CHAPTER IV
RESEARCH METHODOLOGY

A. Type of Research and Research Design

The type of research used in this study is quantitative research with a quasi-experiment approach with a pre-test design and a post-test with two group design. This study involved two groups of interventions. The first intervention group will be given treatment in the form of Foot Reflexology using a Foot Reflection Board. The second intervention group will be given treatment in the form of Buerger Allen Exercise. Observations comparing between the first intervention group and the second intervention group.

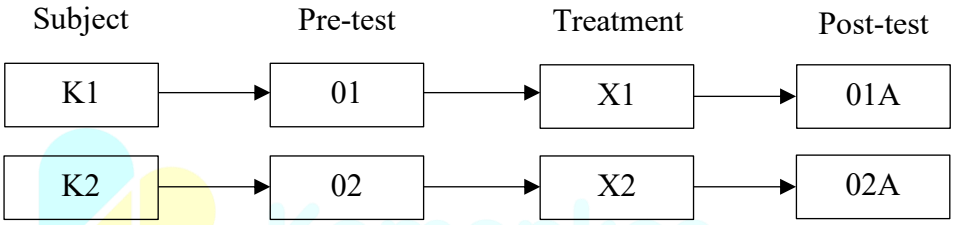

Chart 4. 1 Research design

Description :

K1 = Participant in the Foot Reflexology group using a Foot Reflection Board

K2 = Participants in the Buerger Allen Exercise group

01 = Foot sensitivity measurement before treatment in the Foot Reflexology group using a Foot Reflection Board

02 = Measurement of foot sensitivity before treatment in the Buerger Allen Exercise group

X1 = The first intervention group treatment was given Foot Reflexology therapy using a Foot Reflection Board

X2 = The treatment of the second intervention group was given Buerger Allen Exercise therapy

01A = Measurement of foot sensitivity after intervention in the Foot Reflexology group using a Foot Reflection Board

02A = Measurement of foot sensitivity after intervention in the Buerger Allen Exercise group

B. Research Variables

1. Independent Variables

   The independent variables in this study were Foot Reflexology using a Foot Reflection Board and Buerger Allen Exercise.

2. Dependent Variables

   The dependent variable in this study is the sensitivity of the feet in people with DM.

C. Research Location and Time

1. Research Location

   This research was conducted in the working area of the Sawah Lebar Health Center, Bengkulu City. The reason the researcher chose this Health Center is because the Sawah Lebar Health Center is a Health Center that has the largest number of people with DM in the working area of the Health Center in Bengkulu City.

2. Research Time

   This research was carried out from April to June 2026.

D. Population and Sample

1. Research Population

   The population in this study is people with DM in 2026 in the working area of the Sawah Lebar Health Center with an estimated 136 people in June - August 2025.

2. Research Sample

   The sample in this study is people with DM who have decreased sensitivity of the feet in the working area of the Sawah Lebar Health Center, Bengkulu City. The selection of research samples was determined using Non Probability Sampling with Purposive Sampling technique. The sample used was participants who met the inclusion and exclusion criteria :

a. Inclusion Criteria

1) People with DM who are willing to participate in the study.
2) People with DM who have decreased foot sensitivity on a scale of 0-9.
3) People with DM who do not have skin diseases, a history of past wounds, open wounds and unilateral or bilateral amputations, tendonitis of the ankle, active foot ulcers, and infections.
4) People with DM who can stand upright, can walk without assistance.

b. Exclusion Criteria

1) People with DM who resign and do not participate in the study until it is completed.
2) People with DM who are sick and need to get treatment at the hospital.

According to Roflin et al., (2021) The calculation of the minimum sample number in this study is determined based on the formula of difference of 2 means, which is stated as follows :

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

Description :

n = Number of samples

σ = Standard deviation / standard deviation

$Z_{1-\frac{\alpha}{2}}$ = Standard standard deviation for α 5% (standard deviation α = 1.96)

$Z_{1-\beta}$ = Normal standard deviation for β 90% (standard deviation β = 1.28)

μ_1 = Mean value before intervention obtained from the literature.

μ_2 = Mean value after intervention obtained from the literature.

Based on research by Nakonkhang et al. (2021), In 41 patients in Thailand, the mean value before intervention (μ^1 = 7.89), the mean value after the intervention (μ^2 = 7.69), the standard deviation value or standard deviation σ = 0.31 (σ = 1.62 – 1.31).

a) Search *n*

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

$$n = \frac{0{,}31^2(1{,}96 + 1{,}28)^2}{(7{,}89 - 7{,}69)^2}$$

$$n = \frac{0{,}0961\ (3{,}24)^2}{(0{,}2)^2}$$

$$n = \frac{0{,}0961\ .\ 10{,}497}{0{,}04}$$

$$n = \frac{1{,}0087617}{0{,}04}$$

$$n = 25{,}219$$

$n = 26$

b) Looking for a drop out (error tolerance limit or error tolerance of 10%)

$$n' = \frac{n}{1 - f}$$

$$n' = \frac{26}{1 - 10\%}$$

$$n' = \frac{26}{1 - 0{,}1}$$

$$n' = \frac{26}{0{,}9}$$

$$n' = 28{,}888$$

$$n' \approx 29$$

The sample used in this study consisted of 29 participants in the first intervention group and 29 participants in the second intervention group.

