

THE DEVELOPMENT OF HEALTH-RELATED QUALITY OF LIFE PROGRAMME AMONG TYPE 2 DIABETIC PATIENTS IN TAM BINH DISTRICT, VINH LONG PROVINCE, VIETNAM

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ABSTRACT

Background: The number of diabetic people is rapidly increasing in Vietnam as well as in the world. Type 2 diabetic patients were reported reduced health-related quality of life. The research investigates on: (1) Exploration of the relative factors to health-related quality of life of diabetic patients in Tam Binh district, Vinh Long province, Vietnam in 2018 - 2019. (2) Implementation the health-related quality of life programme of diabetic patients. (3) Evaluation of the effectiveness of health-related quality of life programme of diabetic patients after six months of the implementation programme.

Methods: The participants are the type 2 diabetic patients with aging 35 and over, diabetic duration more than 6 months and living at least 6 months in Tam Binh district. The mixed methods research is used with: Phase 1: The quantitative method is performed to assess the quality of health-related quality of life of 500 type 2 diabetic patients by the Vietnamese diabetes quality of life questionnaire. Phase 2: The quasi-experimental method is designed to set up an empowerment programme, then will compare the health behaviour the 85 diabetic patient group by the Knowledge of diabetes, Attitude toward to deal with diabetes and Practice with diabetic management questionnaire. Phase 3: We will evaluate the effectiveness of the programme of the patients with both questionnaires on phase 1 and 2. The data will be analysed with the Package for Social Sciences version 22 program. One-way analysis of variance is used to evaluate the differences in the domains of the health-related quality of life among the different groups. The T-test is used for analysis on the quasi-experimental research.

Discussion: This research will assess the health-related quality of life of type 2 diabetes in Tam Binh district, Vinh Long province, Vietnam. Diabetes' health-related quality of life is usually lower than the healthy people. However, the other studies showed that this was improved after the implementation programme. Therefore, this experimental study will increase the health-related quality of life of type 2 diabetic patients.

Key words: Diabetes, Vietnam, health-related quality of life, KAP questionnaire, empowerment programme.

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1.0 Introduction

The number of diabetes is significantly rising worldwide, 171 million people in 2000, and it will increase more than double to 366 million in 2030 (Akinci et al., 2008). In 2014, the World Health Organization (WHO) reported that the global diabetic proportion approximated 9% adults, with type 2 diabetes mellitus (T2DM) consisting of approximately 90%, and predicts that diabetes will be the 7th leading death cause in 2030 (Alatawi, Kavookjian, Ekong, & Alrayees, 2016). About two-thirds of diabetic people inhabit in developing countries as Brazil, India, and China, where this is presupposed to inflate during two next decades (Bahia et al., 2011). Moreover, this prevalence is presaged to go up to 69% in developing countries in the period 2010 – 2030 (Alfian, Sukandar, Lestari, & Abdulah, 2016).

The Socialist Republic of Vietnam located in South-East Asia. The recent economic development results, the number of diabetic patients is speedily growing. In 2001, one study in Ho Chi Minh City showed that the diabetes mellitus (DM) prevalence was roughly 2.5 times higher (6.9%) than what was recorded 8 years ago (2,5%) (Yokokawa et al., 2010). The 2002 National Survey found that the prevalence of diabetic people on 30-60 years was 2.7% (Quang, Ha, & Viet, 2012). It is estimated that in 2010, the prevalence of diabetes in the age group of 20 - 79 years was 2.9% (1.65 million), and were projected to rise to 3.42 million people in 2030. In 2010, according to Vietnam's health sector, the disease burden rate and mortality of diabetes were 1.7% and 1.8% (Health, 2015). This indicates that diabetes is increasing in the Vietnamese population.

