CHAPTER IV
RESEARCH METHODOLOGY

A. Type of Research and Research Design

Research designs are generally classified into descriptive, analytical, and experimental approaches. Selecting an appropriate research design is essential to ensure valid comparisons in accordance with scientific principles and to produce reliable and valid findings (Masriadi *et al*., 2022).

This study employed a quantitative research approach using a comparative analytical observational design. The study aimed to compare the *mean* fatigue severity between patients with chronic kidney disease (CKD) undergoing maintenance hemodialysis using an arteriovenous fistula (AVF) and those undergoing maintenance hemodialysis using a catheter double lumen (CDL) as vascular access.

Data on participants' characteristics, vascular access type, and fatigue severity were collected using a cross-sectional design, in which all variables were measured simultaneously at a single point in time.

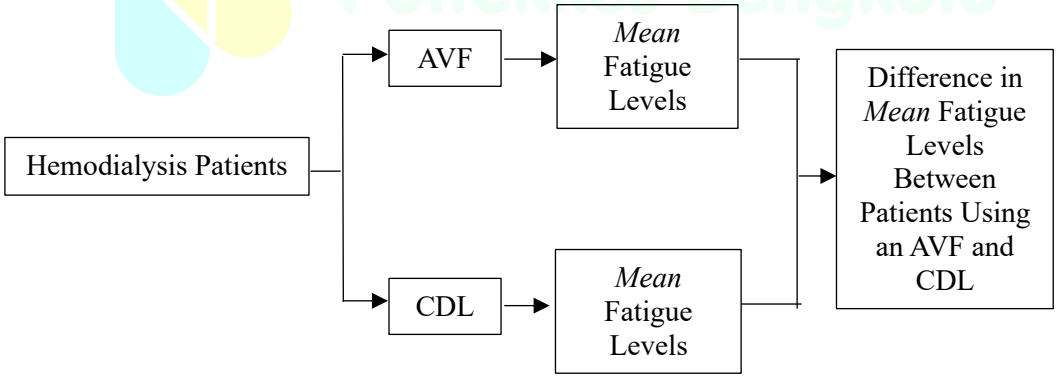

Diagram 4.1 Research Design

B. Research Variables

A variable is a characteristic, attribute, or measurable property possessed or acquired by members of a group that distinguishes them from members of other groups in a research study (Masriadi *et al*., 2022).

The variables in this study consisted of the independent variable, the dependent variable, and respondent characteristics (controlled variables). A detailed description of each variable is presented below:

1. Independent Variables

   An independent variable is a variable that influences or causes changes in another variable (Adiputra *et al*., 2021). In this study, the independent variable was the type of vascular access used for maintenance hemodialysis, namely an arteriovenous fistula (AVF) and a catheter double lumen (CDL).

2. Dependent Variables

   A dependent variable is the variable that is observed or measured, and its value is influenced by the independent variable (Adiputra *et al*., 2021). The dependent variable in this study was fatigue levels.

3. Respondent Characteristics (Controlled Variables)

   Respondent characteristics are factors that may introduce bias into the study findings. These characteristics are associated with both the independent and dependent variables but do not function as intervening variables (Adiputra *et al*., 2021). Respondent characteristics that may influence fatigue severity include age, sex, duration of hemodialysis, comorbidities, sleep quality, hemoglobin (Hb) level, and interdialytic weight gain (IDWG). In this study, the potential effects of these characteristics were controlled through the application of strict inclusion and exclusion criteria, as well as by conducting statistical tests of homogeneity to ensure comparability of baseline characteristics between the AVF and CDL groups.

C. Research Location and Time

1. Research Location

   This study was conducted at the Hemodialysis Units of Dr. M. Yunus Regional General Hospital, Bengkulu Province, and Harapan dan Doa Regional General Hospital, Bengkulu City.

2. Research Time

The study was conducted at Harapan dan Doa Regional General Hospital, Bengkulu City, from January 1 to January 31, 2026, and at Dr. M. Yunus Regional General Hospital, Bengkulu Province, from February 5 to March 5, 2026.

D. Population and Sample

1. Research Population

A population refers to the entire group of individuals or objects possessing specific characteristics defined by the researcher for investigation and from which conclusions are drawn (Adiputra *et al*., 2021).