In the implementation of the study, the researcher obtained 60 participants who met the inclusion criteria and were willing to participate in the study, so that all participants were included in the study. Thus, the number of final samples used was 60 participants, consisting of 30 participants in the Foot Reflexology using a Foot Reflection Board group and 30 participants in the Buerger Allen Exercise group.

E. Data Collection

1. Data Sources

   a. Primary Data

      Primary data is data collected by researchers regarding foot sensitivity in people with DM by taking data as follows:

      1) Data were taken directly by researchers from participants with DM who were controlled at the Sawah Lebar Health Center, Bengkulu City, including name, age, gender, length of time they had DM.
      2) The researcher explained to the prospective participants about the research plan including the objectives, benefits, research procedures and the length of the research time and explained the inclusion criteria of the participants to be researched.
      3) The researcher measured the sensitivity of the feet by means of a physical examination using monofilament test tools and instruments on prospective participants, if prospective participants met the requirements and inclusion criteria set by the researcher, they would be planned as participants.

   b. Secondary Data

      Secondary data in this study is related to the incidence of DM obtained from Poltekkes Kemenkes Bengkulu and the Sawah Lebar

Health Center in Bengkulu City in the form of the number of people with DM in 2026.

2. Data Collection Tools and Research Instruments
   a. Data Collection Form

      The form used to obtain patient data contains participant number, day/date, participant's initials, age, gender, Duration of DM, random blood glucose level.

   b. The instrument to measure the value of the foot sensitivity score using the Semmes Weinstein Monofilament Test and the tool to measure the sensitivity of the foot is the monofilament test.
   c. Standard Operating Procedures (SOP) of Foot Reflection Board and SOP Buerger Allen Exercise.
   d. Foot Reflection Board as a tool used for therapy in the first group. Foot Reflection Board is a complementary therapy tool that combines a map of the foot reflection points with a focused pressure mechanism (similar to acupressure), designed for the treatment of foot reflexology, especially for people with DM with neuropathic symptoms such as numbness.
3. Test Data Collection Tools

   The Semmes Weinstein Monofilament Test is the instrument of choice for detecting peripheral neuropathy in people with DM. This tool is recommended by the American Diabetes Association (ADA) as the primary screening method due to its proven practicality and accuracy. The tool is capable of identifying cases with 80% sensitivity and 100% specificity. An overall accuracy rate of 90.7% and a Positive Predictive Value (PPV) of 100%, which confirms that the positive results of this test are clinically very accurate $p < 0.001$ (Aithal & Bhat, 2024)
4. Data Collection Procedures

   The researcher collected data through interview and observation methods. In addition, the researcher also used a data collection form including name, age, gender, duration of DM, and measured random

blood glucose levels and foot sensitivity scores using a monofilament test. After conducting interviews and observations, the researcher asked participants or their families to fill out questionnaires. In this study, the description of the steps of the data collection procedure is as follows:

a. Explanation of the procedure: The researcher explains to the prospective participants about the research plan including the objectives, benefits, research procedures and length of the research time and explains the inclusion criteria of the participants to be researched.
b. Participant consent: Eligible prospective participants will be asked to sign an informed consent form. If potential participants refuse, the researcher will not involve them in the study.
c. Group division: After expressing consent, the researchers grouped the participants into two groups, namely the Foot Reflexology using a Foot Reflection Board and the Buerger Allen Exercise.
d. Pre-test: At the first meeting, the researcher measured the sensitivity of the legs of the two groups using a monofilament test device before therapy began.
e. Implementation of therapy: The researcher gave Foot Reflexology therapy with a Foot Reflection Board device to the first group, while the second group was given Buerger Allen Exercise therapy.
f. Evaluation (Post-test): The researcher again measured and recorded the sensitivity of the participants' feet at the last meeting of the intervention.
g. Data analysis: All the data collected from the measurement results is then processed using computer software.

F. Data Processing

According by Widodo et al. (2023), the collected data is processed using computer software carefully, following the steps that have been set. After all the data is collected, the researcher then processes the data in the following stages:

1. Editing

   After the data is collected, the researcher conducts the editing stage first. The editing process aims to ensure the completeness, clarity, readability, and consistency of all data sheets that have been obtained.

