ORIGINAL RESEARCH



# Effect of Group Patient Education on Glycemic Control Among People Living with Type 2 Diabetes in Vietnam: A Randomized Controlled Single-Center Trial

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# ABSTRACT

*Introduction*: In low- to middle-income countries such as Vietnam, urgent measures are required to prevent and control type 2 diabetes and its complications. This study measured the effect of a 3-month patient education and self-management intervention in a low-resource setting on diabetes knowledge and levels of blood glucose control.

*Methods*: This was a single-center randomized controlled study among adult outpatients with type 2 diabetes. Patients were randomly assigned to 3-month community intervention consisting of group education for type 2 diabetes knowledge, diet, exercise in combination with usual diabetes care, or to usual diabetes care alone (control). Diabetes knowledge was measured with a modified Michigan University Diabetes Knowledge Test (MDKT). Other study outcomes included change in mean HbA1c, fasting blood glucose (FBG), and systolic blood pressure (SBP).

**Supplementary Information** The online version contains supplementary material available at https://doi.org/10.1007/s13300-021-01052-8.

H. T. K. Thanh (🖾) · T. M. Tien Hanoi Medical University, Vietnam National Geriatric Hospital, 1 Ton That Tung Street, Dong Da, Hanoi, Vietnam e-mail: hokimthanh@hmu.edu.vn Results: A total of 364 patients were randomized, 182 to the intervention group and 182 to control. The two groups were similar regarding main baseline characteristics. The male/female ratio was 45.1%/54.9% and mean age was  $62.2 \pm 9.3$  years. Approximately half the patients (48.1%) were overweight and 15.7% were obese, mean baseline HbA1c was  $8.21 \pm 1.92\%$ , and only 29.9% of participants had a baseline HbA1c < 7.0%. At baseline, diabetes knowledge was "very poor" or "poor" in 63.7% of patients. After a 3-month follow-up, the proportion achieving the target MDKT score increased from 37.4% to 81.3% in the intervention group and from 35.2% to 51.7% in the control (between-group difference P < 0.001). The estimate (SD) of the difference between intervention and control groups was - 1.63 (2.16), 95% CI – 2.07 to – 1.18. Mean changes from baseline HbA1c were  $-0.54 \pm 1.41\%$ and  $-0.18 \pm 1.33\%$  in the intervention and control groups, respectively (P = 0.012). Among those with poor glycemic control (HbA1c  $\geq$  7%) at baseline, mean changes at 3 months were  $-0.80 \pm 1.52\%$  vs  $0.41 \pm 1.47\%$ , respectively, (P = 0.013). Statistically significant decreases in FBG and SBP were also observed in the intervention group at 3 months, but not in the control group. Multivariate analysis revealed the variables with the strongest influence on blood glucose control at 3 months were study group, baseline MDKT score, diabetes duration, and baseline HbA1c (all  $P \le 0.05$ ).

*Conclusion*: Provision of a structured educational program to Vietnamese people living with type 2 diabetes is effective at improving disease knowledge and is associated with better glycemic control. Larger and longer-term studies are now warranted to confirm these findings. *Trial Registration*: This trial was retrospectively registered on 27 May 2020 through the https://clinicaltrials.gov site with the following identifier: NCT04403841

**Keywords:** Developing countries; Diabetes mellitus type 2; Glycemic control; Patient education; Self-management; Vietnam

#### **Key Summary Points**

#### Why carry out this study?

A challenge in low- to middle-income countries such as Vietnam is to implement effective, affordable, and sustainable interventions to reduce the rising prevalence of type 2 diabetes and its complications.

Few data are available on the value of education and lifestyle intervention in type 2 diabetes outside of developed countries.

This was addressed in the current study which evaluated the effects of a patient education and self-management intervention as add-on to usual diabetes care on diabetes knowledge and blood glucose control parameters in Vietnamese patients with type 2 diabetes.

#### What was learned from the study?

A low level of diabetes knowledge was confirmed among the general population as well as overall poor blood glucose control. After only 3 months, patients randomized to three 45-min sessions of additional education and support achieved significantly improved disease awareness and blood glucose control compared with those receiving usual diabetes care alone, particularly in those whose HbA1c was not controlled at baseline.

Structured, group-based educational intervention for people with type 2 diabetes may offer an effective and affordable means of increasing disease knowledge and improving levels of blood glucose control in low- to middle-income countries.

# DIGITAL FEATURES

This article is published with digital features, including a summary slide, to facilitate understanding of the article. To view digital features for this article go to https://doi.org/10.6084/m9.figshare.14222459.

# INTRODUCTION

In Vietnam and other low- to middle-income countries, the rapid transition from an agricultural to more industrial economy with associated changes in lifestyle and nutrition habits has been accompanied by an increase in the prevalence of non-communicable diseases such as type 2 diabetes [1–6]. Estimates based on data from over 1600 individuals participating in community diabetes screening programs over the period 2011–2013 reported a diabetes prevalence of 6.0% and prediabetes prevalence of 13.5% [7]. These rates are projected to rise to 7.0% and 15.7%, respectively, by 2035 as a result of population aging [7].

