Chapter III

Research Design
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RESEARCH DESIGN

3.1 Introduction
A research study cannot be authentic and concentrated unless its study methodology and process are described in adequate detail. It is compulsory for any research worker to follow systematic and appropriate processes in carrying the research work in order to make it more purposeful and directed. Proper and deliberate selection and application of the study tools are demanded to guarantee the exactitude, robustness & dependability of the research work conclusions.

In the present research study, I have tried to commit careful attention and consideration in examining the problem at hand, determining scope and restriction of study, proper choice of appropriate tools; collection of data and its subsequent analysis.

The concerning the study variables, research hypotheses and possibilities, selection of tools, choice of target population, choice of sample, method of accumulation of data and descriptive as well inferential statistical data analysis are adumbrated in this chapter thoroughly.

3.2 Research Design
The terminology, word or expression “Research Design” has to do with the investigator’s orientation and its overall pattern. The research patterns delineate and furnish theoretical account of the method of data collection & its subsequent analysis. From another point of view, research methodological analysis also refers to the functional as well as operational techniques of accumulation of data. This section describes the wider view of the study in conjunction with the hypotheses of study.

3.2.1 Significance of the present study
Till date, there is paucity of data with respect to the studies from Eastern India in evaluating the functional foot care practices in patients with diabetes mellitus based on a validated questionnaire. Moreover, data is also very scanty with regards to the studies which have assessed and authenticated the effect of a diabetic foot on the overall QoL in the diabetic population from Eastern India. This study has been attempted to evaluate the quality of life (QoL) in patients with diabetes mellitus as well as evaluate the knowledge in conjunction with functional foot care on the basis of a validated questionnaire. The present study further intended to estimate the impact of diabetic foot care education on the overall quality of life (QoL) among people with diabetes
attending diabetes clinics in and around Kolkata. The specific data gained on the skill and activities concerning the foot care practices and its impingement on QoL can help wellbeing proficient individual to plan focused self-administration training programs for individuals with diabetes which thus would improve the general well-being related QoL.

India is a nation with various socioeconomic and ethnic background knowledge. There is an unfulfilling demand in distinguishing the barriers to operational foot care practices in various groups of patients. If the distinguished roadblocks can be handled, the operational foot-care exercises may be ameliorated consequently, thereby precluding further foot related problems and subsequent complications. Furthermore, we desired to key out the roadblocks to self-foot care and constituents associated with these roadblocks. Finally, to dig into if there is any impingement of diabetic foot related problem on the overall quality of life and to detect, if on that point, is there any significant association between foot related complications and other macrovascular and microvascular complications of diabetes mellitus.

3.2.2 Hypothesis

H01: The foot care behavior is grossly adequate in the diabetic subjects.

H02: The quality of life is overall good in the diabetic subjects.

H03: The prevalence of peripheral neuropathy is low in the diabetic subjects.

H04: There are no barriers to self-foot care management in our study population

H05: There is no correlation between the foot care behaviour and overall quality of life in the diabetic subjects.

H06: There is no correlation between the peripheral neuropathy and overall quality of life in the diabetic subjects.

3.2.3: Research Approach used in the present study

Exploratory research is research conducted for a problem that has not been studied more clearly, intended to establish priorities, develop operational definitions and improve the final research
design. Exploratory research helps determine the best research design, data-collection method and selection of subjects. It should draw definitive conclusions only with extreme caution. Given its fundamental nature.

In our present study, we have used an exploratory research technique for our research problem, because it hasn’t been studied clearly till date. Though we didn’t intend to develop any operational definitions and relied on the previous validated, but it serves as a best practice for research design, data collection technique and selection of the study participants. Since, we can’t draw any definite conclusions from the exploratory research designs; we have gone a step further conducting the inferential statistics. We have not relied on any sort of secondary data such as reviewing the already published data or literature, data available on internet as they tend to introduce many biases. Furthermore, secondary data may also have ingrained faulty qualitative approaches. Nowadays, with the advent of search engines like google and yahoo supplemented with RSS feed alerts, it is possible to get latest and accurate information. We have also used these tools only to identify the relevant literature for identifying and defining our research problem. Based on the data captured in our field trial, we have analyzed the reliability of all the questionnaires in our study namely QOLID, NAFF, self-foot care knowledge questionnaire, Barriers to self-foot care assessment. We have simultaneously used both Cronbach’s alpha coefficient and inter-item correlation coefficient measured as item-total correlation as a whole.