The population of this study comprised all patients with chronic kidney disease (CKD) undergoing routine maintenance hemodialysis at the Hemodialysis Units of Dr. M. Yunus Regional General Hospital, Bengkulu Province, and Harapan dan Doa Regional General Hospital, Bengkulu City, in 2026. Based on service reports from the hemodialysis units of both hospitals during the period from January to February 2026, the total study population consisted of 224 patients, including 77 patients from Harapan dan Doa Regional General Hospital, Bengkulu City, and 147 patients from Dr. M. Yunus Regional General Hospital, Bengkulu Province.

2. Research Sample

A sample is a subset of the population that possesses specific characteristics and is selected to represent the target population. Sample selection should be based on predefined eligibility criteria to ensure that the sample accurately represents the population under investigation (Adiputra *et al*., 2021).

The sample in this study consisted of patients with chronic kidney disease (CKD) undergoing routine maintenance hemodialysis who experienced fatigue. The participants included patients receiving hemodialysis through either an arteriovenous fistula (AVF) or a catheter double lumen (CDL) as vascular access at the Hemodialysis Units of Dr. M.

Yunus Regional General Hospital, Bengkulu Province, and Harapan dan Doa Regional General Hospital, Bengkulu City.

The sampling technique employed in a study is determined by its research design. In general, sampling techniques are classified into two major categories: probability sampling and non-probability sampling (Masriadi *et al*., 2022). As this study employed a non-experimental research design, participants were selected using a non-probability sampling technique, in which samples were not selected through randomization.

The sampling method used was consecutive sampling, whereby all patients who met the predetermined eligibility criteria were recruited consecutively over a specified study period until the required sample size was achieved.

The sample size was calculated using the formula for comparing two populations with continuous outcome data in a cross-sectional study for hypothesis testing, as described by Eddy *et al*. (2021), in *Population, Sample, and Variables in Medical Research*. The required sample size for each study group was calculated using the following formula:

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

Description of Symbols:

n	=	Minimum required sample size.
$Z_{1-\alpha/2}$	=	Standard normal deviate corresponding to the level of significance, typically obtained from the standard normal (Z) distribution table; 1.960 for a two-sided significance level of $\alpha = 5\%$ (0.05).
$Z_{1-\beta}$	=	Standard normal deviate corresponding to the statistical power, typically obtained from the standard normal (Z) distribution table; 0.842 for 80% power ($\beta = 0.20$).

σ^2 = Pooled variance, typically estimated from previous studies with similar characteristics.

$(\mu_1 - \mu_2)$ = Minimum clinically significant difference between the *mean* values of the two groups, determined by the researcher based on relevant literature or preliminary studies.

According to the study conducted by Sikora *et al*. (2024), in Poland between January 2021 and December 2022, a *cross-sectional* study design was employed involving a total of 232 participants. The study, entitled *Vascular Access Perception and Quality of Life of Haemodialysis Patients*, reported the *mean* vitality score measured using the Kidney Disease Quality of Life Short Form (KDQOL-SF™) questionnaire. The *mean* vitality score was (X_1 = 49,22) among patients using an arteriovenous fistula (AVF) and (X_2 = 38,25) among those using a tunneled central venous catheter (TCVC).. The corresponding standard deviations were (S_1 = 20,43) for the AVF group and (S_2 = 20,22) or the TCVC group. The study included (n_1 = 134) participants in the AVF group and (n_2 = 58) participants in the TCVC group (Sikora *et al*., 2024).