The challenge in these lower-income countries is to establish effective and affordable interventions to prevent the development of type 2 diabetes and its complications that can be successfully accessed, implemented, and

sustained. A number of systematic reviews and meta-analyses have demonstrated that compared with standard care alone, diabetes selfmanagement education (DSME) programs are effective at improving glycemic control, body mass index, and other cardiovascular risk factors in a range of different populations, regardless of the duration since type 2 diabetes diagnosis [8-12]. In particular, group-based programs with active participation appear to provide the greatest benefits. A recent review of 21 studies from the Asian Western Pacific region including Vietnam confirmed these findings, but highlighted an urgent need to develop culturally appropriate DSME and ensure that all communities have access to such programs [10]. Studies conducted in different parts of the world have suggested that many patients lack the skills to self-manage their condition [13, 14]. Vietnam is no exception, with a low level of diabetes knowledge among the general population aged 40-64 years, and significantly lower awareness in rural areas compared with urban areas [14]. Community-based programs, providing culturally appropriate diabetes health education, offer a practical, relatively low-resource solution [15–17]. One such program is the Ngaydautien project (https://ngaydautien. vn), which was launched in 2016 in collaboration with the Ministry of Health, Vietnam National Heart Association, Vietnam Association of Diabetes & Endocrinology, and the private sector. The main goal of this project is to improve control of type 2 diabetes and hypertension through education of patients, providing them with the skills to self-manage their condition. While a few Vietnam-based studies have examined methods of promoting health to patients with diabetes from a nursing perspective [18, 19], there is little research on patients' knowledge of type 2 diabetes and the impact that this has on diabetes management.

The aim of the current study was therefore to evaluate the effects of a patient education and self-management intervention as add-on to usual diabetes care in a low-resource setting on diabetes knowledge and blood glucose control parameters in Vietnamese patients with type 2 diabetes.

# METHODS

#### **Study Design**

This was a single-center randomized controlled study conducted between August 2017 and July 2018 among adults with type 2 diabetes in Vietnam. The study protocol was approved by the independent local Institutional Review Board of Thach That General Hospital and Hanoi Medical University, Hanoi. The trial was registered through the https://clinicaltrials.gov site with the following identifier: NCT04403841. The trial was performed in accordance with the Helsinki Declaration of 1964 and its later amendments. Written informed consent for participation in this study was obtained from all participants.

Male and female outpatients with a diagnosis of type 2 diabetes treated at Thach That General Hospital were screened for study eligibility. Type 2 diabetes diagnosis was based on the criteria of the American Diabetes Association (ADA) [20] as recommended by the Vietnam Ministry of Health: fasting blood glu- $\cos e \ge 126 \text{ mg/dL} (7.0 \text{ mmol/L}); \text{ blood glucose}$ after a 2 h, 75 g oral glucose tolerance test  $\geq 200 \text{ mg/dL}$  (11.1 mmol/L); or any blood glucose value > 200 mg/dL(11.1 mmol/L)accompanied by typical conditions of hyperglycemia. Random sampling was used among nearly 1000 patients with diabetes treated monthly in Thach That Hospital, to ensure that the participants were representative of the whole population. Inclusion criteria were patients diagnosed with type 2 diabetes as defined above; aged 40-80 years old; ability to attend monthly clinic visits; and signed informed consent. All antidiabetes treatments were permitted including insulin. Exclusion criteria included a diagnosis of mental or neurological diseases that could interfere with the ability to comply with study procedures; pregnancy; lactation; known drug or alcohol dependence; and requirement for a change in antidiabetes treatment over the study period. The latter was required to ensure that any changes in HbA1c during the study were due to the educational intervention and not changes in treatment.

#### **Study Interventions and Outcomes**

Patients meeting the inclusion criteria were randomly allocated in a 1:1 ratio to either a community intervention or to usual diabetes care alone (control group) for a period of 3 months. Randomization was based on a single sequence of random assignments (simple randomization). The study was designed and powered to show the superiority of the community intervention over usual diabetes care alone.

Usual diabetes care was consistent with the ADA guidelines [15] and comprised standard dietary and exercise advice in addition to antidiabetes treatment. The community intervention was delivered as part of the Ngaydautien project (https://ngaydautien.vn/gioi-thieungay-dau-tien), a collaborative effort between the Vietnam government and national diabetes and hypertension societies to improve disease self-management. At the inclusion visit, individuals were divided into small groups of 5-10 patients according to their level of awareness, assessed using the modified Michigan University Diabetes Knowledge Test (MDKT) [21, 22]. The typical characteristics of patients in each group and the corresponding educational goals are illustrated in Supplementary Material Table 1. The intervention consisted of group education on type 2 diabetes including, in addition to usual diabetes care, information on diet, exercise, drug therapy, and adherence. This was provided in the form of three 45-min sessions led by trained medical staff educators and is easily performed at any diabetes clinic or hospital outpatient setting. The overall aim of the sessions was to increase patients' knowledge and self-awareness and thus enable them to take charge of their own diabetes self-management. Regardless of disease awareness group, the focus of the individual group sessions was on patient collaboration and exchange of knowledge and information. The educators were trained to communicate with patients in a constructive and sympathetic manner to encourage changes in the patients' health-related behavior and reduce their risk of future type 2 diabetes-related complications. Each education session consisted of five steps: (1) introduction to group members; (2) patient interviews to determine their knowledge on type 2 diabetes, nutrition, exercise, and medication adherence; (3) provision of information, the theme of which changed each month, e.g., diet and balanced nutrition (month 1), how to maintain a suitable exercise program (month 2), and use of type 2 diabetes medication (month 3); (4) question and answers; and (5) provision of the patient toolkit and scheduling of next appointment. The patient toolkit was available as part of the Ngaydautien project, which included a patient leaflet, guidebook, and instructions on how to access the program via www.ngaydautien.vn. Each patient attended the group education monthly, over three consecutive months.

#### Primary Outcome: Disease Awareness

All patients completed a modified MDKT [21] at baseline and at the end of the 3-month trial. The MDKT was selected as it has been widely used in diverse populations [23-28], and because it is a quick and low-cost method of assessing general knowledge of diabetes and diabetes self-care that has previously demonstrated appropriate reliability and validity [21, 22]. The 23-item original questionnaire was translated into Vietnamese and adapted as required on the basis of a pilot test performed in 10 people with type 2 diabetes, which resulted in one question being removed. The modified questionnaire therefore consisted of 22 statements with multiple choice answers with 1 point awarded for each correct answer (Supplementary Material, Document 1). Patients who answered more than 50% of the questions correctly were considered to pass the knowledge test, and patients who answered less than 50% of the questions correctly were considered to fail. The proportion of successful patients (i.e., with MDKT total score  $\geq 11$ ) was the study primary outcome. The four subcategories of the total score considered to assess patients' level of awareness were < 5.5 (very poor), 5.5 to < 11 (poor),  $11 \le 16.5$  (average), and  $\ge 16.5$  (good).