Vinh Long is a province in the Mekong Delta located in the Southwest of Vietnam. In 2018, the population of Vinh Long province was 1,033,600 people. Although there were no specific statistics on diabetes in Vinh Long province, preliminary reports from hospitals were as follows: Vinh Long General Hospital examined and treated about 600 patients with diabetes every day; The district health centers treated an average of 35 patients with diabetes per day. Similarly, Tam Binh district did not have specific statistics on the incidence of diabetes in the community. However, according to a diabetes management program managed by the Department of Disease Control at Tam Binh Health Center in six communes and one town, the number of people with diabetes was 550. At the same time, at the medical department of Tam Binh Medical Center, about 30 patients were treated for diabetes every day. In addition, according to the department's report, the number of diabetic patients was increasing. This shows that the number of diabetic patients in Tam Binh district is increasing.

Almost two decades ago, diabetes damaged practically health dimensions except for mental health and pain. In a recent multinational study, diabetes has notably impacted on general health (Al-Shehri, 2014). The quality of life (QoL) has been recognized as an important concept in diabetic control. Particularly, the health-related quality of life (HRQOL) contained nine domains as general health, activity restriction, physical sustaining, diet and eating customs, treatment, symptom burden, financial side, emotional/mental health, inter-personal relationship (Baptista, Dias, Souza, Verissimo, & Martins, 2017). The researches were reported that diabetic people had a worse HRQOL than without chronic disease people. Type 2 diabetic people were poorer HRQOL than the general population (Bennett, Ouyang, Wu, Barone, & Stewart, 2008). This means that diabetes was decreased the HRQOL.

Although Vietnam had many researches about diabetes, but these mainly researched on the incidence of diabetes and relevant factors. Tran Ngoc Hoang and Nguyen Thi Bich Dao researched the assessment impact of diabetic complications on HRQOL in patients with T2DM in 2014 (Hoang & Dao, 2014) and Huong Thi Thu Nguyen et al (2018) published an article about HRQOL in elderly diabetic outpatients in Vietnam (Nguyen et al., 2018), however, there was a insufficiency of assessing QoL of T2DM in general population in Vietnam. In Vinh Long province, especially Tam Binh District never had the research on this disease. Therefore, this study will deeply investigate of the related factors to HRQOL of diabetic patients as well as establish the HRQOL programme to support the patients along with evaluation of the effectiveness of the HRQOL programme. In order to understand the HRQOL programme among type 2 diabetic patients in Tam Binh district, Vinh Long province, Vietnam. The main aim of the research is to investigate on:

- i. Exploration of the relative factors to health-related quality of life of diabetic patients in Tam Binh district, Vinh Long province, Vietnam in 2018 2019.
- ii. Implementation the health-related quality of life of an empowerment programme of diabetic patients.
- iii. Evaluation of the effectiveness of health-related quality of life programme of diabetic patients after six months of the implementation programme.

2.0 Methods/Design

2.1 Subjects

2.1.1 Study population

The target population for this study is the diabetic patients who age 35 and over years old, which diagnosed with T2DM and lived in Tam Binh district, Vinh Long province, Vietnam.

2.1.2 Selection criteria

All patients who were diagnosed the T2DM more than 6 months, according to the WHO standard with or without treatment. The participants have to be residents and/or live at least 6 months in the Tam Binh district. Also, they have to agree to participate on research and inform written consent. Moreover, these people must not be disabling.

2.1.3 Exclusion criteria

People are less than 35 years old in study time (were born after 1984). Also, diabetic patients have not been or are diagnosed with T2DM under 6 months. Furthermore, the participants have determined the other diabetes types as gestational DM. Besides, the cases do not agree to participate in research or give up halfway who will be excluded. Likewise, there dismiss the



individuals with severe disease require hospitalization or referral treatment. Finally, the people with the inability to communicate due to physical or mental disability will not include on the research.

2.1.4 Research time

The research will be carried out about 12 months from December 2018 to November 2019.