Psychometric measurement of the various available health related QOL measures is indispensable and should be measured in terms of both reliability by internal consistency with the help of a parameter called Cronbach’s alpha coefficient, devised by a scientist named Cronbach. As per the industry standards, a cut-off of Cronbach’s alpha coefficient of 0.7 or more is required to be demonstrated by the instrument. However, there are certain questionnaires namely EDBS, DCP, DQOL, QSD-R and DIMS which have not met this criterion but still are widely used as they exhibit a high internal consistency among different items of the questionnaires. In case the questionnaires don’t exhibit a desired Cronbach’s alpha value, there is an alternative approach by which the internal consistency of the items can be established. It requires measurement of the correlation coefficient of the individual scale items as a whole. This method measures the homogeneity scale with the pre-requisite condition that the individual items should have at least a correlation coefficient of 0.2 with the remaining items of the questionnaire.
The item total correlation of the validated instruments like PAID, ADS, D-39, ADDQoL have all demonstrated an item-total correlation in the range of 0.28 to 0.84.

In our case, we used exploratory research primarily because we wanted to gain familiarity as well gain novel insights with regards to our research problem. Since our research problem is neither too specific nor too general, so we could define few hypotheses for our study objectives. Hence, we needed the exploratory research to acquire a prior experience for formulating a pertinent null as well as alternative hypothesis for carrying out a definitive investigation. But we were aware of the fact that it cannot be used for final decision making though they can provide some vague hint as to why the problem occurs, how it occurs, when it occurs and frequency and magnitude of the problem. But the main inherent drawback with the exploratory research is that it is technically incorrect to extrapolate and generalize the findings of the exploratory research to the entire population. In the medical exploratory research, we primarily intend to understand the etiological factors without much clear expectations. Though, the exploratory methodology is often referred to as ground-based theory for unearthing the theoretical data to formulate a pre-disposed hypothesis. It is particularly useful when the research is in the preliminary stage. It is mainly used either when the data is very difficult to collect or when the topic is very novel. Exploratory research is used when the topic or issue is new and when data is difficult to collect. It has major advantage of inherent flexibility and its ability to address research questions of all types and for generating hypothesis. In applied researches like medical sciences, exploratory research is useful because we often need to take advantage of its flexibility, utility in field-based research. It is also often referred as causal research or formative research.

**Descriptive research:** We have also used descriptive research in order to describe the research characteristics of various parameters as mean, median, mode, standard deviation, variance, coefficient of skewness, inter quartile range etc.

**Causal research:** We also carried out causal research with the objective of establishing the antecedent-outcome relationship which is the gold standard of epidemiology. In our research, we have a set of parameters which we have identified as causative or etiological parameters and other set of variables identified as outcome variables. It is noteworthy that in order to establish causality, we must keep the variable identified as causative factor in order to determine causality, it is important to hold the variable that is assumed to cause the change in the other variable(s) constant. Such type of variables is termed as confounding...
variables and then measure the changes in the outcome variable for one-unit change in the antecedent variable is to determine keeping the confounding variable(s) as constant. Such type of research is often complex but important to elicit the true relationship between the study parameters. There are often many in-depth physiological factors that even the researcher may not be aware of.

There are two research methods for exploring the cause and effect relationship between variables:

**Framing our Research Question:**

A research question can be confined to our discipline or a very specific area within our discipline. It should always end with a question mark and should not be a fragment or broad topic. It should be precise and neither too broad nor narrow. It should always be open-ended and can never be answered in a sentence or phrase. Literature review or reading is the starting pint of conducting any research. One should frame a research question based on the background information and analyzing the same in the present context. One should invest a good amount of time on the various techniques of research methodology, studying similar topics, and interesting studies.

I framed the research question as per my need because I am curious to learn about new things. The research can be defined as a systematic and diligent process of inquiring into each study participants either to make a new discovery or to refute the previous findings, facts, theories or figures which can be further employed to have numerous applications in various fields. Thereby considering together the blend of curiosity that provides the quest for formulating a research question clear enough to guide us in searching our answers.