#### **Clinical Outcomes**

Clinical outcomes were measured at baseline and after the 3-month follow-up.

The primary clinical outcome was change in HbA1c level. Two categories of HbA1c level were also defined for the analysis: controlled and uncontrolled, < 7% and  $\ge 7\%$ , based on guide-line-recommended target HbA1c levels at the time of the study [29–31].

Secondary outcomes included laboratory parameters (fasting blood glucose [FPG], total cholesterol, HDL, LDL, triglycerides), BMI, and blood pressure. Hypertension was defined according to Vietnamese guidelines (SBP  $\geq$  140 mmHg and/or DBP > 90 mmHg) [32].

Classification of BMI level was based on World Health Organization (WHO) criteria for the Asia–Pacific region:  $18.5-22.9 \text{ mg/kg}^2$  (normal weight),  $23-24.9 \text{ kg/m}^2$  (overweight),  $25-29.9 \text{ kg/m}^2$  (obesity level 1),  $\geq 30 \text{ kg/m}^2$  (obesity level 2) [33].

#### **Statistical Analysis**

Sample size estimation was calculated on the basis of the primary outcome and expressed as the proportion of patients with successful test completion after 3 months. The sample size was calculated with SAS® software 9.4 (SAS Institute, Cary, North Carolina, USA) for a superiority design based on a one-sided Pearson chi-square test [34].

The value assumed for the outcome in the control group was 43% according to a previous study undertaken in Vietnam [35]. It was therefore estimated that 270 participants would be needed to detect approximately a 20% improvement with an alpha of 0.025 and a power of 80.0%. With a 20% loss to follow-up anticipated, a total of 340 participants (170 per group) were targeted.

Results are presented as means and standard deviations (SD) for continuous data and frequencies and percentages for categorical data. A chi-square test was used for between-group comparisons of categorical variables. To compare values of continuous variables at the same time point between the control and intervention groups the two-sample t test was used. The Wilcoxon rank sum test was used for MDKT, which did not exhibit a normal distribution. Changes at 3 months were compared to the baseline values with the paired t test (or Wilcoxon paired test for the MDKT).

Univariate logistic regression analysis was used to identify potential factors influencing blood glucose control in patients with uncontrolled HbA1c at baseline based on Wald chisquare test P values (PROC LOGISTIC under SAS 9.4). All variables testing significant in univariate analysis were included in the multivariate logistic regression analysis using a stepwise selection procedure where a significance level of 0.2 was required to allow a variable to enter the model, and a significance level of 0.05 was required for a variable to stay in the model. In this manner, only factors independently significant at the 5% threshold were retained. Odds ratios and their 95% CI and associated Wald chi-square test *P* values were calculated. Statistical significance was assumed when P < 0.05. SAS® (SAS Institute, Cary, North Carolina, USA) software 9.4. was used for statistical analyses.

### RESULTS

#### **Demography and Baseline Characteristics**

A total of 405 patients met the inclusion criteria and were randomized to community intervention or to the control group. A total of 19 patients who did not come to the hospital monthly or moved to another location and 22 patients who changed their antidiabetes medications during the study period were excluded from the analysis. As a result, 364 patients, 182 in the intervention group and 182 in the control group, were included in the analysis (Fig. 1).

Demographic data and clinical characteristics were similar between the control and intervention groups with no statistically significant differences and are summarized in Table 1.

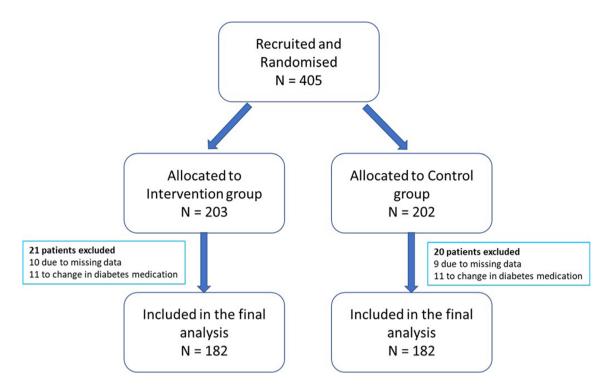


Fig. 1 Flow of patients through the study

Baseline macrovascular complications included coronary artery disease (one angina pectoris and one myocardial infarction, both in the control group), stroke (four individuals, all in the control group), and peripheral arterial disease (four cases of diabetic foot affecting two patients in each group). Baseline microvascular complications included retinopathy (five cases, two in the control group and three in the education group), and neuropathy (two cases both in the control group). Nephropathy was not evaluated in this study.

Mean MDKT baseline score was  $7.70 \pm 2.98$ , with a majority of patients having a very poor or poor knowledge of their disease (63.7%). The baseline rate of successful test completion (36.3%) was comparable in both groups.

Mean baseline HbA1c was  $8.21 \pm 1.92\%$ . The mean value was numerically lower in the intervention group ( $8.09 \pm 1.85\%$ ) than in the control group ( $8.32 \pm 2.09\%$ ). Less than one third of participants had a baseline HbA1c < 7.0% (29.9%) and this proportion was comparable in both groups: 30.8% in the control group and 29.1% in the intervention group.

At baseline, patients were receiving a range of antidiabetes medications including metformin, sulfonylureas or fixed-dose combinations thereof, acarbose, and insulins. The proportion of patients receiving the different treatments was similar between the two groups with the exception of a greater number of patients on insulin in the control group (32 vs 23 patients) and a greater number of patients on metformin alone in the intervention group (12 vs 22 patients); neither of these differences reached statistical significance (Table 2). The doses of antidiabetes medications were also evenly distributed between the control and intervention groups (Supplementary Material Table 2). As part of the study inclusion criteria no changes in antidiabetes treatments or dosing were permitted during the study.