2.1.5 Research location

At the time of the study, patients with T2DM have registered in Tam Binh district - Vinh Long province - Vietnam. Tam Binh has a total natural area of 27,972.1 hectares. The administrative unit of the district is Tam Binh town, and 16 communes are: Tuong Loc, My Thanh Trung, Hoa Loc, Hoa Hiep, Hoa Thanh, My Loc, Phu Loc, Hau Loc, Tan Loc, Phu Thinh, Tan Phu, Long Phu, Binh Ninh, Loan My, Ngai Tu; with 132 hamlets. The Tam Binh population now is 168,049 people (83,436 men, 84,613 women; 5,599 in urban, 162,450 in rural), accounting for 16.14% of the population in Vinh Long province. The population density is 535 people/km² and is divided into urban areas: 3,064 persons/km²; rural areas: 520 people/km².

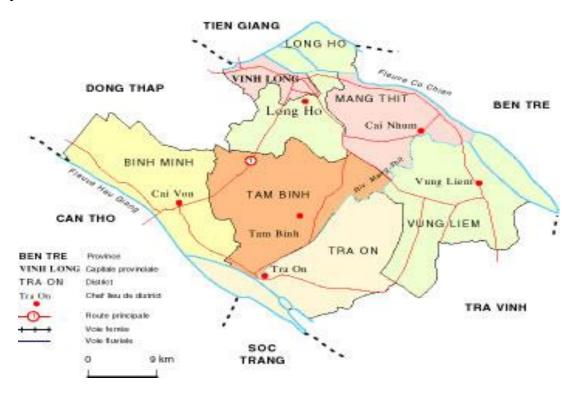


Figure 1. Administrative map of Tam Binh district, Vinh Long province, Vietnam

The Kinh accounted for 96.45%, other ethnic groups made up 3.55% (Khmer 5,309 people, 3.41%, Chinese 176, 0.11% and other ethnic groups 30). Kinh people were distributed everywhere; Khmer people lived in Loan My commune; Hoa concentrated in Tam Binh town. The population in the working age was 100,778 people (52,796 males, 47,982 females). There



were five main religions in the district: Buddhism, Catholicism, Protestantism, Caodaism and Hoa Hao religion. About 36,000 followers believed in 23.28% of the population according to the five main religions (Figure 1).

2.2 Study Methods

2.2.1 Research design

This is a mixed methods research on diabetic population (Figure 2). Phase 1: The quantitative method is performed to assess the HRQOL of patients with diabetes. Phase 2: The quasi-experimental method is designed to develop the implementation of an empowerment programme of diabetic patient group. Phase 3: We evaluate the effectiveness of HRQOL programme of diabetic patients.

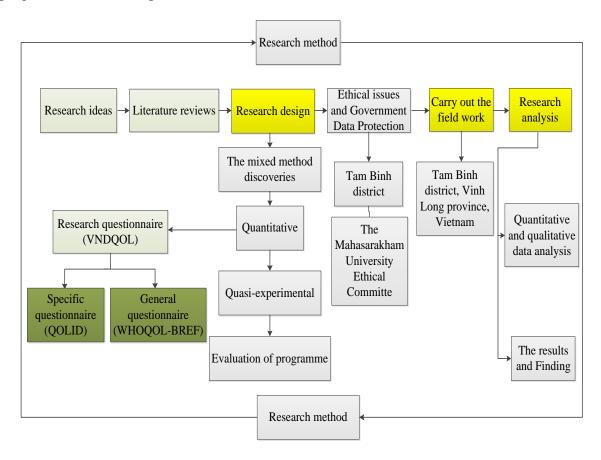


Figure 2. Flowchart of study methodology



2.2.2 Sample size

The study participants were drawn from all eligible individuals in 16 wards and one town in Tam Binh district. The sample size of this research will be calculated with the formula of survey according to proportional formula, as:

$$n = \frac{Z_{\alpha/2}^2 pq}{e^2}$$

Which is valid where:

- n is the sample size
- $Z_{\alpha/2}^2$ is the abscissa of the normal curve that cuts off an area α at the tails (1 α equals the desired confidence level). We desire a 95% confidence level. Therefore, the value for $Z_{\alpha/2}^2$ that is 1.96, is found in statistical tables which contain the area under the normal curve.
- p is the estimated proportion of an attribute that is present in the population. This research is the percentage of HRQOL of type 2 diabetes. According to research by Anumol Mathew et al. (2014), it was found that the average and poor QoL in type 2 diabetes were 58% (Mathew et al., 2014). Thus, we desire the proportion of the HRQOL in this research which is p = 0.58.

$$-q$$
 is $1-p = 1 - 0.58 = 0.42$.

