



Study Protocol

The Effectiveness of Health Education Strategies on Knowledge and Behavior Scores of Individuals with Type Two Diabetes in Preventing Foot Ulcers in Binangonan, Rizal: A Study Protocol

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Abstract

Background: Diabetes Mellitus (DM) is a long-term metabolic disease distinguished by persistently elevated levels of glucose in the bloodstream. It affects 7.5% of adults in the Philippines, translating to 4,303,899 adults with diabetes in 2021. Type 2 DM (T2DM), which results from a combination of genetic predispositions and lifestyle choices, is the most prevalent form of diabetes in the Philippines. Foot ulcers are a common and highly comorbid complication of diabetes. By improving the knowledge and behavior regarding foot care using health education strategies, preventing diabetic foot ulcers is achievable. **Objectives:** This study aims to evaluate the effectiveness of health education strategies in improving the knowledge and behavior of participants diagnosed with T2DM regarding foot ulcer prevention in Binangonan, Rizal. **Methods:** This study uses a quantitative quasi-experimental design. A 2-day workshop will be held by the researchers, including a screening, pretest, orientation on the health education material (HEM), and demonstration of the HEM content, followed by 2-weeks of self-intervention and post-test. The study will include males and females from Binangonan, Rizal, aged 20-79, who are medically diagnosed with T2DM by a physician. The effectiveness of the strategies will be evaluated using paired t-tests based on the mean of the pre-test and post-test scores obtained from the Diabetic Foot Knowledge Subscale (DFKS) and Foot Self-Care Behavior Scale (FSCBS) questionnaire. **Expected Results:** The researchers expect an increase in the post-test scores of the participants in the DFKS and FSCBS questionnaires. This would mean increased behavior and knowledge of foot care practices to prevent diabetic foot ulcers after 2 weeks of self-intervention guided by the HEM and strategies.

Key Words: diabetes mellitus, diabetic foot ulcer, health education strategies, health education material, knowledge and behavior

INTRODUCTION

Diabetes Mellitus (DM) is a long-term metabolic disease distinguished by persistently elevated levels of glucose in the bloodstream.¹ The prevalence of diabetes in the Philippines is 7.5% in adults, which translates to 4,303,899 diabetes cases.² The most prevalent form of diabetes in the Philippines is Type 2 diabetes mellitus (T2DM) which results from a combination of genetic predispositions and lifestyle choices, thus increasing its prevalence in the country.¹ Among the complications of diabetes, the risk of diabetic foot ulcers (DFUs) is 19% to 34%, making it one of the most common and highly morbid complications of diabetes.³ DFU can be

prevented by implementing effective knowledge and practices that decrease the risk of complications, ultimately reducing the likelihood of amputations that can negatively impact a patient's quality of life. In the Philippines, the self-care practices related to foot care among individuals with diabetes are considered adequate.⁴ This implies that most Filipinos have a basic knowledge of foot care.⁴ However, basic knowledge of foot care does not result in a change in foot care practice.⁴ Therefore, insufficient knowledge and inadequate foot care practices among T2DM patients can elevate the risk factors associated with foot complications.⁴

To improve knowledge and practices related to foot care among individuals with diabetes, several studies showed that reinforcement of information regarding foot care would have a change in behavior and knowledge.^{5,6}

Health Education is essential for providing knowledge on foot-care behavior. Health education serves as a vital tool for promoting health and enhancing the well-being of populations, thereby contributing to the development of health capital.⁷ Health education strategies are identified as face-to-face, pamphlets, brochures, and audio-visual mediums.⁸ Several studies have indicated that health education strategies, including the use of audio-visual materials, brochures, and pamphlets, have effectively enhanced knowledge about diabetes-related foot care and improved foot care behaviors. This, in turn, has played a significant role in preventing foot ulcers among patients with Type 2 Diabetes Mellitus (T2DM).^{6,9}

Likewise, there are limited published studies regarding the use of health education strategies to improve knowledge and behavior in preventing DFUs in the Philippines. Appraisals of existing related literature revealed that evidence on the effectiveness of health education strategies as an intervention is only limited to an international setting. One study showed that brief educational programs effectively improve knowledge and behavior in preventing DFU among high-risk patients.¹⁰ Similarly, a systematic review reported that foot care education improved diabetic foot ulcer problems. However, none of these studies was implemented based on a local setting.¹¹

Additionally, the existing literature utilizes other interventions, such as foot-related exercises and orthotic interventions, that are concomitant with health education strategies to improve the knowledge and behavior of patients in preventing DFU.¹² However, there is still limited evidence to support the effectiveness of patient education alone.⁵

There is a limited amount of published research focused on individuals with diabetes in the Philippines. The existing data suggests that patient education is effective in enhancing diabetes knowledge, improving self-efficacy,

positively influencing anthropometric measures, lowering A1C levels, increasing the use of healthcare services, and shaping attitudes toward health.¹³ Moreover, educational tools should form the basis of new and innovative educational strategies in the Philippines.¹⁴ As such, existing health education materials are not sufficient, and developing a new set catered to raise the knowledge and behavior of patients regarding diabetic foot care is needed.