#### Michigan Diabetes Knowledge Test

Mean MDKT values increased in both groups over the 3-month study period, from  $7.86 \pm 2.91$  to  $10.52 \pm 2.08$  in the intervention group (a mean improvement in score of

Table 1         Baseline demographic and clinical characteristic	CS
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Baseline characteristics	Control (N = 182)	Intervention (N = 182)	All (N = 364)	P value (between- group comparison)
Mean age (± SD) (years)	$62.9 \pm 9.4$	61.5 ± 9.2	62.2 ± 9.3	0.148ª
Gender (% female)	54.4	55.5	54.9	0.833 <sup>b</sup>
Duration of disease (% in each category)				
< 1 year	10.4	11.0	10.7	0.297 <sup>b</sup>
1–5 years	51.1	58.2	54.7	
> 5 years	38.5	30.8	34.6	
Mean duration (years)	$4.4 \pm 2.7$	$4.4 \pm 2.6$	$4.4 \pm 2.7$	0.873 <sup>a</sup>
Family history of diabetes (% yes)	30.2	27.5	28.8	0.732 <sup>c</sup>
Regular tobacco smoking (% yes)	15.9	13.2	14.6	0.756 <sup>b</sup>
Regular alcohol consumption (% yes)	22.5	19.8	21.2	0.206 <sup>c</sup>
Comorbidities (% with comorbidity)				
None	43.4	48.9	46.2	0.493 <sup>b</sup>
Arterial hypertension	34.6	34.1	34.3	
Lipid disorders	31.9	28.6	30.2	
Physical activity (% performing)				0.560 <sup>b</sup>
None	15.9	12.6	14.3	
< 3 times/week	18.1	16.5	17.3	
Regularly	65.9	70.9	68.4	
Level of type 2 diabetes awareness (% in each	category)			0.338 <sup>b</sup>
Very poor	28.0	21.4	24.7	
Poor	36.8	41.2	39.0	
Average	35.2	37.4	36.3	
MDKT mean score ( $\pm$ SD)	$7.53\pm2.98$	$7.86\pm2.91$	$7.70\pm2.98$	0.286 <sup>a</sup>
Success (%)	35.2	37.4	36.3	0.663 <sup>b</sup>
Failure (%)	64.8	62.6	63.7	
Mean HbA1c (± SD)	$8.32 \pm 1.99$	$8.09 \pm 1.85$	$8.21 \pm 1.92$	0.259 <sup>a</sup>
% of HbA1c < 7%	30.8	29.1	29.9	0.731 <sup>b</sup>
% of HbA1c $\geq$ 7%	69.2	70.9	70.1	
Mean fasting blood glucose (mmol/L)	$8.72 \pm 2.66$	$8.95 \pm 2.82$	$8.83\pm2.74$	0.432 <sup>a</sup>
BMI (kg/m <sup>2</sup> ) mean ( $\pm$ SD)	22.9 ± 2.9	$22.7 \pm 2.8$	$22.8\pm2.8$	0.458 <sup>a</sup>
18.5-22.9 (n, %)	11 (6.0)	8 (4.4)	19 (5.2)	0.160 <sup>b</sup>

Baseline characteristics	Control (N = 182)	Intervention (N = 182)	All (N = 364)	P value (between- group comparison)
23.0-24.9 (n, %)	76 (41.8)	94 (51.7)	170 (46.7)	
25.0 to $\geq$ 30.0 ( <i>n</i> , %)	95 (52.2)	80 (44.0)	175 (48.1)	
Systolic blood pressure (mmHg)	$124.5 \pm 17.4$	$123.5 \pm 15.5$	$124.0 \pm 16.5$	0.579 <sup>a</sup>
Diastolic blood pressure (mmHg)	$76.8\pm9.5$	$75.3 \pm 9.2$	$76.1 \pm 9.4$	0.121 <sup>a</sup>
SBP $\geq$ 140 mmHg and/or DBP $>$ 90 mmHg at the visit ( <i>n</i> , %)	52 (28.6)	34 (18.7)	86 (23.6)	0.026 <sup>b</sup>
Total cholesterol (mmol/L)	$5.1 \pm 1.3$	$5.1 \pm 1.3$	$5.1 \pm 1.3$	0.834 <sup>a</sup>
Triglycerides (mmol/L)	$2.6 \pm 1.7$	$2.7 \pm 1.8$	$2.6 \pm 1.8$	0.878 <sup>a</sup>

#### Table 1 continued

<sup>a</sup> Student's *t* test

<sup>b</sup> Chi-square test

<sup>c</sup> Fisher's exact test

Table 2 Most common a	antidiabetes	treatments	prescribed	at	baseline
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Treatment	Number (%) patients					
	Control	Intervention	P value <sup>a</sup>			
Oral antidiabetes agents						
Metformin + glibenclamide	99 (54.4)	99 (54.4)	1.00			
Metformin + gliclazide	20 (11.0)	17 (9.3)	0.60			
Metformin alone	12 (6.6)	22 (12.1)	0.07			
Acarbose alone	12 (6.6)	11 (6.0)	0.83			
Insulin-based treatment	32 (17.6)	23 (12.6)	0.19			
Non-insulin-based treatment	150 (82.4)	159 (87.4)				

<sup>a</sup> Chi-square test

 $2.66 \pm 2.49$ ) and from  $7.53 \pm 2.98$  to  $8.57 \pm 2.86$  in the control group (a mean improvement in score of  $1.03 \pm 1.78$ ) (Table 3). The improvement was significant in both groups (intra-group comparison P < 0.001) and significantly more pronounced in the intervention group (between group comparison P < 0.001). The estimate (SD) of the difference between the intervention and control groups was -1.63 (2.16), 95% confidence interval (CI)

− 2.07 to − 1.18. MDKT values were also significantly increased in both control and intervention groups in insulin-treated and non-insulin-treated subgroups, and in subgroups with HbA1c < 7% as well as ≥ 7% at baseline (Table 3). In all these subgroups, the improvement in MDKT values was significantly greater in the intervention group (between group comparison P < 0.001; P = 0.026 for comparison in insulin-treated subgroup).