2. Coding dan Sorting

   The coding stage is the provision of numerical codes (numbers) to category data, thus facilitating the process of analysis and data entry. This coding helps to group the data into intervention groups or control groups. In this study, Foot Reflexology using a Foot Reflection Board tool was coded 0, Buerger Allen Exercise was coded 1, while the male gender was coded 0 and the female was coded 1.

3. Entry Data

   The data entry stage is to enter the answers from the participants into the SPSS program. This entry process is carried out by converting letter data into numerical or number, according to the variables that have been determined. Once the data is collected, it is analyzed based on its type and usefulness.

4. Processing

   The data that has been completed is then statistically tested using a computer program. This test aims to determine the average and frequency values.

5. Cleaning

   The researcher re-checked all the data that had been entered. The purpose of this check is to minimize errors or prevent data loss.

G. Data Analysis

Data analysis is the most crucial stage in research which includes the process of processing, reviewing, and interpreting data. Data analysis aims to obtain variable descriptions, test hypotheses, find relationships between variables or new concepts, and produce meaningful conclusions that can answer research objectives (Widodo et al., 2023). In this study, data analysis was used as follows:

1. Univariate Analysis

   Univariate data analysis was conducted to describe the characteristics of the study participants. Numerical data including age, blood sugar levels at the time, length of time in DM, and foot sensitivity scores were analyzed using descriptive statistics in the form of mean, median, minimum-maximum, standard deviation, and 95% confidence interval (CI) mean. Meanwhile, categorical data such as gender is presented in the form of frequency and percentage distributions. The results of the univariate analysis are then presented in the form of a table to facilitate data interpretation.

2. Bivariate Analysis

   Bivariate analysis was performed to determine differences in leg sensitivity before and after the intervention and to compare the effectiveness of the intervention between the two groups. Before the analysis, the data was tested for normality and equivalence using the Shapiro-Wilk test. Based on the results of the normality test, in the Foot Reflexology using a Foot Reflection Board group, there was data that was not normally distributed, so the analysis of differences in foot sensitivity before and after the intervention was carried out using the Wilcoxon Signed Rank Test. Meanwhile, in the Buerger Allen Exercise group, the data were normally distributed, so the analysis of differences in foot sensitivity before and after the intervention was carried out using the Paired t-test (Dependent t-test).

   To find out the difference in effectiveness between the Foot Reflexology group and the Foot Reflection Board and the Buerger Allen Exercise group based on the difference in the foot sensitivity score value, a normality test was first carried out on the difference data. The test results showed that the data were not normally distributed, so the analysis of the difference in effectiveness between the two groups was carried out using the Mann-Whitney U Test with a 95% confidence level ($\alpha = 0.05$).