Based on these findings, the required sample size for the present study was calculated using the following formula and calculation procedures:

a. Calculate the pooled standard deviation $\sigma^2 = \sqrt{\sigma}$

$$\sigma = \sqrt{\frac{(n_1 - 1){s_1}^2 + (n_2 - 1){s_2}^2}{n_1 + n_2 - 2}}$$

$$\sigma = \sqrt{\frac{(134 - 1)20{,}43^2 + (58 - 1)20{,}22^2}{134 + 58 - 2}}$$

$$\sigma = \sqrt{\frac{(133)(417{,}3849) + (57)(408{,}8484)}{190}}$$

$$\sigma = \sqrt{\frac{55512{,}191 + 23304{,}358}{190}}$$

$$\sigma = \sqrt{\frac{78816,549}{190}}$$

$$\sigma = \sqrt{414,82394}$$

$$\sigma = 20,367$$

b. Determine the required sample size (n)

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

$$n = \frac{2(20,367)^2(1,960 + 0,84)^2}{(49,22 - 38,25)^2}$$

$$n = \frac{2(20,367)^2(2,80)^2}{(10,97)^2}$$

$$n = \frac{2(414,81)(7,84)}{(120,34)}$$

$$n = \frac{6504,2208}{(120,34)}$$

$n = 54,05$ (The calculated sample size was rounded up to 55)

c. Calculate the required sample size after accounting for an anticipated dropout rate (error tolerance) of 10%

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

$$n' = \frac{55}{1 - 10\%}$$

$$n' = \frac{55}{1 - 0,01}$$

$$n' = \frac{55}{0,9}$$

$n' = 61,11$ (The calculated sample size was rounded up to 62)

Based on the sample size calculation, the minimum required sample for each group was 62 respondents: 62 patients using an arteriovenous fistula (AVF) and 62 patients using a catheter double lumen (CDL) as vascular access. Therefore, the minimum total sample size required for this study was 124 respondents.

However, during the data collection period, the researcher enrolled 136 patients who met all the inclusion criteria and agreed to participate in the study. The final sample consisted of 68 patients using an AVF and 68 patients using a CDL as vascular access. This sample size exceeded the minimum required sample and was considered adequate to provide valid and reliable statistical analyses, with a statistical power of 80% and a significance level of 5%.

3. Inclusion and Exclusion Criteria for Sample Selection

a. Inclusion Criteria

Inclusion criteria refer to the characteristics or requirements that members of the target population must meet to be selected as study participants and to ensure that the sample adequately represents the study population (Masriadi *et al*., 2022).

In this study, the sample consisted of 68 patients with chronic kidney disease (CKD) undergoing maintenance hemodialysis using an arteriovenous fistula (AVF) and 68 patients undergoing maintenance hemodialysis using a catheter double lumen (CDL). Participants were required to meet the following inclusion criteria:

1) Patients with CKD undergoing scheduled maintenance hemodialysis at the Hemodialysis Unit of Dr. M. Yunus Regional General Hospital, Bengkulu Province, or Harapan and Doa Regional General Hospital, Bengkulu City.
2) Willingness to participate in the study by providing written informed consent.
3) Aged between 18 and 65 years at the time of data collection.
4) Having undergone regular maintenance hemodialysis for at least 3 months.
5) Having a hemoglobin (Hb) level between 8 and 12 g/dL based on the most recent laboratory measurement obtained within the previous month.

6) Having an average interdialytic weight gain (IDWG) of ≤ 6% of dry body weight over the two most recent hemodialysis sessions.
7) Having adequate cognitive and communication abilities to read, understand, and complete the study questionnaires independently or with assistance from the researcher or a family member.

b. Exclusion Criteria

Exclusion criteria refer to characteristics that prevent potential participants from being included in the study because they do not meet the predetermined eligibility requirements (Masriadi *et al*., 2022).

The following exclusion criteria were established to minimize potential bias and maintain the validity of the study findings:

1) Patients undergoing their first hemodialysis session or those who were still in the adaptation phase of hemodialysis treatment.
2) Patients with an acute medical condition or who were clinically unstable during the data collection period.
3) Patients with a history of cardiovascular disease, malignancy, or active autoimmune disease.
4) Patients with severe communication impairments that could compromise the validity of questionnaire responses.
5) Patients who experienced a sudden decline in consciousness during the data collection process.

E. Data Collection

1. Data Sources

a. Primary Data

Primary data are data collected directly by the researcher from the respondents during the study using research instruments or measurement tools, such as interviews (Masriadi *et al*., 2022).