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	Baseline	3 months	Change from baseline	P value (intra- group comparison) <sup>a</sup>	P value (between- group comparison) <sup>b</sup>
Michigan total score					
Total population (	n = 364)				
Control	$7.53 \pm 2.98$	$8.57 \pm 2.86$	$1.03 \pm 1.78$	< 0.001	< 0.001
Intervention	$7.86\pm2.91$	$10.52\pm2.08$	$2.66\pm2.49$	< 0.001	
Insulin-treated sub	group $(n = 55)$				
Control	$7.44\pm2.91$	$8.56\pm2.83$	$1.13 \pm 1.62$	< 0.001	0.02
Intervention	$8.09\pm2.56$	$10.48 \pm 2.23$	$2.39\pm2.31$	< 0.001	
Non-insulin-treated	d subgroup $(n = 309)$				
Control	$7.55 \pm 3.01$	$8.57\pm2.87$	$1.01 \pm 1.81$	< 0.001	< 0.001
Intervention	$7.83 \pm 2.96$	$10.53 \pm 2.07$	$2.70\pm2.52$	< 0.001	
HbA1c < 7% at b	aseline $(n = 109)$				
Control	$7.11 \pm 2.77$	$8.21 \pm 2.85$	$1.11 \pm 1.84$	< 0.001	< 0.001
Intervention	$7.77 \pm 2.45$	$10.72 \pm 1.74$	$2.94\pm2.33$	< 0.001	
HbA1c $\geq$ 7% at b	paseline $(n = 255)$				
Control	$7.72 \pm 3.06$	$8.72 \pm 2.86$	$1.00 \pm 1.76$	< 0.001	< 0.001
Intervention	$7.90 \pm 3.08$	$10.44 \pm 2.21$	$2.54\pm2.56$	< 0.001	
HbA1c					
Total population (	n = 364)				
Control	$8.32 \pm 1.99$	$8.15 \pm 1.80$	$-0.18 \pm 1.33$	0.077	0.012
Intervention	$8.09\pm1.85$	$7.56 \pm 1.64$	$-0.54 \pm 1.41$	0.001	
Insulin-treated sub	group $(n = 55)$				
Control	$9.70 \pm 2.49$	$9.54\pm2.39$	$-0.16 \pm 1.36$	0.521	0.020
Intervention	$9.97\pm2.17$	$8.60 \pm 2.32$	$-$ 1.37 $\pm$ 2.08	< 0.005	
Non-insulin-treated	d subgroup $(n = 309)$				
Control	$8.03 \pm 1.74$	$7.85 \pm 1.50$	$-0.18 \pm 1.33$	0.10	0.102
Intervention	$7.82 \pm 1.64$	$7.40 \pm 1.47$	$-$ 0.42 $\pm$ 1.25	< 0.001	
Fasting plasma gluce	ose				
Control	$8.72 \pm 2.66$	$8.49\pm2.53$	$-$ 0.23 $\pm$ 2.14	0.143	0.001
Intervention	$8.95 \pm 2.82$	$7.90 \pm 2.03$	$-$ 1.04 $\pm$ 2.57	< 0.001	

Table 3 Change in main study parameters from baseline to 3 months

	Baseline	3 months	Change from baseline	P value (intra- group comparison) <sup>a</sup>	P value (between- group comparison) <sup>b</sup>
Weight					
Control	$55.9 \pm 9.9$	$54.9\pm9.2$	$-$ 1.0 $\pm$ 2.4	< 0.001	0.880
Intervention	$55.8 \pm 9.2$	$54.8 \pm 9.2$	$-1.0 \pm 3.2$	< 0.001	
SBP					
Control	$124.5 \pm 17.4$	$123.6 \pm 14.6$	$-0.9 \pm 17.2$	0.478	0.115
Intervention	$123.5 \pm 15.5$	$119.8 \pm 12.3$	$-3.7 \pm 16.3$	0.003	
SBP in patients w	ith SBP $\geq 140 \text{ mmHg}$	g and/or DBP $\geq 90$	mmHg at baseline		
Control	$145.1 \pm 11.4$	$131.2 \pm 19.7$	$13.9 \pm 14.9$	< 0.001	0.029
Intervention	$148.8 \pm 10.4$	$127.4 \pm 12.6$	$-21.5 \pm 16.2$	< 0.001	

 Table 3 continued

<sup>a</sup> Paired Student's *t* test

<sup>b</sup> Student's *t* test

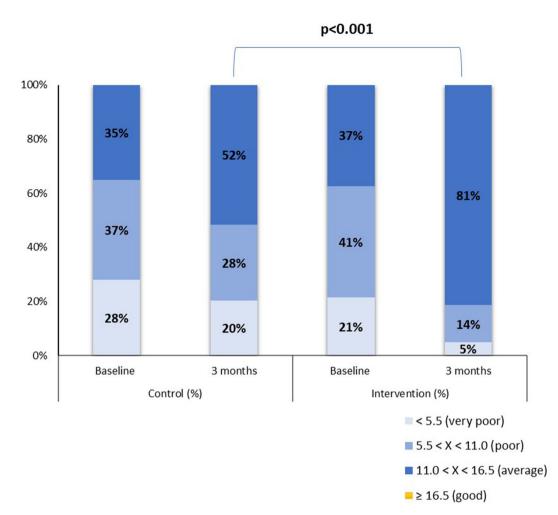
The education sessions were successful at improving the level of knowledge in the majority of participants in the intervention group. When starting the study, the proportion of patients achieving the target MDKT score, i.e., total score  $\geq 11$  (average or good), was 37.4% in the intervention group and 35.2% in the control group. After 3 months of follow-up, the proportion of successful scores (average or good) had increased significantly to 81.3% in the intervention group and to 51.7% in the control group. The rate of success at 3 months was significantly higher in the intervention group compared to the control group (between-group difference P < 0.001) (Fig. 2).