**Internal Criteria used for selection of our research problem:**

I selected my problem based on my research interest and my competency as well as skill set, my experience of the current domain knowledge and personality traits. The other factors such as finances, time and available resources are also taken into consideration. We evaluated our research problem based on five Ws like what is that I want to do research on, why do we want to do research, what is the rationale of doing the research and lastly who are the research participants, where the research is going to be conducted and the timeline of doing the research?

**External Criteria used for selection of our research problem:**
First external criterion we wanted to evaluate is the research ability or amenability of the research problem. Secondly, we discussed with the experts in the subject area whether the idea is viable or not? Additionally, the problem should have pragmatic solutions or else the entire exercise is futile. The relevancy of the research problem was also checked on several parameters viz. importance and magnitude of the problem, urgency of the problem and also how the problem is relevant to the society at large. The utility of the research was also checked based on the applicability of the results and suggestions with regards to its implementation and usefulness of the expected results of the study. The novelty of the topic was also checked by checking in the university grant commission website to avoid duplication of the research.

The practicability, feasibility as well as ethical and political acceptability of the problem was also assessed. The practicability viewed whether the research problem has the data available for collection and further analysis, appropriate methodologies, anticipated co-operations by external stakeholders like various individuals and organizations. The feasibility was checked with regards to the required resources like time, material, facilities or infrastructures, finances and necessary research personnel like data entry operator and a biostatistician. The ethical and political acceptability was checked keeping in mind the acceptance of the problem by the research participants, interest and support by the appropriate authorities in formulating the research problem. To check, the novelty, we screened several topics and shortlisted only those where the data was very scanty, and our methodologies are relatively novel but reasonable when specific to the research problem. The absence of the search result of the current problem in the already published and past academic trials. We aimed our research to form a baseline for other future researchers work by trying to work out the problems in altogether different way.