In this study, the primary data consisted of vascular access type, *fatigue* severity among patients undergoing maintenance hemodialysis, and respondents' characteristics, including age, sex, duration of

hemodialysis, comorbidities, sleep quality, hemoglobin (Hb) level, and *interdialytic weight gain* (IDWG). These data were collected through interviews, observations, and questionnaire administration among patients with chronic kidney disease (CKD) undergoing maintenance hemodialysis at the Hemodialysis Unit of Dr. M. Yunus Regional General Hospital, Bengkulu Province, and Harapan and Doa Regional General Hospital, Bengkulu City, who met the established inclusion criteria. The primary data were collected through the following procedures:

1) Data were collected directly by the researcher from respondents who experienced fatigue and were undergoing routine maintenance hemodialysis at the Hemodialysis Unit of Dr. M. Yunus Regional General Hospital, Bengkulu Province, and Harapan and Doa Regional General Hospital, Bengkulu City.
2) Information regarding vascular access type and respondents' characteristics was obtained through face-to-face interviews with patients receiving routine maintenance hemodialysis at the Hemodialysis Unit of Dr. M. Yunus Regional General Hospital, Bengkulu Province, and Harapan and Doa Regional General Hospital, Bengkulu City.
3) The researcher explained the study protocol to potential respondents, including the study objectives, potential benefits, estimated duration of participation, and the inclusion criteria required for study enrollment.
4) The researcher assessed the fatigue severity of potential respondents. Individuals who met the predetermined inclusion criteria were subsequently recruited as study participants.

b. Secondary Data

Secondary data refer to data obtained through data collection techniques that support primary data. These data are derived from sources such as books, scientific journals, annual reports, relevant

literature, and other documents related to the research topic (Masriadi *et al*., 2022).

In this study, the secondary data served as supporting information obtained from the medical records of the Hemodialysis Units at Dr. M. Yunus Regional General Hospital, Bengkulu Province, and Harapan and Doa Regional General Hospital, Bengkulu City. These data included the total number of patients with chronic kidney disease (CKD) and the number of patients undergoing maintenance hemodialysis using an arteriovenous fistula (AVF) or a catheter double lumen (CDL) as vascular access.

2. Data Collection Instruments

A research instrument is a written guideline used in accordance with the selected research method, including interviews, observations, questionnaires, or documentation, to facilitate systematic data collection (Adiputra *et al*., 2021).

The instruments used in this study included: (1) a respondent characteristics questionnaire; (2) the *Functional Assessment of Chronic Illness Therapy–Fatigue (FACIT-Fatigue) Scale Version 4*, Indonesian translated version adapted from Tennant (2019) dan Sihombing *et al*. (2016), to assess fatigue levels; and (3) the *Pittsburgh Sleep Quality Index (PSQI)*, Indonesian translated version adapted from Alim Ikbal *et al.* 2015 dan Mustofa *et al*. 2022, to evaluate sleep quality. The procedures for using each instrument are described as follows:

a. Data on fatigue among patients undergoing hemodialysis were collected through face-to-face interviews using the Indonesian version of the *FACIT-Fatigue Scale Version 4*. The questionnaire consists of items rated on a five-point Likert scale. For most items, responses were scored as follows: 4 = *not at all*, 3 = *a little bit*, 2 = *somewhat*, 1 = *quite a bit*, and 0 = *very much*. However, Items 7 and 8 were reverse-scored: 0 = *not at all*, 1 = *a little bit*, 2 = *somewhat*, 3 = *quite a bit*, and 4 = *very much*. The total score ranges from 0 to 52, with lower scores indicating greater

fatigue severity and poorer health-related quality of life. A total score of <30 indicates severe fatigue, whereas scores ranging from 30 to 52 indicate mild fatigue. The Indonesian version of the questionnaire has demonstrated satisfactory validity and reliability for assessing fatigue experienced during the preceding seven days (Maesaroh & Agung, 2020; Sihombing *et al*., 2016; Tennant, 2019).

b. Data regarding vascular access and respondents' characteristics were collected using a structured respondent characteristics questionnaire through interviews. The questionnaire included information on participants' name, age, sex, duration of hemodialysis, comorbidities, sleep quality, hemoglobin (Hb) level, and interdialytic weight gain (IDWG).

