

STUDY PROTOCOL

Two Arm Single-blind Parallel Randomized Controlled Trial Effects of Health Education Intervention on Foot Self-care Behavior Among Diabetic Patients: Study Protocol

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ABSTRACT

Introduction: Diabetes is a chronic illness and it has a significant impact on health. Behavioral interventions theory could improve self-care practices of the foot among patients with diabetic. Behavioral interventions could prevent the risk of foot problems. This trial aims at determining the effect of patient education intervention on foot self-care behavior and clinical outcomes among diabetes patients. **Methods:** The study is a two-arm single-blinded randomized controlled trial which will be conducted in the Federal Medical Centre (FMC) Owerri, Imo state, Nigeria involving 160 diabetic patients. A central computer-generated randomization list will be generated. Sequentially numbered sealed opaque envelopes will be used to determine concealment. The sample size is 160; therefore 80 participants will receive three sessions of patient education in addition to usual care (intervention group) for three and six months while another 80 participants (control group) will receive only usual care and will receive health education after the study is completed. The outcome of the intervention effectiveness is measured by modified version of Diabetes foot Self-Care Behavior Scale (DFSBS). **Discussion:** Our hypothesis is that based on the Health Belief Model, patient education intervention can improve foot self-care behavior in the intervention group. Data collection will be done at baseline, and at three- and six-months post intervention. **Trial Registration:** The Clinical Trials Registry- India (CTRI), Reference no CTRI/2021/06/034311.

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INTRODUCTION

Diabetes mellitus (DM) is a chronic disease that arises when enough insulin is not produced from the pancreas or when the insulin it produces cannot be used effectively in the body (1). Diabetes mellitus is a significant public health issue; it is among the four non-communicable diseases (NCDs) world leaders targeted for action (2). A total of 422 million adults worldwide was estimated to live with diabetes in 2014, when compared with 108 million individuals in year 1980. Since 1980 the prevalence of DM has almost doubled from 4.7% to 8.5% globally, in the adult population. This is as a result of increase risk factors such as overweight or obese. The prevalence of DM increased in low and middle-income nations than high-income nations in the past decade (2).

In 2015, it was estimated that a total of 14.2 million individuals with DM live in sub-Saharan Africa. Thus, it is predictable that by 2040 the number will rise to 34.2 million individuals. The prevalence varied among countries, the prevalence ranges from 0.6% in Benin to 18.2% in Réunion, off the coast of Madagascar (3).

The prevalence of DM was reported to be 1.7% among adults between 20 to 69 years in Nigeria (4). A study reported that the prevalence ranging from 2% to 12% across Nigeria (5). The WHO pointed out that in Africa, the number of individuals living with DM is higher in Nigeria compared to other Africa countries (6). According to WHO, in the year 2016 DM was the seventh leading cause of mortality globally. It was estimated that 1.6 million deaths globally in year 2016 were directly caused by DM. In the year 2012, a total of 2.2 million deaths were as a result of high blood glucose (7). Uncontrolled DM increases the risk of possible complications which includes cardiovascular disease, damage of the nerve, stroke, kidney failure, loss of sight,

foot ulcers which leads to lower extremity amputation (LEA) and early mortality (2).

The incidence of diabetic foot ulcer (DFU) largely reflects on diabetes quality of care, the problem of DM is avoidable with appropriate care (8). Patient's inadequate knowledge and practices regarding foot care is the cause of increase occurrence of diabetic foot problems (9). A study conducted in South Africa among type 2 diabetic patients revealed that awareness regarding diabetic foot care could decrease diabetes associated foot ulcer and loss of limb and also help in foot ulcers healing (10).

Globally the prevalence of DFU was 6.3% in the year 2016 among diabetic patients, the prevalence is higher in male 4.5% when compare to female 3.5% and more in type 2 diabetic 6.4%, and 5.5% type 1 diabetics. In Nigeria, the burden of DFU was high, the prevalence rate ranges from 11%-32% amongst hospitalized diabetic patients (11). Among all complications related to diabetes, the most preventable is diabetic foot (12). A study conducted in secondary care rural hospital in Southern India among diabetic patients, reported that lack of knowledge on care of the foot and poor practices on care of the foot were identified as risk factors for foot problems (13).

Appropriate foot self-care behavior would help decrease the risk of DFU and LEA (14). Diabetes education is effective in improving foot self-care behavior and preventing diabetic foot complications (15). A Current evidence from the multicentre evaluation of diabetic foot ulcer in Nigeria, reported that the level of knowledge on foot care among the patients were low. The study observed that almost three-quarter of the diabetic patients did not received any education on foot care since they were diagnosed of diabetes (16).

