	<0.001

Data are shown as median [P25, P75].

[a] = metabolic outcome change between group, non-parametric test, Mann-Whitney U-test.

*** = P<0.001; ** = P<0.01; * = P<0.05, outcome changes within group with Paired T-test.

BMI, body index mass; BP, blood pressure, Thai CVD risk, Thai cardiovascular risk; Thai DM risk score, Thai diabetic risk score; MVPA, Moderate to vigorous intensity physical activity.

DISCUSSION

To maximize the effectiveness of the program, this intervention was emphasized individual approach by the stages of change in face-to-face counselling and technology-assisted via LINE application. The program demonstrated that participants in the experimental group had greater percentage of weight loss and better cardiometabolic parameters than the usual care. These results accorded to large randomized controlled trials including the US DPP (6), Thai DPP (7) and the Da Qing study (8) that could prevent T2DM in long term. Systematic reviews in 2017 reported MNT and weight loss are the strongest evidence altered clinical parameters (9). This program had percentage weight loss 3.11%. At least 3–5% of initial weight loss is clinically meaningful reductions in cardiovascular risk factors (10). Long term lifestyle modification program had average weight loss 5.6 kg in 3 years from the US DPP (6) and 1.5 kg in 2 years from the Thai DPP (7). The reduction in blood glucose and DM risk score was similar to 3-month prediabetes program with individualized MNT by dietitian in the US (5).

Energy balance with a reasonable meal plan by dietitian is the key to achieve weight goal. Energy requirement was calculated by individual with predictive equation. There is no ideal macronutrient distribution for people with prediabetes. Provided MNT was based on individual preferences and metabolic goals. In addition, quality of food patterns should be focused on dense nutrient-rich foods more than specific nutrients. Evidence suggests healthy food such as whole grains, legumes, nuts, fruits and vegetables, and minimal refined and processed foods (11). The nutrient consumption in experimental group was changed by increasing fiber, and decreasing sugar and saturated fat. Increasing water intake was promoted by replacing sugary drink strategy and when exercise (12). Experimental group increased minutes of moderate-intensity physical activity above control group. Active physical activity improves insulin sensitivity and reduces abdominal fat. At least 150 min/week of moderate-intensity physical activity has beneficial effects in prediabetes (13).

CONCLUSION

This study proved that 12-week individual approach with MNT and technology-assisted intervention could reduce percentage of weight change. Proportion of IFG status and other cardiometabolic parameters also improved in experimental group over control group. Change of better outcomes was according to healthier diet pattern, more active physical activity. So intensive lifestyle intervention should be started after diagnosis of prediabetes to prevent or delay diabetes and upcoming complication.

CONFLICT OF INTEREST

There is no conflict of interest in this study.

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