Protocol

Lifestyle intervention trial program to prevent type 2 diabetes in Northern province of Ninh Binh, Vietnam: a protocol

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Abstract: Lifestyle change programs that focus on adopting a better diet and increasing the frequency of physical exercise among pre-diabetic patients has been proved as an effective method to prevent the progression of their condition to diabetes. This paper reports the protocol for a lifestyle prevention program which aims to reduce the risk of developing diabetes among high-risk individuals and pre-diabetic patients in Ninh Binh, Vietnam. Pre-diabetic individuals were screened and selected to participate in the program. The participants were randomized into either a control or intervention group. The intervention group received educational sessions and training on lifestyle modifications for diabetes prevention from experts and the intervention team. They were required to fulfill 150 minutes of exercising per week by joining walking groups or exercising on their own, and must also adhere to the dietary recommendations for a balanced diet. Their changes in weight and waist circumference as well as adherence to food and exercise regimens were monitored on a regular basis, and after 24 months of intervention, all participants in the control and intervention communities underwent a second diabetes screening, and their measures were compared to those taken at baseline. Findings from this study proved that the structured lifestyle intervention program is suitable for the people at risk of diabetes by reducing the severity of their condition, thereby lowering the management cost, as well as supporting the government and health stakeholders to develop the policies for diabetic prevention and treatment.

Keywords: type 2 diabetes, Vietnam, pre-diabetes, diabetes prevention, lifestyle prevention.

1. Introduction

The increasing prevalence of type 2 diabetes mellitus (T2DM) at an alarming rate is associated with escalated premature mortality, co-morbidity, and healthcare expenses globally [1]. A total of 463 million people, which translates to an estimated 9.3% of the world's population, were diagnosed with T2DM, causing about 1.5 million deaths in 2019 [2,3]. Particularly, in Vietnam, type 2 diabetes has become a major public health concern. 5.5% of the Vietnamese population were diagnosed with diabetes, which is considered significant among the Asian countries. In addition, diabetes is ranked the third leading cause of death in Vietnam, and its economic burden is predicted to reach 1.1 billion USD by 2025 [4].

Pre – diabetes is identified as the risk of developing diabetes as the blood glucose levels fall between the normal and diabetes criteria. Pre-diabetes is becoming more widespread, affecting 373.9 million of individuals over the world and 5.3 million adults in Vietnam [5,6]. Around 25% of pre-diabetes patients progresses to overt T2DM within 3-5 years, while up to 70% of population with prediabetes acquire overt diabetes chronically over their lifetime [7]. However, studies have shown that as compared to conventional therapies, one-to-one counselling and pharmacological trials, pre-diabetic risk factor can be more effectively prevented by implementing lifestyle modification program that consist of a healthy diet and frequent physical exercises. This program aimed for pre-diabetics and high-risk patients have yielded a 28% to 58% reduction in T2DM incidence rates worldwide [8]. Therefore, it is crucial to deploy these measures to pre-diabetic patients with a high risk of diabetes development to assist the patients in improving their lifestyle and preventing the progression of illnesses.

However, in Vietnam, the social awareness about pre-diabetes and diabetes, the adherence to treatment and preventive measures has remained limited. Previous studies have shown that only 3.9% of Vietnamese population had acknowledged about the risks and complications of the illness, while almost 70% had never heard of diabetes. Only 0.6% people had personal experiences with the risk factors, while only 21.9% know about the preventive methods against diabetes. In terms of nutrition, the diet of a majority of Vietnamese people also contains a high content of salt, fat, and sugar, with only a minor quantity of fruits and vegetables. Furthermore, 28.7% of Vietnamese adults were reported to limitedly engage in physical exercise [4].

For these reasons, our research team has constructed an effective diabetes preventative program with the primary emphasis on dietary and lifestyle changes that promote physical activity. Our previous study employed education and communication measures to promote weight loss and provide dietary, exercise, and behavior changes advices to effectively prevent diabetes in a group of high-risk Vietnamese citizens. The results showed that after six months of implementing the lifestyle therapies, the studied group showed the recovery rates of normalized fasting and or two-hour glucose were 30.2%, 17.0%, and 5.7% in patients with IFG (Impaired Fasting Glucose), IGT (Impaired Glucose Tolerance), and both IFG and IGT, respectively.