Early diabetes education, particularly education on care of the foot for diabetic patients is the easiest, least expensive, and most effective way of foot ulcers prevention, amputation and mortality (17). Therefore, it is important to establish methods for improving behavior on self-care of the foot, adequate foot care knowledge through interventions, and also to determine the effectiveness of interventions on foot self-care behavior as well as clinical outcomes of the patients.

This trial aims at determining the effect of patient education intervention on foot self-care behavior and clinical characteristics (duration of diabetes, treatment of diabetes, smoking status and hospitalization due to diabetes among diabetes patients). To describe and compare between the respondents in the intervention group and control group at baseline. To determine changes within intervention group from baseline to 3 and 6 months for post intervention for the following characteristics: Primary outcome: foot self-care behavior. Secondary outcomes: knowledge of foot care,

foot care self-efficacy and Health Believe Model (HBM) construct. To compare the changes in intervention group and control group from baseline at 3 and 6 months for post intervention.

METHODS

Study design

The study is a two-arm single blinded parallel randomized controlled trial involving adults with diabetes who have been diagnosed and enrolled into the Federal Medical Centre (FMC) Owerri, Imo state, Nigeria for checkup. The FMC Owerri was chosen as the study site as it is the only federal hospital in Imo State, Nigeria and it caters for patients referred from various private and government health facilities in Imo State. A central computer-generated randomization list will be generated. Sequentially numbered sealed opaque envelopes will be used to determine concealment. The sample size is 160; therefore 80 participants (intervention group) will receive three sessions of patient education in addition to usual care and follow-up for three and six months post intervention while another 80 participants (control group) will receive only usual care and will receive health education after the study is completed. The outcome indicator of intervention effectiveness is measured by modified version of Diabetes foot Self-Care Behavior Scale (DFSBS). This study will use randomization with allocation concealment in order to reduce selection bias (18). Our hypothesis is that based on the Health Belief Model, patient education intervention can improve foot self-care behavior in the intervention group. Data collection will be done at baseline, and at three- and six-months post intervention.

Randomization and patient recruitment

A technique using a random sequence generator program by an independent project biostatistician in the Hospital Health Information Unit will be responsible for the allocation sequence and allocation concealment which will be used to randomly allocate the sample population into the intervention and control groups in a ratio 1:1 respectively. Allocation concealment will be at the randomization stage, this is to reduce selection bias. This will be done by the independent person from the pharmacy department, using number code sequence in a sealed envelope. Only permanent residents of Imo state will be included in the study to decrease attrition and drop-out from this study. The patient name and date of birth will be written on the envelope and recorded on a separate sheet of paper. The information containing the allocation codes will be made visible only after the corresponding envelopes are opened at the time of consultation, and this is only after the enrolled diabetic patients complete all baseline assessments. The envelope will be kept in the patient's folder for subsequent follow-up.

Development of intervention programme

The foot self-care program is a newly developed

programme by the researchers. It is developed for diabetic patients based on HBM by Rosenstock (19). The theory is an effective model of health education, which focused mainly on diseases prevention and adoption of behaviors to prevent disease; it is a significant precise model used to determine the association between health beliefs and behaviors. The theory is an appropriate framework to approach the issue of diabetes management to prevent diabetes complications. This intervention was formulated to improve diabetic patient’s knowledge, perceived susceptibility, perceived severity, perceived benefits, perceived barriers, self-efficacy and cue to action. The theory elaborates how perceived susceptibility which is an influential factor motivate people to practice healthy behaviors, which in turns facilitates and influences the diabetic patients’ engagement in improving foot self-care behavior.

In developing the module, literature review was conducted, pilot test was done and face validity as well as content validity. The questionnaire was given to 30 diabetic patients, who will not participate in the main study, they will be selected from a different location, but they will have similar characteristics. The comments of the participants will be evaluated, to know if they understand the questions, corrections will be made on the wordings. The contents of the HBM module recently developed by the researcher are in Table I.

The HBM intervention module will use six behaviour change techniques, namely, Perceived susceptibility, Perceived severity, Perceived benefits, Perceived barriers, Self-efficacy and Cue to action. The patients will be advice to report any difficulties encounter and any misconception. Table II shows the application of HBM behaviour techniques in HBM Intervention programme.