H. Research Flowchart

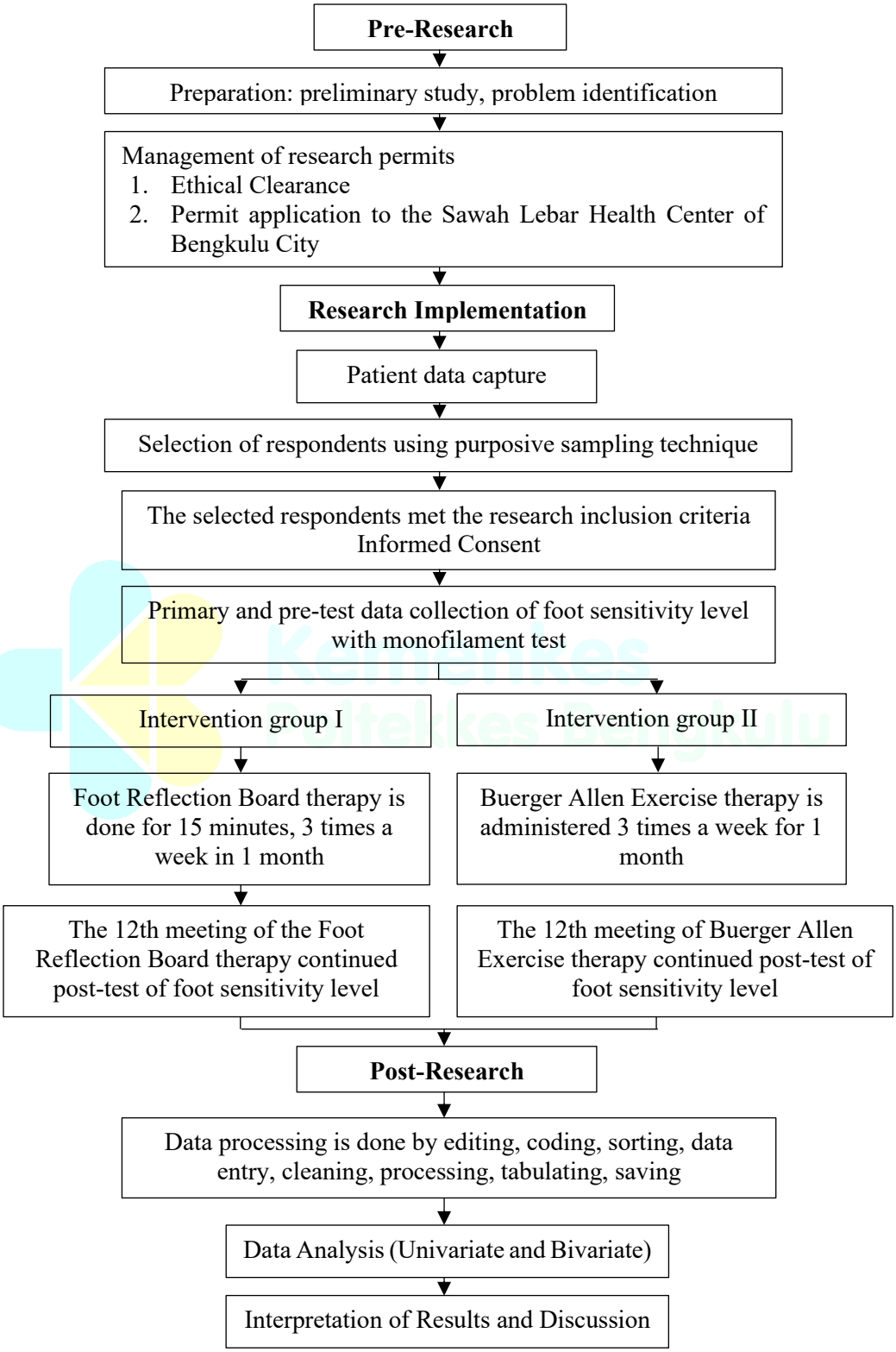

Chart 4. 2 Research Flowchart

I. Research Ethics

The researcher has applied for ethical clearance to the KEPK State University Institution of the Ministry of Health of Bengkulu and has been tested and has been declared ethically feasible according to 7 (seven) WHO standards 2011, with the letter number of KEPK. BKL/235/03/2026, by looking at the basic principles of research ethics in health research as follows:

1. Respect for persons

   This principle emphasizes respect for the participants' decisions, so that the researcher ensures participation is voluntary and provides a complete explanation of the objectives, procedures, benefits, and risks of therapy. Each prospective participant has the full right to refuse or resign at any time without negative consequences to the services received.

2. Beneficence and non-maleficence

   This research was carried out based on the principle of maximizing benefits (beneficence) and minimizing risks (non-maleficence). The desired benefit is the potential for increased foot sensitivity in people with DM, while losses such as discomfort are minimized by ensuring the intervention is carried out carefully and according to procedures by the researcher.

3. Respect for privacy and confidentiality

   Every individual has a basic right to privacy and the freedom not to provide personal information. Therefore, researchers are required to maintain the confidentiality of participants' identities and personal information, and must not display names or addresses in measuring instruments. Instead, researchers simply use codes such as participants' initials or identity numbers to protect privacy.

4. Respect for justice an inclusiveness

   Researchers are obliged to maintain the principles of openness and fairness by being honest and careful. This openness is realized

through the explanation of the research procedure, while fairness guarantees that all research subjects receive the same treatment and benefits regardless of gender, religion, ethnicity, etc.

J. Research Schedule

Table 4. 1 Research Schedule

No	Activities	Month											
		9	10	11	12	1	2	3	4	5	6	7	8
1.	Completion of the Thesis Proposal												
2.	Thesis Proposal Seminar Examination												
3.	Revision and Approval of the Thesis Proposal												
4.	Submission of the Thesis Proposal to the Study Program												
5.	Obtaining Ethical Clearance												
6.	Obtaining Research Introduction and Permission Letters												
7.	Preliminary Research Survey												
8.	Conducting the Research and Data Collection												
9.	Obtaining the Certificate of Research Completion												
10.	Data Entry, Analysis, and Interpretation of Research Findings												
11.	Preparation of the Research Report												
12.	Thesis Examination												
13.	Thesis Revision												
14.	Thesis Approval by the Board of Examiners and the Head of the Study Program												
15.	Submission of the Thesis to the Study Program												

16.	Preparation of a Journal Manuscript												
17.	Submitting Manuscript to Scientific Journal												
18.	Submitting the Journal Article Letter of Acceptance (LOA) to the Study Program												
19.	Submission of the Published Journal Article to the Study Program												