### HbA1c

At the 3-month follow-up, there was a significant decrease in mean HbA1c in the intervention group from  $8.09 \pm 1.85\%$  to  $7.56 \pm 1.64\%$  (intra-group comparison P < 0.001) compared with a non-significant decrease in the control group from  $8.32 \pm 1.99\%$  to  $8.15 \pm 1.80\%$  (Table 3). Mean changes from baseline HbA1c were  $-0.54 \pm 1.41\%$  and  $-0.18 \pm 1.33\%$  in the intervention and control groups, respectively. The estimate (SD) of the difference

between the intervention and control groups was 0.36 (1.37), 95% CI 0.08–0.64 and the between-group difference in change in HbA1c at 3 months was significant (P = 0.012). The intervention was effective at significantly reducing HbA1c levels in both insulin-treated and noninsulin-treated subgroups with the betweengroup comparison reaching significance in the insulin-treated subgroup (P = 0.011, Table 3).

When considering the subgroup of patients with poor glycemic control (HbA1c  $\geq$  7%) at baseline, mean changes in HbA1c from baseline were  $-0.80 \pm 1.52\%$  vs  $0.41 \pm 1.47\%$ , respectively, in the intervention and control groups (between-group difference P = 0.013). In contrast, there was no relevant intervention impact on HbA1c evolution in the subgroup of individuals with a baseline value < 7%. The intervention was also effective at reducing HbA1c in both insulin- and non-insulin treated subgroups with HbA1c > 7% at baseline. In patients on mean HbA1c reductions insulin, were  $-1.49 \pm 2.14$  (vs  $-0.32 \pm 1.46$  on control; P = 0.035 with Student's *t* test and 0.061 with Wilcoxon test). For patients not on insulin, reductions were  $-0.67 \pm 1.34$ (vs  $-0.43 \pm 1.48$  on control; *P* = 0.221 with Student's t test and 0.052 with Wilcoxon test).



**Fig. 2** Proportion of patients by category of Michigan University Diabetes Knowledge Test total score at baseline and after 3 months in the intervention and control groups

Numbers of patients were too small for analyses of effects of control and intervention in insulinand non-insulin treated patients with baseline HbA1c < 7%.

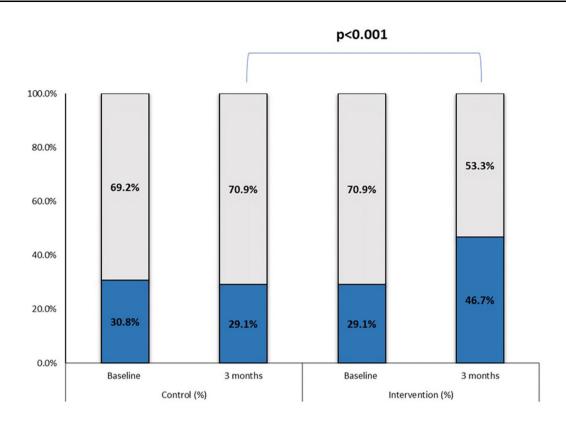
The distribution of patients according to HbA1c ranges by randomization group at baseline and 3 months is shown in Fig. 3. The proportion of patients whose HbA1c was controlled (< 7.0%) changed from 29.1% at baseline to 46.7% at 3 months in the intervention group, an increase of 17.6% (32 subjects whose HbA1c was uncontrolled at baseline achieved glycemic control at 3 months). In contrast, the proportion controlled in the usual care group remained essentially the same at 30.8% at baseline versus 29.1% at 3 months. The proportion of patients with HbA1c < 7% at

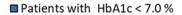
(P < 0.001, Chi-square test for independence between Michigan total score and intervention/control groups)

3 months was significantly higher in the intervention group than in the control group in both the total population (P < 0.001) and the non-insulin treated subgroup (P = 0.002). In the insulin-treated subgroup, the number of patients with HbA1c < 7% at 3 months was increased, but did not reach statistical significance because of the small numbers of patients involved.

#### Fasting Plasma Glucose

FPG was also decreased at 3 months from  $8.95 \pm 2.82$  to  $7.90 \pm 2.03$  mmol/L in the intervention group and from  $8.72 \pm 2.66$  to  $8.49 \pm 2.53$  mmol/L in the control group, with





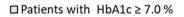


Fig. 3 Proportion of patients according to HbA1c category at baseline and 3 months in the intervention and control groups (P < 0.001, Chi-square test for independence between HbA1c category and intervention/control groups)

the decrease only reaching significance in the intervention group (intra-group comparison P < 0.001). Mean changes from baseline FPG were  $-1.04 \pm 2.57 \text{ mmol/L}$  and  $-0.23 \pm 2.14 \text{ mmol/L}$  in the intervention and control groups, respectively. The estimate (SD) of the difference between the intervention and control groups was 0.81 (2.36), 95% CI 0.32–1.30 and the between-group difference in change in FPG at 3 months was significant (P = 0.001).

#### Weight

No significant effect of the intervention was observed on weight at 3 months of follow-up (Table 3). Mean weight decreased by 1 kg in both groups. In obese patients (BMI >  $23 \text{ kg/m}^2$ ), the mean decrease in weight was slightly higher but not significantly different between groups (- 1.6 and - 1.8 kg, respectively, in the control and intervention groups).