Participants eligibility

Eligibility criteria will be the basis for selection of study participants and only those diabetic patients who meet these criteria will be involved in the study, however, those that do not meet the enlisted criteria will be excluded from the study.

Table I: Content of HBM Programme

Unit	Topics and Contents in HBM programme
	Introduction to diabetes and foot care
1	Perceived susceptibility <ul style="list-style-type: none"> • Introduction of program • Introduction to diabetes • What is diabetes • What are the complication of diabetes • What are the causes of diabetic foot ulcers
2	Perceived severity <ul style="list-style-type: none"> • Prevention of diabetic foot ulcer • Wash your feet with lukewarm water and soap, dry your feet, especially between the toes • Apply moisturising lotion, do not apply between toes • Check your feet for blisters, cuts and redness, if these are present, consult your doctor • Trim your nails straight across and file the edge with nail file • Change socks daily, avoid dirty and tight socks • Never walk barefoot either indoors or outdoors • Examine your shoes daily for cracks, stones, nails which may cause injury to the feet
3	Perceived benefits <ul style="list-style-type: none"> • Importance of foot care • Importance of preventing foot ulcer
4	Perceive barrier <ul style="list-style-type: none"> • Consequences of not taking care of the foot • Importance of preventing amputation
5	Self-efficacy <ul style="list-style-type: none"> • Empowering diabetic patients with adequate knowledge to comply with foot self-care practices • Practical demonstrations of foot care to patients • Allow patients to demonstrate foot care to know how confident they are when performing foot self-care
6	Cue to action <ul style="list-style-type: none"> • Encourage patients to have good perception on foot care, this will change their foot self-care behavior. • Cues to action can activate health behaviour when appropriate beliefs are held. These ‘cues’ comprised various range of activates, including people’s insights of symptoms, social influence, and health education campaigns. Lifestyle modification: exercise, diet,

Inclusion criteria

We will recruit a total of 160 diabetic patients that enrolled in diabetic out patient’s clinic of FMC Owerri Imo state Nigeria. All diabetic patients between 18 years or more who attend the diabetes clinic for usual follow-up in FMC Owerri Imo state, Nigeria. are eligible to partake in this study. Diabetes patients presented with or without diabetic foot problem are eligible to partake in this study.

Table II: Session of health education which address the constructs of HBM

Week	HBM Constructs	Content	Mode of Delivery	Time duration
Week 1	Perceived susceptibility	<ul style="list-style-type: none"> • Introduction to diabetes, • Introduction to diabetes foot care 	Lectures and discussion (PowerPoint)	30 minutes
Week 1	Perceived severity	<ul style="list-style-type: none"> • Knowledge of foot care 	Discussion	30 minutes
Week 2	Perceived benefits	<ul style="list-style-type: none"> • Importance of foot care 	Lectures and discussion	30 minutes
Week 3	Perceived barriers	<ul style="list-style-type: none"> • Discussion to know if the patients have any concern or barriers in performing foot self-care 	Lectures and Discussion video session	30 minutes
Week 4	Self-efficacy	<ul style="list-style-type: none"> • Empowering diabetic patients with adequate knowledge to comply with foot self-care practices • Practical demonstrations of foot care to patients 	Discussion and demonstration	30 minutes
Cue to action		<ul style="list-style-type: none"> • Educational booklet will be provided to increase patients’ family support in how to care for the foot 	Brief discussion at the end of each session	10mins

Exclusion criteria

Diabetic patients with history of mental health condition. Diabetic patients with visual or hearing impairment. Diabetic patients admitted in the ward due to complicated diabetes. Diabetes patients with both legs amputated will be excluded from the study.

Sample size calculation

The estimation sample size was based on sample size formula for analytical study by (Lemeshow, Hosmer, Klar & Lwanga, published in 1990, cited in Aday & Cornelius in (2006) which tests the alternative hypothesis with two groups means. The formula is given as follows:

$$n = \frac{2\sigma^2 [z_{1-\frac{\alpha}{2}} + z_{1-\beta}]^2}{(\mu_1 - \mu_2)^2}$$

Where,

- n = Sample size
- $Z_{1-\alpha/2}$ = Z statistic for level of confidence of 95% = 1.96
- $Z_{1-\beta}$ = Z statistic for 80% power = 0.842
- σ = Pooled standard deviation
- μ = Mean score (group 1 and 2)