- e is the desired level of precision. We desire a $\pm 5\%$ precision.

Therefore, when replacing the results with the formula we get the sample size as follows:

$$n = \frac{(1.96)^2(0.58)(0.42)}{(0.05)^2} \approx 374.33$$

With this result, we will select n = 380 diabetic people. However, we need extra 30% sample size to exclude those who do not agree to continue to participate in the study. Therefore, the minimum sample size of research is n = 380 + 30%*380 = 494 diabetic people.

2.2.3 Research content

Some characteristics of sample study are assessed as follows: The age is confirmed the mean, ranging from a minimum to a maximum. Next, the gender of participants in this study include female and male. Besides, the diabetic duration is calculated from first diagnosed to study time. It includes mean, minimum, maximum and medium of duration of T2DM. Moreover, the marital status includes the married, never married, widowed/widower, separated/divorced for analysis. Furthermore, the literacy of subjects in this study is separated to illiterate, primary school, secondary school, high school and more than high school.





Likewise, type of family has two types such as small family that has 1-2 generations and big family which is over 2 pedigrees. Although, there are some of ethnicity in Tam Binh district, in there we distribute three ethnic groups, as Kinh, Khomer and others (Chinese, Cham people).

In addition, the alcohol intake is divided into drinker and non-drinker. Similarly, the smoking includes smoker and non-smoker. About the glycemic, we use the fast check meter to audit blood glucose of all people who 35 and over years old in Tam Binh district. The HbA₁C, we check for individuals, who chose to complete questionnaire, on before and after the health empowerment programme which is the HbA₁C SD meter. About type of treatment, we separate use tablet, insulin, both, diet and exercise. Finally, the complications or other chronic diseases include DM with and without complication.

The HRQOL includes nine domains as general health, activity limitation, physical endurance, diet and eating habits, treatment, symptom burden, financial aspects, emotional/mental health, inter-personal relationship.

2.2.4 Methods of data collection

Socio-demographic sheet: The assessment tool for this study assign into 27 questions which is to collect the data about the participants' socio-demographic status. The socio-demographic information sheet covers the following areas of interest: 1) gender, age, educational level, marital status, type of family, ethnicity, income status, employment; 2) health profile: duration of DM, alcohol, smoking, glycemic, HbA₁C, type of treatment, presence of complications or other chronic diseases.

The HRQoL questionnaire: The instrument use in this study which is the Vietnamese diabetes quality of life (VNDQOL) questionnaire. The VNDQOL use to assess the HRQOL in this study. It contents 68 items which include 27 items about background information and 41 items describe the HRQOL. This questionnaire is taken from the WHOQOL-BREF and QoL instrument for Indian diabetes patients (Jitender Nagpal, Arvind Kumar, Sonia Kakar, & Bhartia, 2010). The response format is a 5-point Likert scale with various sets of wordings. Item responses are summed within domains to produce a domain score which are then transformed in a scale from 0 to 100 as recommended in the developer's manual. Higher scores indicate better HRQOL. The VNDQOL is self-administered by respondents. The forty-one QoL items build within 9 groups as follow on supplementation 1.

Expert review: The draft of this questionnaire will be translated into Vietnamese. Then, the both English and Vietnamese questionnaire versions will be sent to 5 experts, who took PhD and over position, who is working on the diabetic field and have the knowledge about the QoL. After, there has the answer from them, this questionnaire will be confirmed and sent back to them again to confirm the accuracy.