**Moving from Broad topic of research to Focused topic:** We adopted a general approach in moving from a broad topic to a general topic. First and foremost, we identified what were the problems that were faced and what are the solutions for the problem. We attempted to create sentence specific statement and add a direct question to the topic. The scope of the research topic was considered based on two parameters. Firstly, in case the topic is too broad, it may be difficult to churn out focused and relevant information. On the other hand, if it is narrow, it becomes difficult find out any information at all. We used up the available clues to determine the scope of research topic based on the length, the volume of resources and publications available.
as well as on the popularity of the topic. The general scheme of approach we adapted was based on the historical, sociological and geographical angles with reference to our study population. From a mere interest of conducting research in diabetic foot, I identified few topics that are relevant and deeply researchable. There are few topics which are widely talked and debated. The topics were further discussed with research director to find it whether it is significant to others and worth solving at the same time. It included a herculean task of skimming the texts and scanning research topics headings, repeated visits to the library and spending long hours in literature review and collecting proper references. The topics were finally short listed after background reading and brainstorming of the concepts. The selected topic must be part of the larger system, to identify parts of various topics and their inter-relationships, identifying the characteristics and the categories included in it, determining its value. We avoided formulating questions which had readymade answers. The smaller questions have also been combined to form larger questions, particularly the more significant questions. Last but not the least, we also tried to formulate too many questions and settle for quite many relevant questions only. This was done to narrow the topic to a manageable extent. We wanted our topic to be a part of the broader system to widen its applicability in future by other researchers. We identified parts of the topics and their inter-relationship. We specifically avoided questions which had readymade answers as identified in the review of literature. We cross-checked and determined the value for each of the included objectives. The smaller objectives were combined into larger and more significant objectives. The objectives were framed keeping in mind so that they can draw the attention of a reader and motivate further research in the related field. The question was asked as to why a reader should be interested in our study objectives. The idea was further refined by applying the S.O.C.R.A.P.R. model which dwells on the similarities of ideas, opposition of ideas, contrast ideas, relationships, and anthropomorphism for interpreting the reality with respect to human values, personifications for giving objects or descriptions of human qualities and to avoid any duplication. We started with an originating question and the problem was started in a general way but was specific enough to gather reasonable amount of information. A conceptual model was built upon to understand the nature of the problem. The questions were framed related to the topic until it draws some interest for the anticipated area. A survey of the available literature and past studies were conducted in this regard. The ideas were developed via discussion with the guide and experience survey method. The problems were rephrased in consultation with the
guide and research in-charge which included refining the primary and secondary objectives, null and alternative hypothesis, operational definitions, concepts and terminologies, study assumptions and postulates, feasibility of the study with regards to ability of the researcher, , timeline, financial resources, availability of data, scopes and limitations with respect to environmental conditions. The methodology was also reviewed with regards to what kind of data is expected and if really such kind of data is possible to be collected within the research period. The research problem was not borrowed but rather but rather framed that suits our research setting and competency. In order to address a right question, the topic has been read with a problem to solve topic approach in order to avoid an endless gathering of data. The objective is to have an unbiased and unattached approach without having any motherly complex to the topic. At the same time, one must maintain the flexibility and an uncommitted approach before selecting and finalizing the topic. One of the major challenges is to ensure that the materials and methodology to be used should not be done before the selection of problem. Efforts were being made to avoid any superficial problems which are obvious as well as to avoid any controversial and overdone topics. We also excluded the topics which were too narrow or too vague in nature. The gaps in the research area were mainly identified by a conducting an extensive review of literature to identify new problems. Finally, it was being discussed with experts and doctors for making any revision if needed. A preliminary feasibility study was undertaken in order to check the availability of necessary pre-requisite data and also to gauge the co-operation of the different stakeholders involved in research. A checklist for novelty, significance and usefulness was maintained if the research was conducted in a well-marked direction to the required destination. An extra effort or caution was taken in understanding any great problem and to ensure that we don’t include too many problems to be solved in one thesis proposal which is practically not possible. A lot of time was spent on note taking, writing and understanding the problem. A preliminary outline was made to record thoughts which can be discarded later if required, diagrams can be drawn to connect disparate and disconnected facts. This process facilitated to start working on the research problem from the very beginning and encouraged critical thinking for understanding the sources in a better way and to draft it more effectively. All this step has been undertaken to choose an interesting problem which is primarily focused on the immediate problem and to derive ideas or solutions for solving the immediate problems. The primary challenge was to convert the topic to a researchable problem and to transform the present project
into a research work by formulating the problems and study objectives in a careful manner. Finally, it was borne in mind that the research question framed should be easily and fully researchable, neither too broad, narrow or challenging and should reflect our own thoughts and opinions on the immediate problem.

3.3 Research Methodology (Sample, Data Collection & Analysis Techniques)

3.3.1 RESEARCH TOOLS:
Pro-forma for case records for collecting socio-demographic details of the study participants. Validated questionnaires namely WHO-QoL BREF, ADS, NAFF and others mentioned vide infra.

WHOQOL-BREF instrument: It is a health related QOL questionnaire consisting of 26 items. It evaluates the individual’s perception in relevance of their cultures, beliefs and value systems with regards to their personal goals as well as standards and concerns. There are five responses to each item varying from 1 (very dissatisfied) to 5 (extremely satisfied).

Appraisal of Diabetes Scale (ADS): The ADS are an abbreviated, seven item diabetes specific scale which evaluates the patients’ feelings and attitudes about diabetes. The specific scale covers one most important aspect of diabetes- specific HRQOL, the effect of diabetes on the psychological functioning. Each item in this questionnaire uses Likert scale with five potential answers (1 - not all, 2 - slight, 3 - moderate, 4 - very and 5 - extremely). The total score can vary from 0 (best health) to 35 (worst health). Hence, lower score on ADS scale indicates better QOL.

Nottingham Assessment of Functional Foot Care (NAFFC): NAFFC was developed by Lincoln and colleagues in 2007. The responses of the study participants against each items of the questionnaire were recorded on a categorical scale ranging from 0 to 3 in which 0 means never, 1 means rarely, 2 means sometimes and 3 means often.