This study aims to evaluate the effectiveness of health education strategies in improving the knowledge and behavior scores of T2DM participants in Binangonan, Rizal, on DFU prevention after two (2) weeks of self-intervention using health educational materials. Participants with T2DM who engage in a structured health education intervention focused on DFU prevention will demonstrate a statistically significant increase in knowledge and behavior scores compared to baseline measurements, as assessed by validated outcome measure tools, after two weeks of self-intervention.

METHODS

Ethical Considerations. This study is approved by the Ethical Review Committee and complies with the principles outlined in the Declaration of Helsinki, the Ethical Guidelines for Health-Related Social Research established by the Philippine Health Research Ethics Board, and the Data Privacy Act of 2012. This study is registered with the Philippine Health Research Registry (Registry ID: PHRR240205-006657).

Study Design. This study will utilize a quantitative quasi-experimental design without a control group and will focus on the evaluation of the effectiveness of health education strategies in improving the knowledge and behavior of patients with T2DM on DFU prevention through a pre-test and a post-test with the absence of randomization, as such method is typically implemented in studies wherein conducting an RCT is not feasible.¹⁵

Setting. Binangonan, Rizal, which encloses a total of 40 barangays, is the community where the research study was conducted because of the number of T2DM cases in the area that suits the

scope of the research study. The Department of Health has updated the number of Type 2 Diabetes mortality and morbidity cases in Rizal in 2022, wherein a total of 865 morbidity cases and a total of 157 mortality cases, all of which are individuals with Type 2 diabetes.¹⁹ Given the prevalence of 7.5% of diabetes in adults in the Philippines,² Binangonan likely faces similar issues, making it a relevant location for diabetes-related health education. A municipal health office and health education units in Binangonan suggest a structured health promotion and education system, indicating a willingness to engage in health-related issues, which can support disseminating health educational materials. With this data, educational health strategies are to be implemented in this community because they are suitable for assessing patient knowledge and behavior on foot ulcer prevention and overall foot care. Additionally, since the community is one of the partner communities of the Simbahayan Organization, the built relationship can aid in implementing the study in this setting. During the study, minimal limitations may occur, such as logistical constraints, physical discomfort, and research-related injuries or accidents during the study.

Sample Size. The sample size will be computed using the statistical software JAMOV. Since the Cohen's *d* was found to be 0.92 for the pretest and posttest, it was determined that a total of 15 participants would be necessary to achieve a statistical power of 90% with a two-tailed two-sample test.¹⁶

Participants Selection. This study will use purposive sampling to recruit males and females from Binangonan, Rizal, aged 20-79, who are medically diagnosed with T2DM by a physician (fasting blood sugar of ≥ 126 mg/dL or total plasma glucose, random plasma glucose of ≥ 200 mg/dL, or Hb1AC of $\geq 6.5\%$).¹⁷ On the other hand, it will exclude individuals medically diagnosed with Type 1 diabetes, cognitive impairments (MMSE ≤ 24), and with a medical history of end-stage renal disease and anemia, given the fact that the last two are closely associated with poor healing, a higher risk of amputation, and an increased likelihood of mortality.¹⁸ In addition, individuals with wounds in the foot area will be excluded as the study will

not focus on direct wound care to wounds located in the foot area or anything pertaining to wound healing.

Participant recruitment will begin with posting digital and physical recruitment materials through social media and at the Community-Based Rehabilitation Center of Binangonan, Rizal, respectively. In return, individuals may notify the researchers through Facebook/SMS regarding their interest in participating. Patients will be screened based on the exclusion and inclusion criteria. If eligible to participate, they will be asked to sign an Informed Consent Form.

Instruments. The Mini-Mental State Exam - Filipino (MMSE-P), Diabetic Foot Knowledge Subscale (DFKS), and Foot Self-Care Behavior Scale (FSCBS) will be used in this study. The DFKS and FSCBS were translated and validated from English to Filipino during Phase 1 of the research study. The Diabetic Foot Knowledge Survey (DFKS) and the Foot Self-Care Behavior Scale (FSCBS) will be employed to evaluate the participants' baseline knowledge and practices related to diabetic foot care. Subsequently, these instruments will be re-administered to evaluate any changes in the participants' knowledge and behavior regarding diabetic foot care following the provision of education.