c. Interdialytic weight gain (IDWG) was calculated based on the difference between the patient's pre-hemodialysis body weight and the post-hemodialysis body weight recorded during the previous dialysis session, using the following formula: IDWG (%) = [(Pre-HD body weight − Previous Post-HD body weight) / Previous Post-HD body weight] × 100 (Dewi *et al*., 2022; Ipema *et al*., 2016).

d. Sleep quality data were obtained through face-to-face interviews using the Indonesian version of the *Pittsburgh Sleep Quality Index (PSQI)*. The questionnaire consists of 19 self-reported items that generate seven component scores representing the fundamental dimensions of sleep quality. These components assess subjective sleep quality, sleep latency, sleep duration, habitual sleep efficiency, sleep disturbances, use of sleep medication, and daytime dysfunction related to poor sleep quality. Each item is scored from 0 to 3 according to the scoring criteria of the instrument. The global PSQI score is calculated by summing the scores of the seven components, yielding a total score ranging from 0 to 21. A global PSQI score of ≤5 indicates good sleep quality, whereas a score of 6–21 indicates poor sleep quality. The *PSQI* has been recommended by the Kidney Disease: Improving Global Outcomes (KDIGO) and the

National Kidney Foundation–Kidney Disease Outcomes Quality Initiative (NKF-KDOQI) as an appropriate instrument for assessing sleep quality among patients undergoing dialysis (Alim Ikbal *et al*., 2015; Mustofa *et al*., 2022).

3. Validity and Reliability Testing of The Data Collection Instrument

Fatigue severity among patients with chronic kidney disease (CKD) undergoing maintenance hemodialysis was assessed using the *Functional Assessment of Chronic Illness Therapy–Fatigue (FACIT-Fatigue) Scale*, Version 4, Indonesian-translated version. The validity and reliability of this instrument were previously evaluated by Sihombing *et al*. (2016). The *FACIT-Fatigue Scale* is a concise, valid, and reliable instrument for assessing fatigue severity and monitoring anemia-related symptoms and their impact on patients with chronic kidney disease. Instrument validity was evaluated using the *Pearson correlation* test, whereas reliability was assessed using *Cronbach's alpha*. The analysis demonstrated that all questionnaire items were valid, as the calculated correlation coefficients (*r*-calculated) exceeded the critical value (*r*-table = 0.279). Furthermore, the instrument demonstrated acceptable reliability, with a *Cronbach's alpha* coefficient of 0.646 (> 0.60). Based on these findings, the Indonesian version of the *FACIT-Fatigue Scale* was considered both valid and reliable for assessing fatigue severity among patients with CKD undergoing maintenance hemodialysis (Sihombing *et al*., 2016).

Sleep quality was assessed using the Indonesian-translated version of the *Pittsburgh Sleep Quality Index (PSQI)*. The Indonesian version of the *PSQI* was previously validated and culturally adapted by Alim Ikbal *et al*. (2015). The instrument demonstrated good internal consistency, with a *Cronbach's alpha* coefficient of 0.79, while the content validity index reached 0.89. These findings indicate that the Indonesian version of the *PSQI* is a valid and reliable instrument for measuring sleep quality among patients with chronic kidney disease undergoing maintenance hemodialysis (Alim Ikbal *et al*., 2015; Mustofa *et al*., 2022).

4. Data Collection Procedures

Data were collected from the study population through the following procedures:

a. The researcher introduced themselves to the prospective respondents and explained the purpose, benefits, procedures, duration of the study, and the confidentiality of participants' personal information. Subsequently, informed consent was obtained from each respondent.
b. The researcher invited eligible participants to take part in the study and requested that those who agreed sign the informed consent form as evidence of their voluntary participation.
c. The researcher requested permission to access the respondents' medical records to obtain the secondary data required for this study.
d. The researcher distributed the respondent characteristics questionnaire, the fatigue assessment questionnaire, and the sleep quality questionnaire. Participants were guided when necessary to ensure that they understood how to complete the questionnaires. The researcher remained available until all questionnaires had been completed and checked them for completeness.
e. The researcher reviewed all collected data, including vascular access type, respondents' characteristics (age, sex, duration of hemodialysis, comorbidities, sleep quality measured using the Indonesian version of the Pittsburgh Sleep Quality Index (PSQI), hemoglobin (Hb) level, and interdialytic weight gain [IDWG]), fatigue severity measured using the Indonesian version of the FACIT–Fatigue Scale Version 4, and information obtained from the respondents' medical records to ensure that all data were complete and accurate.
f. After the required sample size had been achieved, the researcher verified that all participants met the predetermined inclusion and exclusion criteria.
g. Following confirmation of the eligible study sample, the researcher entered the raw data into a Microsoft Excel spreadsheet and organized

them in a master data table. The dataset was subsequently imported into IBM SPSS Statistics Version 26 for data management and statistical analysis.