Taking into account the shortcomings of the earlier research, the present study aims to evaluate the effectiveness, feasibility, and acceptability of large-scale, 2-year diabetes intervention program with a primary emphasis on lifestyle changes in communities of Ninh Binh province. In this paper, we constructed the protocol for the study, which employs education and counselling approaches to encourage weight reduction and give nutritional, exercise, and behavior modification guidance in order to effectively develop diabetes prevention.

Overall, the objectives of the present study are as follow:

1- To implement a locally appropriate diabetes prevention program through lifestyle interventions into real-life settings in various communities of Ninh Binh province in 2 years.

2- To evaluate the effectiveness, feasibility, acceptability of lifestyle intervention program by comparing changes between various groups.

2. Experimental Design

2.1. Study design and setting

The lifestyle prevention program is a randomized controlled trial which aims to reduce the risk of diabetes development among high risk and pre-diabetic patients.

The study was conducted in Ninh Binh province, which is located in the south of the Northern Delta of Vietnam and covers an area of 1,383.7 square kilometers. It consists of 12 districts with 554,700 residents living in both metropolitan and provincial areas. In recent years, Ninh Binh province has experienced accelerated social and economic devel-

opment that attracts a significant number of people migrating to the cities, hence the increasing prevalence of diabetes in this area. In the year of 2020, Ninh Binh Provincial Hospital took care of around 5000 diabetic patients, with 200-2000 patients being hospitalized for assessment and treatments in Outpatient Department and Department of Endocrinology within nine months [9].

The target sites included Tam Diep (designated as community A) - an industrial town of Ninh Binh province and Ninh Binh city (designated as community B). The two sites are 12 km apart and have total population of over 190,000 people. Both towns have different dietary cultures and development plan. Tam Diep has a population of 74,649 people residing in 5 wards and 4 communes, and 65% of which lives in an urban environment. The town is a well-known tourist attraction due to pleasant weather and beautiful natural scenery. On the other hand, Ninh Binh city has a population of 110,649 people living in 11 wards and 3 communes, hence its severe air pollution.

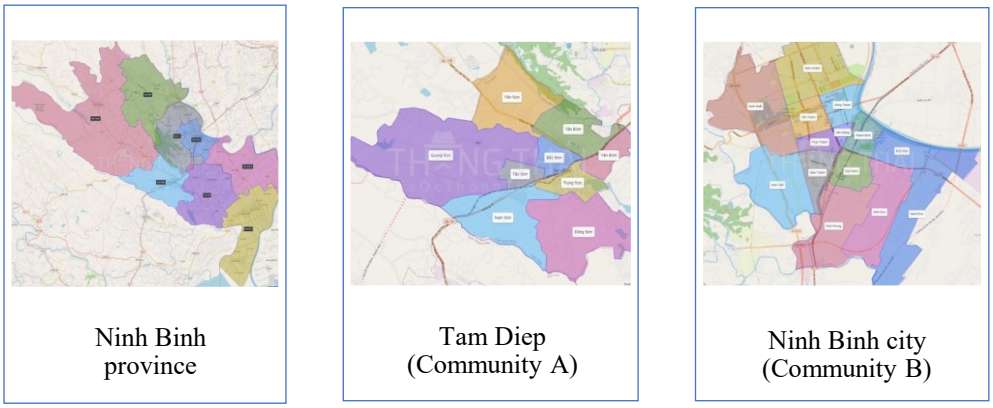

Figure 1. Study area of the program

2.2. Participants

2.2.1. Sample size calculation

The power and sample size were calculated according to the recent data collected from (1) the National Research of Diabetes Prevalence in Vietnam in 2008; (2) Bac Ninh province, Vietnam in 2009 and (3) other surveys in Asia-Pacific regions. The incidence of diabetes among individuals with IFG/IGT at baseline used was 22%; the prevalence of IFG/IGT in Vietnamese population was about 15%-20%.

