Original Article

Effects of a Health Promotion Program Conducted by Nurses on Stabilization of HbA1C in Subjects at Risk for Diabetes: A Phase III Randomized Controlled Trial

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Background: Although pre-diabetes subjects are at increased risk for developing type 2 diabetes, several studies have shown that lifestyle modification can decrease the number of cases that progress to diabetes. Data from Thai pre-diabetes population relative to the effect of medium-term intervention to lower hemoglobin [HbA1C] and prevent the onset of diabetes are scarce.

Objective: To investigate the effect of a nurse-managed 6-month health promotion program designed to lower HbA1C and other risk factors for diabetes, and to prevent the onset of diabetes among Thai persons diagnosed with pre-diabetes.

Materials and Methods: This 6-month randomized controlled trial was conducted at the outpatient department of the Siriraj Hospital, Thailand's largest national tertiary referral center-during the 2012 to 2014 study period. Subjects at risk for diabetes were recruited and randomly assigned to either the intervention group or the control group. Study group subjects participated in the study's health promotion protocol, with control group subjects receiving only routine self-care recommendations for preventing diabetes. Clinical and laboratory characteristics in both groups were recorded at baseline and at preestablished time points.

Results: One hundred twenty-five pre-diabetes subjects were included, with 61 and 64 subjects assigned to the study and control groups, respectively. At the 6-month time point, 9.3% in the study group and 8.6% in the control group could reduce their HbA1C level by more than 0.5%. Increase of HbA1C at the end of study was less frequent in the study group than in the control group (16.7% vs. 36.2%, respectively; $p = 0.025$). Diet and exercise behavior with self-efficacy improved more in the study group than in the control group. Prevalence of metabolic syndrome was significantly reduced from 50% to 23.8% in the study group ($p<0.001$).

Conclusion: The nurse-managed health promotion program investigated among Thai pre-diabetes subjects in the present study improved HbA1C, several risk behaviors, and the incidence of metabolic syndrome. Implementation of this program may benefit both patients and health care systems by increasing patient health and lowering diabetes-related costs.

Keywords: Thailand Health promotion program, Nurses, HbA1C reduction, Diabetes, Health belief model

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The prevalence of diabetes is increasing worldwide[1], and many cases of diabetes are undiagnosed[2]. Compared to healthy subjects, diabetes patients have higher morbidity and mortality, and lower quality of life. Accordingly, the identification of subjects at high-risk for diabetes or pre-diabetes and the implementation of a plan to prevent the onset of type 2 diabetes are important steps toward improving patient health status and lowering the cost of treating this enormously expensive disorder. Several studies demonstrated that lifestyle interventions could play a pivotal role in delaying or preventing the onset of diabetes[3-7]. A lifestyle interventions program, that consisted of 7% reduction in bodyweight, increased consumption of low-calorie foods, low-fat foods, and fiber; moderate intensity exercise for at least 150 minutes per week; and close follow-up by a case manager or nutritionist, could decreased the incidence of diabetes by 58%[5]. Several studies that have been conducted in Thailand were able to successfully demonstrate the effectiveness of lifestyle modification for preventing diabetes in subjects at high risk for developing this disease[8-11]. However, those studies were limited in their ability to comprehensively investigate the effects of preventive intervention in pre-diabetes population in several

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aspects, including non-randomized controlled trials design, short duration study periods study subjects from rural communities and villages only, and absence of laboratory monitoring. Accordingly, the aim of the present study was to investigate the effect of a nurse-managed 6-month health promotion program design to lower hemoglobin A1C [HbA1C] and other risk factors for diabetes, and to prevent the onset of diabetes among Thai persons diagnosed with or at risk for developing prediabetes.