2.2.5 The steps of data collection

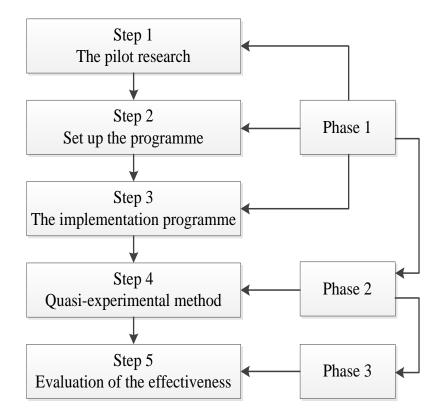


Figure 3. The flowchart of data collection

Phase 1

Step 1: The pilot research on exploration of the factors relative to the HRQOL of diabetic outpatients in Tam Binh health center, Tam Binh district, Vinh Long province, Vietnam in 2018 – 2019 by using the health behaviour and VNDQOL questionnaire. The questionnaire is administered with a sample about 9% of research sample size on this chapter. Therefore, this pilot sample size is n=9%*494 = 44.46. Finally, we will choose 45 diabetic patients for the pilot research. The participants with type 2 diabetes diagnosed more than half year ago and between the ages of 35 to 65 years is included in the study; the volunteers with any other chronic illness which require the patient to be admitted in the hospital for more than two weeks in the past one year, gestational diabetes mellitus or inability to communicate due to physical or mental disability are excluded from the study. This questionnaire is used for evaluation the HRQOL of these patients. After that, the data is analysed to confirm its valuation with Cronbach's Alpha and the Item Objective Congruence.

Step 2: Set up the programme of HRQOL of diabetic patients in Tam Binh district, Vinh Long province. The experts will check again about the questionnaire. This means that we will update the questionnaire according to the previous experts' evaluation and the results of the pilot study. We then send the revised questionnaire to experts for confirmation.

Step 3: The implementation the HRQOL programme of diabetic patients in the fields in Tam Binh district.



Phase 2

Step 4: Quasi-experimental method compares the diabetic education and communication programme about the knowledge of diabetes, attitude toward to deal with diabetes and practice of the diabetic management of the diabetic participants before and after the attending this programme. We assess on the 35-65 years old on the sample size about 85 volunteers in the total of the people in 17 communes (5 participants per each commune) who are checked the HRQoL on phase 1.

The aims of program will help diabetic patients to change the health behavior on the diabetic control progress. The program has to be designed to save time about fifteen minutes, brief content, intelligibility. The Knowledge, Attitude and Knowledge (KAP) questionnaire will be used for the evaluation the result on before and after of this programme. This questionnaire includes the three parts as the diabetic knowledge, the diabetic attitude, the diabetic practice (see supplementation 2). The information about diabetes will be design with the brochure which has totally the necessary knowledge for participants to understand about the diabetes (see supplementation 3).

The program will be built for the three stages. Stage 1, we will interview the volunteers by the KAP questionnaire. Stage 2, we will discuss by face to face about the diabetic lore and send the diabetic brochure which is designed to cover all variable needed empowerment for the volunteers. Stage 3, we will ask the diabetic KAP again with the same KAP questionnaire to take the outcome of the empowerment programme.

The diabetic brochure will be designed according to WHO and the Ministry of Health of Vietnam, and it will be confirmed by the five experts who are the same people to assess the VNDQOL. It shows the define, type of diabetes, some diabetic symptoms, the diagnose, managing and complication test, some complication, how to prevent and treatment adherence.

In addition, the KAP questionnaire will be built the three part which the each has ten multiple choice questions. This questionnaire will be commented by the similar five experts on the step 1. The 85 participants will be asked for the answer two times that are the first and after activity programme. Then, we will compare two results for the analyzing of the quasi-experimental.