To observe a relative reduction of 30% in incidence of diabetes in the Intervention Arm compared to the Control Arm, a sample size of 928 individuals with IFG/IGT, half of which were in the Intervention Arm, was required, given a 80% power and a two-side significant level of 0.05 [10]. About 500 IFG/IGT patients were recruited in each arm to allow a 15% dropout.

2.2.2. Selection criteria

The target population were male and female participants from the age of 30 to 69 at a high risk for diabetes (as identified by a risk score assessment and impaired baseline measurement of glucose). The risk factors were based of the Global Guidelines on Screening for Diabetes 2005 and a Vietnam Nationwide survey on diabetes in 2003-2008. Risk factors for diabetes included age, overweight/obese (BMI ≥ 23kg/m, waits circumference ≥ 80 cm for women and ≥ 90 cm for men); history of IGT and/or IFG; first-degree relative(s) with type 2 diabetes; history of gestational diabetes [11]. Individuals who experienced (1)

pregnancy, (2) a prior history of diabetes, (3) hypoglycaemic medication (4) chronic diseases up to three years, and (5) psychological/physical disabilities were considered ineligible for participating in the present study.

2.2.3. Screening for high-risk individuals

Based on the most recent information of local demographics available at the ward clinics, a list of local residents at the age of30- was produced. Risk assessment questionnaires, consent papers, and the project information booklet were sent to the participants on the lists to identify people with high risk indicators.

Community A: In order to recruit high-risk individuals with IFG and/or IGT at baseline in each community, we screened high-risk individuals using OGTT to detect IFG and/or IGT and diabetes. Individuals with pre-diabetes were randomized into the intervention arm or the control arm. To avoid impacts from the intervention group, we selected our control groups and intervention groups from different areas. Ninh Binh and Tam Diep towns both have national highways that split the towns into two areas of the east and the west. We randomly selected areas as the control sites or intervention sites so that the distance between the two was at least 7 km.

Community B: A second selected cohort of individuals were recruited and randomized using the same method. The control and intervention sites were also separated by at least 7 km.

2.3. Data collection

Data were collected at baseline and at the end of study. The trained interviewers interviewed participants according to a structured questionnaire to collect data on the participants' socio-demographic information, medical history and behavioral measures. The participants' anthropometrics measurements. including weight, height, waist circumference, hip circumference, and percent body fat were also collected (Table 1). Their systolic and diastolic blood pressure were measured twice in a sitting position after participants rested for at least 5 min in order to collect the mean of the two values to use in analysis. Blood samples were collected and centrifuged immediately in the morning after a participant had fasted for at least 8 h prior to the clinic visit. Aliquots of plasma were stored at 2–8 °C in iceboxes and then transported into the Biochemistry Laboratory of the National Institute of Diabetes and Metabolic Disorders for analysis within 6 h. Lipid profile including total cholesterol (TC), triglycerides (TG), high-density lipoprotein cholesterol (HDL-C), and low-density lipoprotein cholesterol (LDL-C) were measured by enzymatic methods. Insulin were measured by electro Chemi Luminesense methods. Lipid profile and Insulin were analyzed using the Cobas C311 and E411 automated immunology analyzers.

Table 1. Study variables and measurement tools

Variable	Component	Measurement tools
Socio-demographic measures		Age, sex, ethnicity, marital status, educational level, occupation, residency, income
Medical history		Use of any medications, family history of diabetes, history of hypertension and dyslipidemia, medical and reproductive history
Behavioral measures	Tobacco use	WHO STEP questionnaire
	Alcohol use	WHO STEP questionnaire
	Sedentary behavior	Time spent watching television
	Physical activity	Walk-step questionnaire
		Participants was asked to fill out daily activity logs, recent average activity and exercise behaviors.