Materials and Methods

Subjects

This 6-month randomized controlled trial was conducted at the outpatient department [OPD] of the Faculty of Medicine Siriraj Hospital, Mahidol University, Bangkok, Thailand. Siriraj Hospital is Thailand's largest national tertiary referral center. Subjects that attended our OPD for a health check-up that met the inclusion criteria were recruited. The protocol for the present study was approved by the Siriraj Institutional Review Board [SIRB] (COA No.Si364/2011), and complied with the principles set forth in the Declaration of Helsinki (1964) and all of its subsequent amendments. Written informed consent was obtained from all participants.

Willing subjects that met the following inclusion criteria were included, 1) aged 18 years or older; 2) Thai diabetes risk scores of 6 or more, which indicated that he/she had an 11% to 20% increased risk of developing type 2 diabetes within the next 12 years[2], and 3) HbA1C levels of 5.7% to 6.4% or one of the following, fasting plasma glucose [FPG] levels of 100 to 125 mg/dl, high-density lipoprotein [HDL]-cholesterol levels of less than 35 mg/dl, triglyceride levels greater than 250 mg/dl, history of gestational diabetes mellitus or delivery of an infant with a birth weights heavier than 4 kg. Subjects that were unwilling or unable to participate in study group program activities were excluded.

Study protocol

Included subjects were randomized into the study or control group using a randomization table (Figure 1). Each participant underwent a complete history, and physical examination, answered the diet and exercise behavior questionnaire, answered the self-efficacy questionnaire, and had screening laboratory tests, including FPG, HbA1C, and lipid profiles, at baseline and at the end of the study.

The control group received routine self-care recommendations including 30 to 60 minutes individual counseling in every module for preventing diabetes at randomization. Participants were followed-up by telephone at weeks 4, 12, and 24 to assess health risk behavior.

The study group was asked to attend a group activity at week 1, 2, and 8. Each participant was then followed-up by telephone every two weeks until the end of the study. All activities aimed to assess health risk behaviors and to encourage healthy behaviors, including food selection, exercise, and stress management.

Group activity: Subjects in the study group were divided into smaller groups (5 to 6 members), to participate in group activities, each of which two to four hours in length. Group activities included germane general knowledge, information and training regarding how to exercise and select healthy foods, and cognitive modification. All group activities were conducted by at least one nurse using the Health Belief Model[12], the Self-Efficacy Theory[8-10], and group process techniques[8] (details relating to each group activity are given in Supplement 1).

Individual activity: During the telephone follow-up, the nurse would observe for and seek to correct

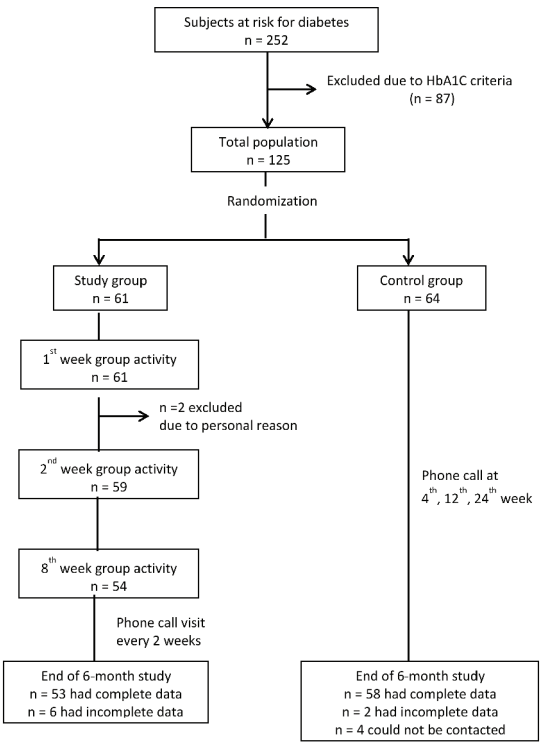

Figure 1. Study protocol.

participants who could not effectively modify risk behaviors or who had any problems after the group activity. The nurse would also attempt to help and motivate the participant to readjust his/her attitude and perspective toward healthy behaviors.