Diabetic self-foot care knowledge questionnaire: The validated diabetic foot self-care knowledge questionnaire was from diabetic foot self-care education. The diabetic self-foot care knowledge questionnaire mentioned above is an 11-item questionnaire. It assesses the DM patients’ knowledge regarding self-foot care management. In the diabetic foot self-care knowledge questionnaire mentioned above, for a response of “Do know” against each particular knowledge question, the respondent is awarded “1 mark” and “0 mark” if the response is “Don’t Know”. Hence, the maximum score that can be acquired is 11 and the minimum score is 0.
Clinical Assessment of Diabetic Peripheral Neuropathy: Presence of diabetic peripheral neuropathy was assessed by touch-pressure sensation, vibration loss test, and measurement of vibration perception threshold, temperature sensation, pain sensation and checking the ankle reflex.

3.3.2 RESEARCH PROCEDURE:
Participants – Adults (from 30 to 60 years of age) with diagnosis of type 2 diabetes mellitus.
Study Area – Patients who are attending the tertiary care center in central part of Kolkata over a period of 20 weeks.
Study Period – June 2018 to December 2018
Research Design – Experimental pre-test post-test design with a control group.
Sample Design – Data was collected from consecutive patients attending the clinic who gave consent for the study and was included as study participants. Patients and patients’ relatives were fully explained by their mother language (Bengali) about the study. After getting informed consent from them, participants were recruited in the study accordingly to the inclusion & exclusion criteria as mentioned previously. The data was captured based on the validated questionnaires as described vide-supra by the proper interview technique and the pro-forma was accordingly filled. The response was coded appropriately, and the collected data was compiled using Microsoft excel software in a master sheet. Further statistical analysis of the compiled data would be done with the help of SPSS Version 20 for windows and SAS version 9.1 for windows.

Sample Size Calculation:
Sample size (n) was calculated by using the following formulae,

\[ \text{Sample Size, } N = \frac{(Z_{1-\alpha})^2 p(1-p)}{D^2} \]

Here,
Level of significance, \( \alpha = 5\% \)
\( Z_{\alpha/2} = \) Standard normal for level of significance (at 5% type 1 error, \( p<0.05 \) it is 1.96) – From Z table at type 1 error at 5%
CI= 1- \( \alpha = 95\% \)
Therefore, \( Z_{1-\alpha} = Z_{0.95} = 1.96 \) (at 5% type 1 error)
The sample size results were calculated manually using the formulae above and also calculated using the software, namely “Statcalc version 7.3" and Sample size calculator for prevalence studies version 1.0.01, April2006.

**Method of Data Collection:**

- Interview and history taking from the patients with the help of validated questionnaires.
- The primary data are captured from the patients with regards to QoL, foot care knowledge, functional foot care practices, and barriers to self-foot care management as follows: The QoL data was collected by administering WHOQOL-BREF and ADS questionnaire. Data regarding functional foot care practice was collected by administering the validated NAFF questionnaire. Similarly, data regarding foot care knowledge and barrier to foot care assessment was collected in the form of a questionnaire.
- Secondary data with regards to macrovascular complications and microvascular complications are collected from the treating physicians’ clinic electronic database or physical records like case record form of the patient, prescription etc.
- Neuropathy examination of the foot of the diabetes patients for identification of diabetes peripheral neuropathy in collaboration with the treating physician.
- Record Keeping – The data captured from the patients are preserved both in the form of hard copies as well as soft copies. All the study variables are entered in the Microsoft excel to maintain an electronic database of the study participants.

**Schedule of Data Collection:** Firstly, the selected patients were subjected to detailed history taking to capture the socio-demographic parameters & clinical examination of the foot. Subsequently, the patients were administered the questionnaires (mentioned vide-supra) to investigate for the quality of life (QoL), knowledge of self-foot care management, functional foot care practice and barriers within the specified study period (June 2018 to October 2018). Simultaneously, the selected patients were assessed for the presence of peripheral diabetic neuropathy (June 2018 to October 2018).

The subset of patients with peripheral diabetic neuropathy was segregated into two groups; one of the groups was educated with standard preventive functional foot care practice as
recommended by the “International Diabetes Federation Clinical Practice Recommendations on the Diabetic Foot – 2017 (IDF CPR 2017)” in a classroom programme. After three months of the classroom programme, the QoL as well as the clinical parameters of peripheral neuropathy was again collected respectively for both the groups of peripheral diabetic neuropathy patients i.e. group which received education and which didn’t.