Anthropometry measures	Dietary habits	Food Frequency Table questionnaire, 24-hour Dietary Recall questionnaire
	Body weight	Standardized, calibrated scale.
	Height	Standardized meter
	Body Mass Index	Weight and Height
	Waist circumference	Tape measurement
	Hip circumference	Tape measurement
Percent body fat	Percent body fat	
	Blood pressure	BP was measured using standard procedures with an electronic sphygmomanometer
	Lipid profile including total cholesterol (TC), triglycerides (TG), high-density lipoprotein cholesterol (HDL-C), and low-density lipoprotein cholesterol (LDL-C)	Enzymatic methods
Program evaluation	Insulin: Fasting Plasma levels of insulin; Insulin sensitivity, beta cell function and Insulin resistance	Fasting Plasma levels of insulin was measured from a venous blood sample. Insulin sensitivity, beta cell function and Insulin resistance: was calculated using the homeostasis model assessment software (HOMA Calculator version 2.2), available from http://www.ocdem.ox.ac.uk/. We used pairs of fasting plasma glucose (in mmol/l) and RIA insulin (in pmol/l) concentrations.
	Diabetes Incidence	Fasting plasma glucose, 2-hour post-load glucose were administered to diagnose diabetes at baseline, and 24 months after intervention. The incidence of Diabetes was calculated by determining the proportion of individuals progressing from pre-diabetes to diabetes at each time point. *Criteria for the diagnosis of Diabetes:* - Fasting glucose ≥126 mg/dl (7.0 mmol/l); fasting was defined as no caloric intake for at least 8 h, or - 2-h glucose ≥200 mg/dl (11.1 mmol/l) during an oral glucose tolerance test (OGTT) using a glucose load containing the equivalent of 75 g anhydrous glucose dissolved in water. - A random plasma glucose ≥200 mg/dl (11.1 mmol/l).
	Pre-diabetes incidence	Pre-diabetes was diagnosed by fasting plasma glucose, 2-hour post-load glucose

		at baseline, and 24 months after intervention. Reversion from pre-diabetes to normal was calculated by determining reversion rate from IFG/IGT to normal at each time point. *Criteria for the diagnosis of prediabetes:* - Fasting plasma glucose 110–125 mg/dl (6.1–6.9 mmol/l): considered as IFG. 2-h plasma glucose in the 75-g OGTT 140–199 mg/dl (7.8–11.0 mmol/l): considered as IGT. Conducting incremental cost-effective analyses in which the net costs and net effectiveness of the intensive lifestyle program and the standard lifestyle advice was calculated and expressed as a ratio. Quality-adjusted Life-year (QALY) was used to determine the cost-effectiveness of the lifestyle intervention by assessing the incremental costs and benefits per case of diabetes prevented.
	Evaluation of recruitment, adherence, and program acceptability	Evaluation of the project's recruitment was made from a database created to track how many individuals were screened for the study, how many return for baseline measures, how many agree to randomization and finally how many were enrolled in the study.
	Evaluation of Adherence	Attendance was recorded
	Evaluation of Program Acceptability	The acceptability of the intervention was assessed through focus group discussions with 20% of participants who received the lifestyle intervention.

2.5. Intervention

The intervention was applied on 2153 people with IFG/IGT. The intervention process was divided into two phases, from the first to the 12th month and from the 12th to the 24th month.

2.5.1. The first phase (from the 1st to the 12th month)

The first phase, which took place from the first to the 12th month, focused on educating the pre-diabetic patients in order to enhance their knowledge about diabetes and prevention methods.

A total of 20 local medical staffs from Provincial Health Preventive Center and Ward Health stations (WHS)were recruited to form the prevention team. They participated in a three-day training course as a facilitator and diabetes prevention educator on the intervention components, playing the key role in (1) setting and monitoring goals for lifestyle behaviors, as well as (2) maintaining group facilitation and communication skills.

A total of 5 educational sessions by the prevention team and experts from the National Institute of Diabetes and Metabolic Disorders on diabetes prevention were provided to all pre-diabetic patients and high-risk individuals in the intervention communities. Several classes on 10 topics, including (1) Overview of diabetes; (2) Lifestyle modifications of diabetes prevention; (3) Physical activity for diabetes prevention; (4) Nutrition goals, principles and assessment; (5) Food choices; (6 and 7) Meal planning; (8) Weight loss; (9) Set up walking groups; and (10) Summary session) were given at the Ward People's Committees Halls. The instruction was in various format and was combined with the community activities. The prevention team used materials and tools such as leaflets, booklet, visuals, and brochure provided by the project.