Outcome assessment

The following clinical factors were compared between baseline and the end of the 6-month study period, as shown below:

1. HbA1C (clinically significant change was considered to be ≥0.5% improvement between baseline and 6-months);
2. Clinical characteristics, including body weight, body mass index, and waist circumference;
3. Laboratories results, including FPG, HbA1C, triglycerides, and HDL-cholesterol;
4. Behavior and Self-Efficacy Test score modified[8,13] [5-point Likest scale, with a score range from 10 to 50, and interpretation using the midpoint criterion that was categorized into the following three levels: low (less than 60%), medium (60% to 80%), and high (more than 80%)]; and
5. Incidence of metabolic syndrome using National Cholesterol Education Program Adult Treatment Panel III [NCEP ATP III] for the diagnosis of metabolic syndrome[14].

Laboratory analysis

Plasma glucose levels were measured by the hexokinase method using an automated Roche Modular P800 Chemistry Analyzer (Roche Diagnostics, Basel, Switzerland). HbA1C levels were measured by turbidimetric inhibition immunoassay using a Roche COBAS Integra 800 Chemistry Analyzer (Roche Diagnostics, Basel, Switzerland). Total serum cholesterol, HDL-cholesterol, and triglycerides were measured by enzymatic colorimetric assay using an Automated Roche Hitachi 917 Immunoassay System (Roche Diagnostics, Basel, Switzerland).

Sample size calculation

Previous study[5] showed that intensive lifestyle modification could reduce plasma glucose by 58% whereas behavior modification in routine work could reduce plasma glucose about 15%. This program was integrated with routine works, therefore, we expected that the reduction of plasma glucose from our program would be 40%. Type 1 error and type 2 error was set at 5% and 20%, respectively. Therefore, the sample size per group was 50 persons. The follow up period of the present study was 6-month with an expected drop out of 10%, therefore, the number of participants in each group should be 60 persons.

Statistical analysis

Data analysis was performed using SPSS Statistics version 18 (SPSS Inc., Chicago, IL, USA). Demographic and clinical data were interpreted using descriptive statistics. Data are presented as percentage, number and percentage, or mean ± standard deviation. T-test, Chi-square test, or Fisher's exact test were used to compare data between groups, as appropriate.

Pair t-test and McNemar test were used for intra-group comparisons. For all analyses, a *p*-value less than 0.05 was regarded as being statistically significant.

Results

Baseline characteristics

One hundred twenty-five subjects at high-risk for developing diabetes were randomized. Sixty-four and 61 participants were randomly allocated to the control group and study group, respectively. Most subjects were female (93/125, 74.4%), with mean age of 54.7±9.6 years, a mean BMI of 27±4.1 kg/m^2, and a mean HbA1C of 6.0±1.8%. There was no difference in demographic, clinical, and laboratory characteristics, behavior score, or self-efficacy score between groups (Table 1).

Effect of health promotion program on reduction of HbA1C

Based on the pre-established definition of clinical significance in the present study, 9.3% in the study group and 8.6% in the control group had HbA1C reduction of 0.5% or more. As shown in Figure 2, at the 6-month time point, a significantly lower number of people in the study group had increased HbA1C, when compared to the control group (16.7% versus 36.2%, respectively; $p = 0.025$).

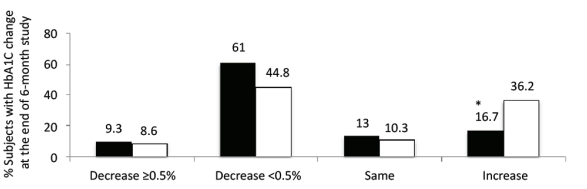

Figure 2. Subjects with HbA1C change at the end of 6-month study (%) compared between study group (■) and control group (□).