3.3.3 Plan for Statistical Analysis: The data collected from the sample was subjected to appropriate statistical analysis. Data was analyzed through appropriate data analysis plan to determine significance level and power of study.

Data Analysis: SAS (Statistical Analysis System) version 9.4 for windows, SAS Institute Inc. Cary, NC, USA and Statistical Package for Social Sciences (SPSS Complex Samples) Version 21.0 for windows, SPSS, Inc., Chicago, IL, USA was used for the analysis of the quantitative data. Qualitative data was analyzed thematically. Descriptive and inferential statistical analysis would be carried out in the present study. The QoL was compared between the two groups of patients i.e. patients with peripheral neuropathy and patients without peripheral diabetic neuropathy by unpaired t-test with the background assumption that patients with peripheral diabetic neuropathy have low QoL.

Changes in the parameters of functional foot care assessment before and after the diagnosis of DM for the related group would be tested by Paired t-test (for parameters on quantitative scale) or McNemar’s test (for categorical variables). Multiple logistic regression analysis would be used to assess the predictors associated with poor foot care knowledge and poor quality of life. Association of the variables between the foot care knowledge and QoL would be tested by Chi-square or Fischer’s exact test.

3.3.4 DESCRIPTION OF THE STUDY POPULATION AND SAMPLE

i. Population at large and the intended sample Size
Population for the study were the patients with type 2 diabetes mellitus based in and around Kolkata, since the study is primarily to be carried out in the department of endocrinology and metabolism, medical college and hospital, a tertiary care center in central part of Kolkata. The patients who will qualify the inclusion and exclusion criterion will be eligible for enrollment in the present study.

ii. Inclusion criteria: Adults in the age between 30-80 years age, Type 2 diabetes mellitus
iii. **Exclusion criteria:** Type 1 diabetes, mature onset diabetes of young, fibrocalculous-pancreotogenic diabetes, any other form of secondary diabetes, patients not willing to give consent for the study, patients having established end stage organ dysfunction, carcinogenicity or any other significant illness which may alter the quality of life of the patients.

**Ethical Issue:** No ethical issue will be involved as it will be purely a non-interventional observational study. The patients who consented to take part in this study were administered the questionnaire. If at any point of time, the study participants wanted to withdraw, they were free to do so.

### 3.3.5 SCREENING OF DIABETIC FOOT FOR PERIPHERAL NEUROPATHY:

**Evaluation for Touch and Pressure Sensation:** Evaluation for Touch and Pressure Sensation: By employing the 10-gram Monofilament, one can evaluate the four primary regions on the plantar surface of the foot (averting areas of callus). The monofilament must be placed perpendicularly on every area of the foot until the monofilament folds and hold the equivalent for two seconds each time with the patient's eyes being shut and respond in affirmative each time they experience it. The ideal locales for screening are the plantar surfaces districts of the first, third and fifth metatarsal heads just as the plantar surface of the big toe. The diagnosis of neuropathy can be chosen if the patient fails to elicit any experience any one out of the four areas being tested.

**Evaluation for Vibration Loss:** The screening for loss of vibration in the foot can be done by employing a 128-Hz tuning fork. The first step is to ask the patient to close the eyes. Then place the patient’s foot onto a flat surface and subsequently tap the surface with the tuning fork. Subsequently, put the vibrating tuning fork on patient’s distal big toe (hallux) joint and inquire with the patient if they can experience vibration. It has to be demonstrated first by showcasing the patient on the bony prominence on their hand first. Ask the patient to answer either yes or no when inquired if they can feel the vibration. In case, the patient cannot experience vibration on the big toe region, we have to continue checking out the other bony prominences moving towards the proximal region until the patient can sense the vibration.

**Evaluation for temperature sensation:** The temperature sensation can be tested with the help of a Tip-Therm instrument or test tubes, one at a time, first with cold water (5–10°C) and second time with warm water (35 to 45°C). The instrument has to be placed on the dorsal aspect of the patient’s foot at once on the skin and enquire the patient what they feel. The temperature
sensation testing result can be graded into different categories as normal sensation, weak sensation or loss of temperature sensation. It has to be borne in mind that sensation of temperature is lost in alignment with sensation of pain because both the sensation is being driven by the small, non-myelinated nerves. Hence, if the patient has developed a loss of temperature sensation, then pain sensation can be assumed to be lost usually.