2.5.2. The second phase (from the 12th to the 24th month)

The second phase, which was ranged from the 12th to the 24th month, focused on lifestyle counselling to assist pre-diabetic patients in improving their lifestyles in order to avoid developing diabetes (Table 2).

Another three-day training session was offered to the prevention team. In the advanced course on food, exercise, and weight management, they received additional trainings on diabetes prevention education, a plan of interventions for the second stage, as well as the recommendations and advice from the International Diabetes Federation (IDF) counselling committee. The workshop also covered lessons learnt about successful counseling and educating persons with pre-diabetes on diabetes prevention such as healthy exercising and eating habits.

Additionally, in order to avoid interruption, the Red cross association, Women association, Youth Union and patients' family members cooperated with the healthcare workers to encourage the pre-diabetic patients in intervention arms to adhere to the preventive measurements and adjust to their experimental lifestyles. To ensure the consistency with the protocols, all members of the social organizations involved in the project were required to attend a half-day meeting held by WHS or Ward People's Committees Halls to discuss about the second stage of intervention in detail.

Participants are encouraged to apply the knowledge from the educational sessions during the first phase to improve their daily routine. To promote healthy exercising habits, participants were required to join in walking groups for at least 150 minutes per week in the park, WHS, community centers, or other public places in the neighborhood. In case they were unable to join a walking group, they were allowed to engage in other forms of exercises and the result was recorded at the end of the week. Pre-diabetic patients were also advised to adhere to the balanced diet recommended by prevention team, which included lowered fat and sugar intake, enhanced fruit and vegetable consumption.

The prevention team monitored changes in weight and waist circumference as well as adherence to food and exercise regimens on a regular basis The prevention team maintain contact with participants to investigate their commitment to the program. Through these phone calls, they also gave advice on maintaining the new lifestyle with exercise and healthy diet. Participants were also able to gain instant access with the prevention team either in person in the counseling rooms at the ward's clinics or by phoning the project's hotline.

Table 2. Summary of some of the activities of the project

No	Activities	Number
1	Population of communities	70,000
2	Number of wards involved in the project	15
3	Website was developed (http://noitietdaithaoduong.vn)	01
4	Number of local medical staffs trained on diabetes and prevention	40
5	Number of collaborators were recruited and selected for the prevention team trained on diabetes prevention: diet, physical activity and weight management.	40
6	Educational booklets, leaflets had been distributed (set)	2,153

7	Ward-radio messages	250
8	The number of World Diabetes Day events	03
9	The number of people engage in World Diabetes Days	Over 3,500
10	The number of diabetes educational classes have been held	20
11	The number of educational sessions	158
12	Number of questionnaires distributed	40,000
13	Number of questionnaires selected	23,715
14	Number of people with high risk scores screened to detect pre-diabetes/diabetes	7,192
15	Number of people with pre-diabetes detected	2,172 (30.2%)
16	Number of people with diabetes detected (new cases)	482 (6.7%)
17	The number of blood samples of people with pre-diabetes collected to investigate Lipids and insulin	1,010
18	The number of cases with hypertension	2,738 (45.5%)
19	The number of pre-diabetes were followed up (both intervention and non-intervention groups)	2,153

2.5.3. Evaluation

After 24 months of intervention, all participants in control and intervention communities were screened for diabetes again using OGTT. Their blood pressure, anthropometric, and biochemical measurements collected using the same methods as baseline measurements.

People who were diagnosed with diabetes were referred to the centers or hospitals of endocrinology and diabetes for management and treatment. People who were diagnosed with pre-diabetes were given recommendations on how to prevent their condition from progressing to diabetes.