Table 1. Baseline clinical and laboratories characteristics in each group

Characteristics	Total population (n = 125)	Study group (n = 61)	Control group (n = 64)	*p*-value
Age (years)	54.7±9.6	55.9±9.3	53.6±9.8	0.175
Female	93 (74.4)	47 (77.0)	46 (71.9)	0.508
History of gestational diabetes	4/93 (4.3)	1/47 (2.1)	3/46 (6.5)	0.619
Education				0.448
≤ high school education	67 (54)	31 (51)	36 (56)	
> high school education	58 (46)	30 (49)	28 (44)	
Salary (baht/month)				0.407
≤20,000	90 (72)	46 (75)	44 (69)	
>20,000	35 (28)	15 (25)	20 (31)	
Body weight (kg)	69.8±12.6	69.1±12.8	70.5±12.4	0.560
BMI (kg/m^2)	27.0±4.1	27.8±4.3	27.9±3.9	0.885
Waist circumference (cm)	92.6±9	92.5±8.5	92.8±9.5	0.861
Behavior test (score)	23.7±5.7	23.1±6.1	24.2±5.3	0.091
Self-efficacy test (score)	35.4±7.2	35.5±7.4	35.4±6.9	0.051
FPG (mg/dl)	98.5±9	98±9	99±9	0.307
HbA1C (%)	6.0±0.2	6.0±0.2	6.0±0.2	0.495
Triglyceride (mg/dl)	132 (38 to 441)	110 (38 to 354)	117 (39 to 441)	0.142
HDL-cholesterol (mg/dl)	55±13.8	58±14	53±13	0.054

Data presented as number and percentage, mean ± standard deviation, or median (min-max)

BMI = body mass index; FPG = fasting plasma glucose; HbA1C = hemoglobin A1C; HDL = high-density lipoprotein

Table 2. Compare outcome within group before and after intervention

Factor	Study group, mean ± SD		*p*-value Before-After	Control group, mean ± SD		*p*-value Before-After	*p*-value after 6-month Study vs. Control
	Before	After		Before	After		
Behavior test score	23±6	30±4	<0.001*	24±5	26±5	<0.001	<0.001*
Self-efficacy test score	35±7	38±6	0.006*	35±7	35±7	0.472	0.005*
Body weight (kg)	69.2±12.8	66.9±12.9	<0.001*	70.5±12.4	69.0±13.1	<0.001	0.388
Waist (cm)	92.5±8.6	89.0±8.9	<0.001*	92.8±9.5	90.6±9.7	<0.001	0.390
BMI (kg/m^2)	27.8±4.3	26.9±4.3	<0.001*	27.9±3.9	27.2±4.0	<0.001	0.697
HbA1C (%)	6.02±0.19	5.86±0.27	<0.001*	6.05±0.17	5.99±0.32	0.090	0.025*
FPG (mg/dl)	97.7±8.6	95.1±8.7	0.009*	99.4±9.4	96.4±10.0	0.058	0.472
HDL-cholesterol (mg/dl)	57±14	58±13	0.900	52±13	53±14	0.591	0.046*
Triglyceride (mg/dl)	122±65	110±62	0.024*	142±81	112±59	0.012	0.316
Metabolic syndrome (%)	50.0	23.8	<0.001*	42.6	36.1	0.363	0.786

Data presented as mean ± standard deviation or percentage

BMI = body mass index; FPG = fasting plasma glucose; HbA1C = hemoglobin A1C; HDL = high-density lipoprotein

* *p*-value <0.05

Effect of health promotion program on other risk factors for diabetes

At the 6-month time point in the study group, the mean Behavior Test score and Self-Efficacy Test score were both significantly improved from baseline (Table 2). This improvement resulted in a significant decreased in body weight, waist circumference, fasting plasma glucose, HbA1C, and triglycerides, from baseline (Table 2). The incidence of metabolic syndrome also decreased significantly in the study group. At 6 months in the control group, the mean Behavior Test and Self-Efficacy Test scores, body weight, waist circumference, and triglycerides also significantly improved. However, the increase in the end-of-study mean scores for both tests was significantly higher in the study group than in the control group (Table 2). Correspondingly, the improvement in HbA1C was higher in the study group than in the control group.