Based on the study by Chen et al. in 2011, in Taiwan, among farmers and fishermen with type 2 diabetes (20); the mean (standard deviation) score for foot self-care score at pre-test is 32.32(6.76) and the mean score for foot self-care at post-test is 36.22(6.95). These values were used in sample size calculation. For a 95% confidence interval, $Z_{1-\alpha/2} = 1.96$, and for power of 80%, $Z_{1-\beta} = 0.842$. Pooled standard deviation was calculated as followings:

$$\sigma = \sqrt{\frac{\sigma_1^2 + \sigma_2^2}{2}}$$

$$\sigma = \sqrt{\frac{6.76^2 + 6.95^2}{2}}$$

$\sigma=6.86$

Replacing the pooled standard deviation and mean into the formula:

$$n = \frac{2(6.86)^2 [1.96 + 0.842]^2}{(32.32 - 36.22)^2}$$

$n = 48.5$

Hypothesis testing, 2 groups:

As there are two groups; pre-test and post-test among the sample size estimated was multiplied by a factor of two.
 $n = 48 \times 2 = 96$

Adjustment for estimated response rate:

Assuming 80% of the patients approached will agree to participate in this study;
 $n = 96 / 0.8 = 120$

Adjustment for eligibility:

Assuming 90% of patients who agreed to participate will be eligible for the study upon screening;
 $n = 120 / 0.9 = 133$
 To adjust for 20% attrition Valentine & Cooper, 2008 {21}
 $133 \times 20/100 = 26.6$
 $= 27 + 133 = 159.6 = 160$

Based on the above sample size, the required minimum sample size for each group, n is 80 therefore 80 for each arm. Therefore, sample size for the study is 160. This number was chosen because it is a more manageable sample size for RCT.

Training of research team

Two nurses that are willing to abide by the study instructions will be trained; they will be employed into the study to serve as research assistants. They will be involved in the recruitment of the participants and also will assist in ensuring the informed consent form is completed by the respondents and also assist during data collection. The researcher/research assistance will explain to the participants that they can leave the study at any time when they demand to do so, without any consequences.

Intervention

The two groups are the intervention group and control group. Respondents of the intervention group will receive health education on foot care and usual clinic care, while respondents of the control group will receive only usual care. Usual care is care instructed to manage their diabetes as usual, based on what the doctor or practice nurse advised, which would normally include appropriate medication, monitoring of blood glucose, advice regarding diet and physical activity, and referral to the diabetes education self-management both for newly diagnosed and ongoing diabetic patients.

All the respondents will be followed up for six (6) months after recruitment into the study. Health Education will be given to the intervention group immediately after administering the questionnaires then follow up for 3 and 6 months for post intervention. Baseline measurement on behavior regarding self-care of the foot, knowledge, foot self-care efficacy and Health Belief Model construct will be performed for both intervention groups and control groups. The intervention comprised of six modules, design to cover each of the constructs of Health Belief Model (Figure 1).

The Purpose of this intervention is to apply the Health

Belief Model constructs to increase the participant's knowledge to comprehend the risk of diabetic foot ulcers (perceived susceptibility), the risk, and problems from the physical, mental and economic dimensions

outcome is foot self-care behavior. The covariates are demographic profile and clinical characteristics. The secondary measures are knowledge of foot care, foot care self-efficacy and HBM construct. The questionnaire will be administered in English.

This study further aim to compare the intervention group and control group in the following aspects:
 To compare the changes between intervention group and control group from baseline, at 3 and 6 months for post intervention for the following characteristics:
 Primary outcome: foot self-care behavior
 Secondary outcome: knowledge of foot care and foot care self-efficacy

Health belief model construct (such as perceived susceptibility, perceived severity, perceived benefits, perceived barriers, self-efficacy and Cues to action)

Ethics approval and consent to participate

Ethical clearance was first gotten from the Ethics Committee for Research involving Human Subjects of University Putra Malaysia (JKEUPM) Reference no. JKEUPM-2020-264. afterwards another ethical approval was obtained from Federal Medical Centre Owerri Imo State, Nigeria Reference no. FMC/ OW/ H REC/VOL.2/ OO4 . Written informed consents will also be obtained from each respondent that are willing to participate in the survey before data collection. The inform consent contain information about the research: the purpose, duration and the procedures, the benefits, the risks, confidentiality, how the data and results obtained would be used, and freedom to withdraw at any point of the research. Also, it contains the name and contact of the researcher. All documents will be in English. The trial is registered with The Clinical Trials Registry- India (CTRI), Reference no CTRI/2021/06/034311.