#### **Blood Pressure and Lipids**

In the intervention group there was a significant reduction in systolic blood pressure at 3 months from a mean of  $123.5 \pm 15.5$  mmHg at baseline to  $119.8 \pm 12.3$  mmHg at 3 months (intra-group comparison P = 0.003) (Table 3). No relevant changes in mean SBP were observed in the control group. Mean changes from baseline in the intervention and control groups were  $-3.7 \pm 16.3$  and  $-0.9 \pm 17.2$  mmHg,

respectively; the difference between groups did not reach statistical significance. In both groups, reductions in blood pressure were more pronounced in those with values  $\geq 140/$ 90 mmHg at baseline, but significantly greater in the intervention group (P = 0.029) (Table 3). Small improvements in lipid parameters were observed, but did not differ significantly between groups.

#### Factors Influencing Blood Glucose Control

Variables shown by univariate analysis to significantly influence the transition to blood glucose control (HbA1c < 7%) were study group (control vs intervention, P < 0.001), HbA1c at baseline (< 7% vs  $\geq$  7%, P = 0.006), and diabetes duration (P = 0.029). Fasting blood glucose, insulin, and baseline MDKT score did not reach statistical significance, but met the 0.2 significance level cutoff required for entry into the multivariate analysis.

Multivariate analysis showed that variables influencing blood glucose control in this study were study group (OR 3.78, 95% CI 1.82, 7.85, P = 0.0004), MDKT score (OR 1.99, 95% CI 1.00, 3.93, P = 0.0489), diabetes duration (OR 0.86, 95% CI 0.75, 0.98, P = 0.0240), and baseline HbA1c (OR 0.74, 95% CI 0.58, 0.94, P = 0.0156).

### DISCUSSION

The current study provides data to support the value of community education intervention as an adjunct to antidiabetes therapy in Vietnamese patients with type 2 diabetes, a region in which there is currently a lack of knowledge concerning the optimal lifestyle intervention programs in type 2 diabetes to ensure both adherence as well as long-term health outcomes [10]. In patients randomized to the intervention group, three 45-min sessions of additional group education and support resulted in significantly improved disease awareness and glycemic and blood pressure control in a population with a wide range of disease severity. Baseline HbA1c is a predictor of HbA1c change in patients responding to treatment [36, 37], and in line with other studies the greatest overall decrease in HbA1c was observed in the insulin-treated subgroup, who were also the most poorly controlled at baseline.

Results of the multiple logistic regression analysis suggested that patients most likely to benefit from the program and achieve blood glucose control were those who already had a certain level of knowledge of their disease, who had a shorter duration of illness, and a lower baseline HbA1c. It is possible that in patients with less knowledge of the disease and more severe diabetes, a longer period of education may be required to see improvement. Educational interventions may also be less effective in terms of blood glucose control in individuals with marked beta cell dysfunction, but should still be maintained to preserve remaining function and reduce cardiovascular disease risk factors [38].

Strict glycemic control is associated with a reduced risk of diabetes-related complications, particularly in those who have not suffered years of uncontrolled HbA1c levels [39]. Early achievement and maintenance of near-normal glycemia from the time of diagnosis is therefore essential for optimal outcomes. While the duration of this study was relatively short (3 months), the reductions in HbA1c of -0.5%overall and -0.8% in the subgroup uncontrolled at baseline (HbA1c > 7%) would be clinically meaningful if sustained over the long term for reducing the risk of diabetes complications, particularly in patients with lower baseline values. An HbA1c reduction of 0.5% is considered clinically significant by guidelines for the management of type 2 diabetes [30, 40] and the US Food and Drug Administration accepts a non-inferiority margin for HbA1c change from baseline of 0.3% or 0.4% [41].

The HbA1c reductions were also supported by concomitant reductions in FPG that again reached significance in the intervention group. Studies have reported that strict blood glucose control can delay or prevent the progression of complications associated with diabetes [42–44]. Indeed, projections from the observational United Kingdom Prospective Diabetes Study (UKPDS 35) suggested that for each 1% reduction in mean HbA1c there would be an associated 14% lower rate of fatal and non-fatal myocardial infarction and death from any cause, 21% lower rate of death related to diabetes, and 37% reduction in the risk of microvascular complications [44]. The types of antidiabetes therapy the patients were receiving were evenly distributed between the intervention and control groups and the regimens were not altered for the duration of the study. Any observed differences in HbA1c between the groups can therefore be attributed to the intervention and not because of differences in study medication.

In the current study, well over half the participants (55.0%) had a baseline HbA1c  $\geq$  7.0% despite treatment, a figure that is in line with data from the Vietnamese cohort of the DiabCare Asia observational study which reported that 63.9% of patients receiving treatment for type 2 diabetes for at least 1 year did not meet the ADA recommended HbA1c target of < 7.0% (< 53 mmol/mol) [45].

A major factor limiting the efficacy of current diabetes management is a lack of patient education. A population-based survey conducted in a largely rural area in central Vietnam in 2014 reported that more than two-thirds of the 480 participants did not understand or had never heard of type 2 diabetes, and less than half of those diagnosed had reported a history of type 2 diabetes [46]. As the vast majority of day-to-day care in type 2 diabetes is managed by patients and their families, education is therefore urgently required, particularly in rural areas where levels of education are the lowest and access to quality medication is the most restricted.

While DSME programs are well integrated in Western developed countries [10], Vietnam's healthcare system, like that of many in developing countries, was designed to deliver acute care, and until recently did not typically include patient education. As a result, there is a paucity of studies on diabetes education in patients in developing countries [12]. With the current epidemic of type 2 diabetes this is now changing and the Vietnamese government has put in place a national strategy for non-communicable diseases for 2015–2025 that includes the control and prevention of diabetes [47]. Diabetes education is an important component of this strategy, and must result in long-term behavioral changes in the patient to be of value. Examples include following a diet plan; avoiding high-fat foods; reducing consumption of white rice, a food with a high glycemic index and a staple part of the Vietnamese diet; increasing levels of physical activity; self-monitoring of blood glucose; and foot care [48]. While decreasing an individual's HbA1c level may be the ultimate goal of diabetes self-management, it is not the only objective. Health promotion, and especially promotion of behavioral change towards a healthy diet and physical activity, are important interventions, with low costs in the management of type 2 diabetes and will also benefit other comorbid conditions such as obesity and hypertension [48]. The results of the current study demonstrate that this is possible with community group education sessions. After only 3 months, 81.3% of patients in the intervention group compared with 51.6% of patients in the control group passed the diabetes knowledge test.