The Mini-Mental State Exam - Filipino (MMSE-P) is an 11-item screening tool used to assess and record cognitive performance through simple questions and tasks, wherein a score of 25 to 30 falls under persons with no cognitive impairment.²⁰ The MMSE-P has been validated with psychometric properties of 85% sensitivity and 86% specificity. The FSCBS(15 items) assesses diabetic individuals' behavior and foot care practice. The patients are tasked to choose the most appropriate response [never, rarely, sometimes, often, or always] to each question (see Supplementary Material A). The Filipino Translated Version of the FSCBS underwent content validity and reliability testing, and the results were an S-CVI score of 0.92, entailing content validity, Cronbach's alpha score of 0.85, entailing internal content consistency, and a test-retest reliability score of 0.73 using Pearson's Correlation Coefficient, entailing reliability of the whole questionnaire. On the other hand, the DFKS (5 items) is utilized to assess diabetic

individuals' foot care and knowledge. Potential response choices for the DFKS were (1) "Yes," (2) "No", and (3) "I don't know" (see Supplementary Material B). Responses were categorized as correct or incorrect, and the total score was calculated by summing the number of correct responses. The Filipino Translated Version of the DFKS subscale also underwent content validity and reliability testing, and the results were an S-CVI score of 0.96, entailing content validity, Cronbach's alpha score of 0.72, entailing internal content consistency, and Test-retest reliability score of 0.76 using Spearman's coefficient, entailing reliability of the whole questionnaire.

Intervention. The intervention will consist of a Filipino-translated version of the Health Education Module (HEM) (refer to Supplementary Material C). This module is designed to enhance patients' knowledge and behaviors related to foot care, along with a two-day workshop that will provide orientation and demonstrations of foot care techniques.

The HEM is a valid and culturally adapted educational brochure on knowledge regarding foot care designed to prevent diabetic foot ulcers among individuals with diabetes. It has 100% content validity and an S-CVI of 1. It consists of three categories discussing diabetes, its complications, patient education on foot self-care practices, and the importance of appropriate footwear choices.

Data Gathering Procedures Initially, a letter that includes a request for approval to implement the study in their locale and the researcher's intention to recruit via posters, online publication materials, and through the CBR Binangonan unit's contacts will be sent to the Local Government Unit (LGU) through the head and units of the Community-based Rehabilitation (CBR) in Binangonan, Rizal. To ensure a conducive learning environment, the face-to-face 2-day workshop will be held on a basketball court, which will be reserved beforehand. On the first day, the researchers will hold an orientation for the information on the research study and its importance. The recruitment criteria will also be explained to ensure that they fit the criteria for sampling, as the screening will also be done afterward. The

screening includes food and medication intake, such as antidiabetics taken before the session and allergies to lotions or creams. The administration of the MMSE will follow this to assess the cognitive ability of the participants before answering the questionnaires. Afterward, with the assistance of the researchers, the PIS-ICF will be read and signed. The MMSE's English and Filipino versions will be made available for the participants. The orientation and screening will be held for 30 minutes. After this, a pretest using the DFKS and FSCBS questionnaires will be implemented to evaluate the knowledge and behavior of the participants toward DFU prevention. This will be done in a 5-10-minute one-on-one session with the participants to ensure that the researchers can address queries and clarifications if necessary and guide the participants in answering the items. Deployment of the questionnaires, nonetheless, does not require specialized training. This is because the questionnaires are self-administered, and the faculty co-authors will supervise distribution.

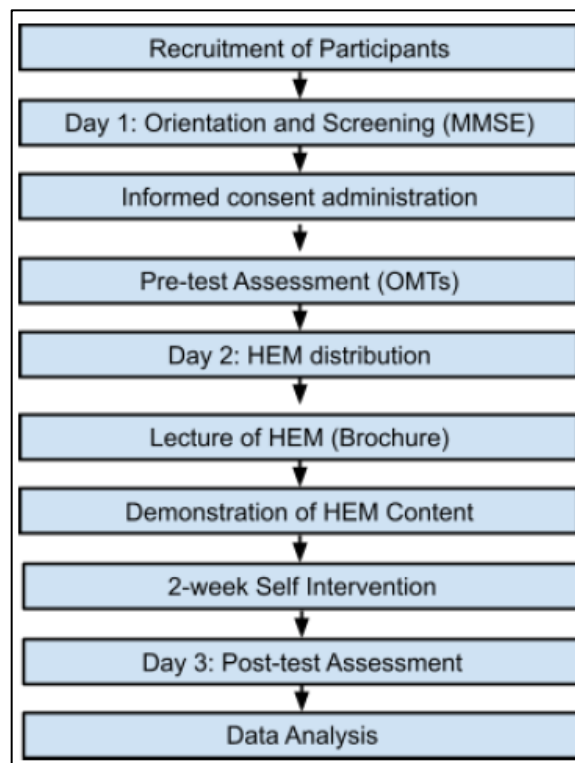


Fig 1. Flow Chart of Data Gathering Procedures

On the second day, the health education material (brochure) will be distributed to the participants, followed by a group session led by the researchers to discuss the contents of the