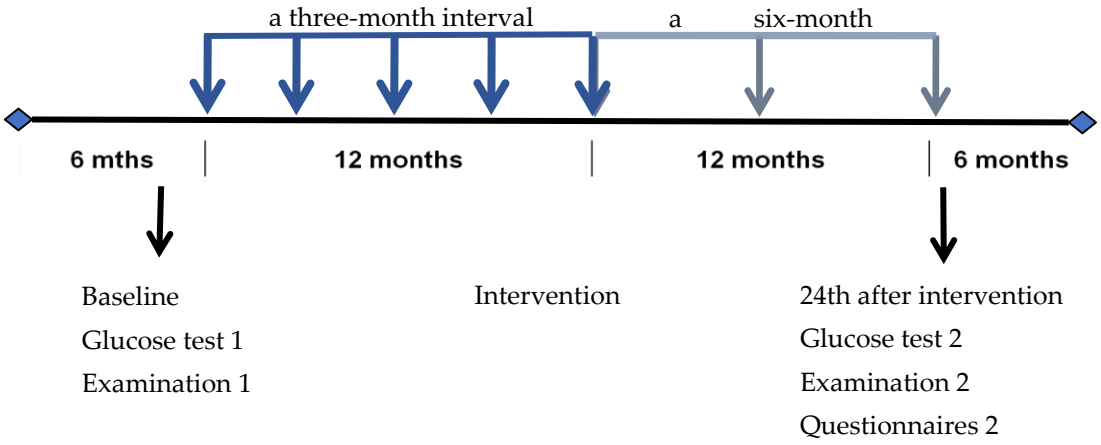

Figure 2. Summary of the study flow

2.6. Outcomes measurement

The primary outcomes of the study were the incidence of type 2 diabetes based on the OGTT test.

Secondary outcomes of the study include anthropometrics measurements such as weight, height, BMI, waist circumference, hip circumference, and percent body fat of the participants; the patients' biochemical measurements such as the blood pressure, their lipid profile and their insulin; the behavioral changes among pre-diabetic and high-risk individuals, and the impact of these changes on prevalence and their risk of developing diabetes; the cost-effectiveness, feasibility and the acceptability of the lifestyle intervention.

2.7. Data analysis

All data were managed by Epidata software and compressed before transmitted.

2.8. Ethics

The project was authorized by official dispach No: 16/UBND-VP6 of Ninh Binh Province People's Committee for the implementation of this diabetes prevention research project. Written informed consent is also obtained from all the study participants.

3. Expected Results

This paper outlines the methodology for a 2-year cluster randomized controlled trial of a lifestyle intervention program to reduce the incidence of type 2 diabetes mellitus in individuals with pre-diabetes or at high risk of developing diabetes in communities of Ninh Binh province. The research aims to introduce a culturally tailored diabetes prevention program using lifestyle interventions, including encouraging healthy excising habits, as well as providing guidance and advice on weight loss and balanced diet, into real life settings.

The outcomes of this program will be used to evaluate changes in lifestyle, anthropometric and biochemical measurements, and diabetes incidences among different groups in order to determine the cost-efectveness, viability, and acceptability of educational sessions and counseling in promoting healthy behaviors and reducing diabetes. This will build on the similar efforts previously made on older adults aged 50–65 with metabolic syndrome in Ha Nam, Vietnam, which results in a retention rate of 80.8%, an increase in walking (P = 0.018), moderate intensity activity (P = 0.018), and total physical activity (P = 0.001), a decrease in mean sitting time (P 0.001), and healthier dietary habits, including a decrease in the consumption of animal internal organs (P = 0.001) and the use of cooking oil for daily meal preparation (P = 0.001) [12, 13].

The successful completion of this experiment will help those at risk of developing diabetes minimize the severity of their illness, as well as benefit the families of the patients and society by decreasing the costs associated with diabetes treatment. It will also contribute to the knowledge on the prevalence and risk factors associated with pre-diabetes and related chronic diseases, as well as lead to better policy and practice related to diabetes and NCDs prevention in Vietnam.

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Institutional Review Board Statement: The project was authorized by official dispach No: 16/UBND-VP6 of Ninh Binh Province People's Committee for the implementation of this diabetes prevention research project. Written informed consent is also obtained from all the study participants.

Informed Consent Statement: Informed consent was obtained from all subjects involved in the study. Written informed consent has been obtained from the patient(s) to publish this paper.

Data Availability Statement: Not applicable.

Conflicts of Interest: The authors declare no conflict of interest.

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