The intervention was also associated with a significant reduction in SBP. Recent epidemiological data from Vietnam in individuals aged 25 years or older reported hypertension in 29% of those surveyed [49]. Furthermore, among those receiving antihypertensive drugs, 38% had blood pressure levels that were not controlled. Vietnamese hypertension guidelines recognize the need to reduce blood pressure levels population wide [32]. Reductions in SBP and DBP of at least 2 mmHg have been shown to significantly reduce the incidence of cardiovascular disease in both hypertensive and normotensive individuals [50], and therefore the blood pressure reductions achieved in the current study are considered clinically meaningful. While the effects of the intervention on lipid parameters and BMI did not reach significance. a longer study duration may have been required to demonstrate these effects. In this study, 70% of the population were farmers, an occupation with moderate to intensive levels of physical activity, making it difficult to observe changes in weight over a short period of time.

As a result of its chronic nature, the severity of its complications and the means required to control them, type 2 diabetes is a costly disease not only for the affected individual and their family but also for the health authorities. Reductions of HbA1c have been systematically associated with healthcare cost reductions [51]. This underlines the importance of achieving lower HbA1c levels, particularly in uncontrolled patients, in countries with limited economic resources. Any costs of educational intervention sessions must therefore be weighed against the potential reduction in long-term complications and associated treatment costs that can be achieved with improved blood glucose control.

A meta-analysis of the effect of self-management education for adults with type 2 diabetes on glycemic control, which included 31 randomized controlled trials, found that the intervention decreased HbA1c by 0.76% (95% CI 0.34–1.18) more than the control group at immediate follow-up, but that the benefit declined 1–3 months after the intervention ceased [52]. Therefore, provision should also be made for periodic reinforcement to maintain behavioral changes in the long term.

Most research on the value of education and lifestyle intervention in type 2 diabetes is from developed countries, and there is an urgent need for this to be extended to low- to middleincome countries who are now experiencing the greatest increases in type 2 diabetes [53]. Previous studies have also called for further research into the efficiency of various health-promoting strategies in a Vietnamese context [18, 19]. The current research goes some way to fulfilling this need, providing important data on the value of interventions to improve patient education in Vietnam and demonstrating that improvements in blood glucose control are achievable after only 3 months of intervention.

#### Strengths and Limitations

A strength of this study was that it provided practical experience on the effectiveness of diabetes health education in routine clinical practice in a country where a large proportion of the inhabitants have a relatively low level of education and poor economic status. Such a patient-centered approach to increase diabetes knowledge is likely to increase adherence to diabetes self-management programs. Baseline imbalance and confounding bias may occur despite randomization. However, given the large sample size and similar baseline characteristics of the two groups, the observed differences in patients' diabetes health-related knowledge and the small improvements in HbA1c in the intervention group after only 3 months of follow-up were likely related to the intervention rather than confounding factors. These findings therefore warrant further investigation in a larger trial to determine the HbA1c reductions that can be achieved and whether these can be maintained long term.

In line with most studies that have evaluated diabetes education programs, the study was open to all patients with diabetes who could benefit from the education, and not restricted to those newly diagnosed. A recent systematic review of studies that implemented DSME programs within 12 months of the initial type 2 diabetes diagnosis reported a small but statistically significant improvement in HbA1c (-0.21%) compared with usual care [54]. It is possible that the difference was small because people with newly diagnosed type 2 diabetes are more likely to engage in behavioral changes following diagnosis regardless of whether or not they participate in an educational program [55]. The potential benefits of early patient education may also be long term, and evaluation and follow-up of the Ngaydautien project in newly diagnosed patients who have received little or no prior self-management education will be an important avenue for future research.

A limitation of this study was that it was restricted to a single hospital. The local population and their lifestyles may therefore not be reflective of the general Vietnamese population. As participants lived locally and attended the same hospital, information on the intervention could have been shared between the two randomization groups. Such "indirect" education could have influenced the behavior of individuals in the control group and thus limited the differences observed between the two randomization groups. The MDKT was adapted for the Vietnamese population on the basis of a pilot conducted in 10 Vietnamese individuals with type 2 diabetes. То date the modified

questionnaire has not been formally validated in a Vietnamese population, but its reliability and validity have been demonstrated in Western populations [16]. A further limitation was that data on adherence to treatments were not collected.

# CONCLUSIONS

Data from Vietnam show that a structured, group-based educational intervention for people with type 2 diabetes can significantly increase disease knowledge and improve levels of blood glucose control. Larger studies are now warranted in a more varied Vietnamese population to assess the benefits of diabetes education on patient behavior, adherence to drug therapy, and glucose control long term.

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**Disclosures.** Dr Thanh Ho and Tien Tran declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest. This article does not contain any studies with human subjects performed by any other authors.

Compliance with Ethics Guidelines. The study protocol was approved by the independent local Institutional Review Board of Thach That General Hospital and Hanoi Medical University, Hanoi. The studies involving human participants were reviewed and approved by IRB VN 01001 (Hanoi Medical University Ethic Committee) No. IRB 00003121. The trial was registered through the https:// clinicaltrials.gov site with the following identifier: NCT04403841. The trial was performed in accordance with the Helsinki Declaration of 1964 and its later amendments. Written informed consent for participation in this study was obtained from all participants.

**Data Availability.** The datasets generated and/or analyzed for this study are available from the corresponding author upon reasonable request.

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