health education material to enhance participant understanding and engagement with the study. Subsequently, a demonstration of the prevention of DFUs will be implemented to supplement the content of the brochure. Three main parts of the demonstration are feet inspection, proper washing and drying of feet, and appropriate usage of footwear. With this, the participants will be grouped into 3 small groups of members each as they take turns visiting each station. To ensure consistency of discussions among subgroups, the researchers created and utilized the same PowerPoint presentation while following a general script that is deployed for each station. The first station will focus on proper foot inspection, which includes looking for blisters, calluses, corns, or sores in the spaces between the toes. The second will revolve around proper washing and drying of the feet, using the recommended water temperature, and using topical creams or lotions and lubricating oils. Lastly, the third station will be on the appropriate usage, inspection, and fitting of proper footwear. Throughout the demonstration of each assigned researcher, the participants will also be asked to demonstrate the foot care techniques presented, such as foot inspection and proper application of lotions. This will be done to assess the participants' understanding of each intervention. Two weeks will be given to the participants to practice the foot self-care techniques. Given the duration of this timeframe, participants must continue the intake of their prescribed medications. When the participants have questions, clarifications, or other concerns regarding the study, they may reach out through Facebook Messenger or SMS. After a week of self-intervention, the researchers will send an SMS reminding them to continue answering the "monitoring sheet," read the HEM, and be reminded of the follow-up post-test. After two weeks, the researchers will administer a post-test using the same two questionnaires, with the participant's pretest scores as the baseline. Upon completion, the researchers will compare and analyze the scores gathered. The study will be conducted from February 2024 to November 2024.

Information collected from this study will be kept confidential by securely storing the completed questionnaires in envelopes by one

researcher to ensure data privacy and confidentiality. Access to the encoded data will be done only by two researchers on personal computers and laptops secured with personalized passwords. Each of the participants' encoded names will be codified for anonymity during the data analysis process. The data gathered from this research will be kept for ten years after publication. After ten years, all data will be deleted from the database.

Data Analysis. Descriptive statistics will be utilized to characterize the participants included in the study. For nominal variables, frequency and proportion will be calculated, while mean and standard deviation will be used for interval and ratio variables. Inferential statistics will be performed to determine the effectiveness of the HEM. A Paired T-test will be utilized since it is used to analyze dependent samples. As such, this method will be utilized to determine whether there is a significant difference between the mean scores of the pre-test and post-test. A confidence interval of 95% and a p-value of less than 0.05 will be regarded as statistically significant. A 95% confidence interval will be used to ensure the accuracy of the data and minimize errors.

EXPECTED RESULTS

An improvement in the participants' knowledge of the effects of diabetes on the feet is expected. This includes its risks, such as slow wound healing, and how they can manage their foot, such as using iodine or alcohol to clean wounds and carefully trimming their toenails. Moreover, an increase in foot self-care practices is also expected. This involves proper foot inspection, foot washing, proper drying of the foot, moisturizing the skin, nail cutting, evaluating footwear, choosing the right type of footwear, checking socks for any issues, avoiding going barefoot, and maintaining a positive attitude towards foot care. The increase in scores on the DFKS & FSCBS means an increased knowledge and behavior, respectively, on diabetic foot care, and thus, the health education strategy is an effective intervention tool. In addition, the results imply that a seminar with demonstrations and provision of a HEM with

self-intervention can be effective in establishing proper knowledge of diabetic foot and foot self-care behaviors. With the aforementioned results, the process done in the study on providing health education strategies and the use of HEM will be a guide for Physical Therapists to implement them in their practice. In addition, these results may be used by future researchers to further investigate the effectiveness of health education strategies as an intervention, either alone or in conjunction with other interventions such as exercise.

Supplementary Materials

[Supplementary Material A. Foot Self-Care Behavior Scale \(FSCBS\) \(Filipino Version\)](#)

[Supplementary Material B. Diabetes Foot Knowledge Subscale Questionnaire \(DFKS\)\(Filipino Version\)](#)

[Supplementary Material C. Health Education Material](#)

Individual Author's Contributions

All authors contributed equally to the development of this manuscript.

Disclosure Statement

This study is not affiliated with any funding agency.

Conflicts of interest

One of the authors developed health education material for utilization. This author is also part of the editorial board of PJAHS.

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