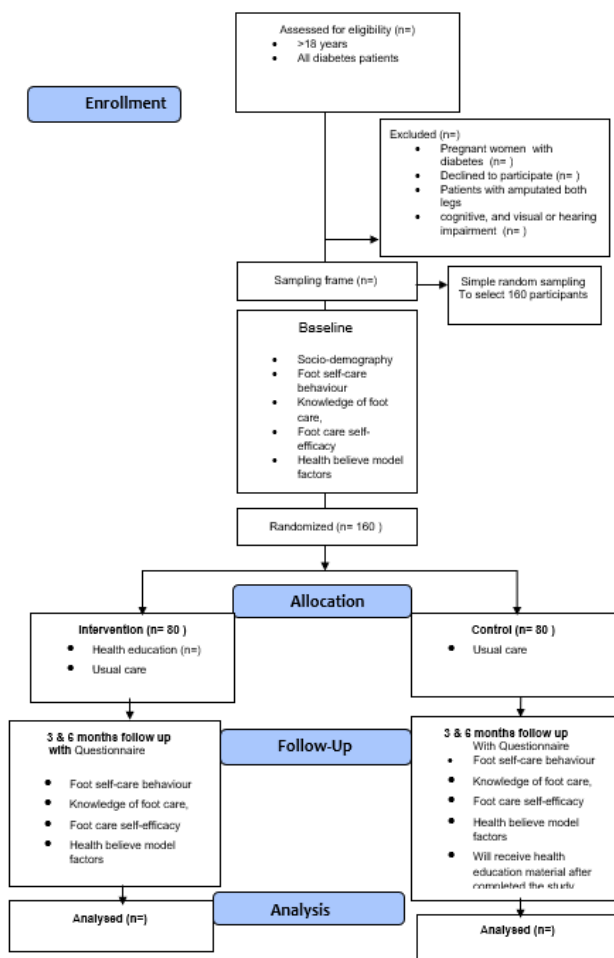


Figure 1: Study Flowchart adapted from CONSORT Schulz et al. (22).

(perceived severity); get optimistic symptoms from their environment (cues to action) and have confidence that the diabetic foot ulcer prevention program is useful and applicable (perceived benefits) and believe that the preventive measures are not expensive compare to the benefits (perceived barriers) and eventually lead to diabetic foot ulcer prevention.

The questionnaire has been validated, it will be pre-tested among 30 diabetic patients, the questionnaire will be self-administered at baseline and follow-up visits. The questionnaire comprises of 6 sections which include: Section A: Socio Demographic Profile, Section B: Clinical characteristics, Section C: Foot self-care behavior, Section D: knowledge on foot self-care, Section E: Foot care self-efficacy, Section F: Questions on constructs of health belief Model. The modified version of Diabetes foot Self-Care Behavior Scale (DFSBS) (23, 24, 25, 26) will be used as instruments for data collection in this study to determine the effects of the intervention on the outcome measures. The primary

Data collection

Informed consent form will be given to the patients that willingly accept to partake in the study, after that they will be asked to read and sign the form. Afterwards, the participants will be required to fill up a structured pre-tested baseline questionnaire written in English language. Amendments to the final questionnaire will be based on findings from the pretest. The diabetic patients will be required to fill up another follow-up questionnaire at 3rd and 6th months (follow-up). Internal consistency reliability using coefficient alpha index (Cronbach alpha) will be assessed, reliability values of 0.70 or higher is considered valid and will be used as standard for reliability (27).

Data Analysis

In this study, Statistical Package for the Social Sciences (SPSS) version 25 will be used to analyse data. For final analysis, intention to treat (ITT) analysis will be employed. Thus, based on the concept, all patients in intervention group will be analysed by randomized treatment task.

However, it will be irrespective of noncompliance, deviation from protocol, attrition and other incidences once randomization is done. The results will present descriptive analysis together with calculations of means, 95% confidence intervals (CI) of means and frequencies of categorical variables. Independent student t-test would be used for the bivariate comparative analysis of descriptive socio-demography mean scores of the 2 groups and within groups at baseline, 3 and 6 months. Repeated measure Anova would be used for the changes within intervention group from baseline to 3 and 6 months post intervention and also compare the changes between intervention group and control group at 3 and 6 months post intervention.

DISCUSSION

In our study, intervention group will receive health education, this will empower the participants for foot selfcare behavior. The health education intervention programme is feasible and effective method. It may contribute in the implementation of the National foot care education and prevention policy and help reduce foot ulcers, amputation and death as a result of diabetic foot ulcers.

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