Phase 3

Step 5: The evaluation of the effectiveness of HRQOL programme of diabetic patients on step 4 by the KAP and VNDQOL questionnaires after six months of the empowerment programme. We will return again to the seventeen communes for the checking of the 85 participants in phase 2. The result of two questionnaires will be analyzed for the assessment of the empowerment programme effectiveness (Figure 3).



2.2.6 Error control measures

The sample must conform of selection and exclusion criteria. Participants must attend the implementation program and complete all the questionnaire which is two times.

2.2.7 Data analysis

After overviewing the questionnaire, each one is coded, and the usable number of questionnaires is determined. Data is coded and transferred into specially designed formats for data entry using the Statistical Package for Social Sciences version 20 programme. Cleaning of data is done; the data is analyzed by performing the following statistical analyses. A descriptive statistical analysis of frequency, mean and standard deviation is carried out on all the codified variables. Independent sample t-test is used to make comparisons among the demographic variables of respondents. The level of significance selected for this study is < 0.05.

One-way analysis of variance is used to evaluate the differences in the domains of the HRQOL among the different groups. In case of the presence of significant differences in the HRQOL domains among the groups and the independent variable composed of more than one level, a procedures called "post-hoc multiple comparisons" is used to determine these differences. The t-test is used for analysis on the quasi-experimental research.

2.2.8 Research ethics

Participants are assured anonymity that participation is voluntary and they can choose to discontinue their participation at any time. They are informed that their participation will have no bearing on any future professional relationship with the current medical provider or the researcher.

This research investigation has been carried out with the integrity and has at all times respected and ensured patient confidentiality and privacy of personal details. All researchers have scrupulously respected the ethical principles that all biomedical research must ensure. The principles of non-maleficence, legality, free will and beneficence have been faithfully accomplished. The research has to be allowed by the MSU ethic committees. Permission and approval letters are received to recruit patients from government in Tam Binh district.

3.0 Discussion

Diabetes causes serious deterioration in general QoL mainly affecting the HRQOL (Trikkalinou, Papazafiropoulou, & Melidonis, 2017). In fact, DM patients had remarkably lower HRQOL than non-diabetic people (Choi et al., 2011). Therefore, HRQOL is an important measure of diabetes control and treatment. This study provides a deeper understanding of VNDQOL implementation and community intervention in Vietnam.



A number of studies have reported that the incidence of T2DM varies according to social demographic characteristics such as age, gender, occupation, education, marital status, and family status (Akinci et al., 2008) (Nguyen et al., 2018). Moreover, the HRQOL was also affected by these factors of the patient (Mathew et al., 2014).

Many reports showed that the HRQOL score decreased in T2DM patients. Furthermore, the components of HRQOL are also influenced by patient factors such as age, gender, occupation, marital status, family type, education level, income, duration of illness, comorbidities, blood glucose level, HbA1C, treatment (Akinci et al., 2008) (Alfian et al., 2016).

People with diabetes often have little knowledge about their disease so they do not have the right attitude to the disease, resulting in poor care practices and poor adherence to treatment. This is shown in the research of La Ngoc Quang, et al in 2012 (Quang et al., 2012).

However, the HRQOL score increases after conducting health interventions. This is evident in the study of Liliana C. Baptista, et al in 2017 (Baptista et al., 2017).

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List of abbreviations

DM: Diabetes mellitus

HRQOL: Health-related quality of life

KAP: Knowledge, attitude and practice questionnaire

QoL: Quality of life

T2DM: Type 2 diabetes mellitus

VNDQOL: Vietnamese diabetes quality of life questionnaire

WHO: World Health Organization MSU: Mahasarakham University

Declaration

Authors declare that this study protocol is our production only. It does not conflict with the others.

Authors contribution

- Author 1: This is the doctoral student to write the study protocol.
- Author 2: This is the supper advisor to check and repair the study protocol.
- Author 3: This is the co-advisor to check and repair the study protocol.
- Author 4: This is the co-advisor to check and repair the study protocol.

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