Discussion

The present study demonstrated that increased awareness of the risk of progression to diabetes in

both groups, control and study, could improve their preventive behaviors, based on improvement in behavior test score. Almost 10% of patients in both groups were able to reduce their HbA1C level by more than 0.5%. However, subjects in the study group could maintain or reduce their HbA1C level more than subjects in the control group (83% versus 63%, respectively). This difference between groups may be explained by both the group process method and close telephone follow-up to help subjects in the study group readjust their perspective toward sustained healthy behaviors. Recent studies have shown that group-based education in type 2 diabetes improved HbA1C levels, because this instructional method facilitates discussion and support from within the group[8,9,11]. The present study also showed more improvement in risk factors in the study group than in the control group. Importantly, only the study group showed significant improvement in the incidence of metabolic syndrome from baseline to 6 months. Given that internal factors, such as level of awareness, stress, and beliefs, affect behavior, the program that we designed using the Health Belief Model, and Self-Efficacy Theory[12] could help study participants to manage their internal factors. This resulted in increased awareness, improved self-efficacy, and a realization of the benefits of health behavior modification. A study from China found higher self-efficacy to be associated with better performance of diabetes self-care behaviors[3].

The Diabetes Prevention Program that studied the effect of intensive lifestyle modification for three years on reduction in diabetes incidence (consisting of 16 group activities within 6 months, and then a monthly group activity for three years) found the program hard to implement and sustain due to high workload, high time consumption, and high cost[5]. The program in the present study consisted of only three group activities, so the list of possible topics for activities was reduced to those we considered to be the most essential (i.e., focused essential information, food and exercise information and training, and stress management). By reducing the number of different types of potentially deliverable information, we were able to allow more time for participants to discuss and share their experiences and challenges. After the three group-activities were delivered, participants were contacted by telephone every two weeks to monitor and evaluate participant compliance and progress. Our finding that the studied intervention was effective, in both time and cost, permits us to recommend its implementation in real-world settings. Similar to the nurses who participated in and authored the present study, nurses involved in delivering this program must have a firm foundational understand of health promotion concepts and a positive attitude that will influence and motivate program participants.

The present study has some mentionable limitations. First, this study was conducted solely by nurses in the context of an insufficient number of available nutritionists and physician inability to participate due to heavy workload. A group process consisting of multidisciplinary team that includes physicians, nurses, and nutritionists may have more collective motivational power to improve and sustain behavior modification. Second, the 6-month duration of the present study, while longer than many previous studies, may not have been long enough to elucidate the ling-term effects of this program. As such, a longer duration study of this behavior modification program is warranted. Third and last, post-activity session follow-ups were conducted by telephone only. If the post-activity session follow-ups were to include various forms of popular social media, it is possible that the overall effectiveness of the program might increase.

Conclusion

The nurse-managed health promotion program investigated among Thai pre-diabetes subjects in the present study significantly improved HbA1C, several risk behaviors, and the incidence of metabolic syndrome. Implementation of this program may benefit both patients and health care system by increasing patient health and lowering diabetes-related costs of the hospital.

What is already known for this topic?

The Diabetes Prevention Program showed that intensive lifestyle intervention (consisting of 16 group activities within six months, and then a monthly group activity for three years) can prevent the development of type 2 diabetes in pre-diabetes subjects. However, the intervention in that program is hard to implement and sustain due to high workload, high time consumption, and high cost in general hospital.

What this study adds?

A nurse-managed 6-month health promotion program using the Health Belief Model, and Self-Efficacy Theory in pre-diabetes subjects, can improve HbA1C, several risk behaviors and the incidence of metabolic syndrome and can be applied in every general hospital setting.

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Potential conflicts of interest

The authors declare no conflict of interest.

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