**Measuring for Vibration Perception Threshold:** The vibration perception threshold has to be measured utilizing electromechanical instruments namely the bio-thesiometer and a vibrameter. A VPT value of greater than 25 V in at least any one of the feet has been linked with a higher cumulative incidence of subsequent neuropathic ulceration. A VPT value in the range between 16 and 24 V suggest intermediate risk profile, and VPT values lower than 15 V, correspond to low risk and are regarded to be normal.

**Measuring the sensation of pain:** Pain is one of the usual encounters in a subject with diabetic foot. But on certain occasion, it can manifest as in sub-group of patients with diabetes. Majority of the patients with painful diabetic peripheral neuropathy (PDPN) often complain of several kinds of painful sensation, such as stinging, lancinating pain, electric like shocks, burning, as well as aching pain in the extremities of the lower limb, just as throbbing torment in the limits of the lower limb.

**Rating of pain in Foot:**
The total symptom score system (TSS) is a recommended diagnostic method. It has to be noted that the entered symptoms admit numbness, cutting, burning as well as stinging pain. The total symptom score (TSS) score is the sum total of four feelings mentioned vide infra, ranging from 0 to 14.64. A symptom score of greater than 3 is considered as positive pain score. There is another simple method to evaluate the severity of pain by asking a set of six questions assigning a positive score of 1 for a response of “yes” and score of 0 for a response of “no”.

<table>
<thead>
<tr>
<th>Issues</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Did the patient feel prick pain?</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>2. Did the patient feel hot/burning?</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>3. Did the patient feel numb?</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>4. Did the patient feel electric shock?</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>5. Is the pain limited to joints?</td>
<td>-1</td>
<td>0</td>
</tr>
</tbody>
</table>
A total score of 4 or 5 refers to a high likelihood of neuralgia; a score of 2 or 3 considers a middling likelihood of neuralgia; a score of 1 excludes not all neuralgia whereas a score of 0 or -1 excludes neuralgia.

**Checking for ankle reflex:** The diabetic subject’s ankle reflex as well as patellar reflex has to be evaluated either on the Achilles ligament with the assistance of a percussion hammer. This might be frail in the more seasoned patient; subsequently it's anything but a particular test. In this manner, the appraisal for engine neuropathy by examination of the small toes just as flexion and expansion of the huge toe and lower leg is increasingly dependable. As the movement of sickness sets in, the shortcoming increments up the leg spreading from the natural musculature to outward musculature. Now, it is judicious to require the patient to stroll on their toes just as on the heels to assess extraneous muscle quality. This vital component of neuropathy much of the time goes imperceptibly on the grounds that clinicians don't look for it. There is a solid relationship of motor neuropathy with naturally decay of the muscle. It assumes a huge job in the vulnerability of the small toes which advancing to shortcoming of the lower leg and the knee. The general step insecurity is probably going to influence the subject's capacity to stroll just as deal with their glycemic control. They may likewise have an increased danger of falling. However, there is a certain caveat with this test; since it can give false negative results in the older patients; hence it is not a sensitive test. Thereby, the assessment for motor neuropathy by examination of the lesser digits just as flexion and expansion of the huge toe and lower leg is more reliable. Owing to the progressive nature of diabetic foot disease, the weakness increments up the leg spreading from the inborn musculature to extraneous musculature.

**SCOPE OF RESEARCH WORK:**
1. It could bring an improvement in the foot care knowledge.
2. It could bring an improvement in the functional foot care practice.
3. It could bring an improvement in the quality of life.
4. It could identify the barriers to self-foot care management.

**LIMITATIONS OF STUDY:**
1. The study is only an observational study not a strong randomized controlled study design.
3. The study will look only at the clinical data and cannot rule out bias due to calcification in the lower limb arteries.

2. The study will identify several barriers to functional foot care assessment and not study the impact of correcting these barriers.

**WORK PLAN**

1. Preliminary visits to the center.

2. Negotiating with the center for research.

3. Library visits.

4. Literature review.

5. Data collection

6. Data Analysis

7. Data Interpretation

8. Result and Discussion

9. Summary Submission

10. Pre-Thesis

11. Thesis Submission