h. The researcher analyzed the collected data, including vascular access type, respondents' characteristics (age, sex, duration of hemodialysis, comorbidities, sleep quality measured using the Indonesian version of the Pittsburgh Sleep Quality Index [PSQI], hemoglobin [Hb] level, and interdialytic weight gain [IDWG]), and fatigue severity measured using the Indonesian version of the FACIT–Fatigue Scale Version 4.

F. Data Processing

Data processing is a systematic procedure for organizing data obtained from interviews, field observations, and documentation into a meaningful format that facilitates interpretation and the development of valid conclusions. The collected data are classified into categories, organized into analytical units, selected according to their relevance, analyzed systematically, and interpreted to ensure that the findings are comprehensible to both the researcher and other readers (Masriadi *et al*., 2022).

In this study, the collected data were processed using computer software through several sequential stages, namely *editing*, *coding*, *data entry*, *cleaning*, *processing*, *tabulating*, and *saving*. These procedures were performed to ensure that the data were well organized, accurate, and ready for statistical analysis. The stages of data processing are described as follows:

1. *Editing*

   Following data collection, all completed questionnaires were carefully reviewed to ensure completeness, accuracy, and consistency. The researcher verified the respondents' demographic questionnaire, the *Functional Assessment of Chronic Illness Therapy*–Fatigue (FACIT-Fatigue) Scale Version 4 (Indonesian version), and the *Pittsburgh Sleep Quality Index* (PSQI) (Indonesian version). Each completed questionnaire was examined to ensure that no responses were omitted. In addition, field observation forms were reviewed and corrected before data analysis. This procedure

ensured that the collected data were complete, consistent, and suitable for further processing.

2. *Coding*

During the *coding* stage, numerical codes were assigned to all variables to facilitate data management and statistical analysis. Categorical variables recorded in text form were converted into numerical values, and each respondent was assigned a unique identification code to maintain confidentiality and simplify data management. For the independent variable (vascular access type), code 0 represented the catheter double lumen (CDL) group, whereas code 1 represented the arteriovenous fistula (AVF) group. The dependent variable, fatigue levels, was calculated using the total FACIT-Fatigue score and summarized using the *mean*. For descriptive analysis, fatigue level was categorized into two groups: code 0 for severe fatigue (total score 0–29) and code 1 for mild fatigue (total score 30–52).

Respondent characteristics were coded as follows: Age: code 0 for >50 years, code 1 for 35–50 years, and code 2 for <35 years. Sex: code 0 for female and code 1 for male. Duration of hemodialysis: code 0 for >3 years, code 1 for 1–3 years, and code 2 for <1 year. Comorbidities: code 0 for ≥3 comorbidities, code 1 for 1–2 comorbidities, and code 2 for no comorbidities. Sleep quality: the total PSQI score was calculated and categorized as code 0 for poor sleep quality (total score 6–21) and code 1 for good sleep quality (total score ≤5). Hemoglobin (Hb) level: code 0 for 7.0 to <10.0 g/dL, code 1 for 10.0–11.0 g/dL, and code 2 for >11.0 g/dL. Interdialytic Weight Gain (IDWG): code 0 for the high-risk category (>6%), code 1 for the moderate category (4%–6%), and code 2 for the mild category (<4%). Assigning numerical codes to each variable ensured a systematic data management process and facilitated statistical analysis.

3. *Entry Data*

The collected data were entered into IBM SPSS Statistics Version 26 installed on the researcher's computer according to the predefined study variables. Data were organized based on their source, method of collection,

time of collection, characteristics, and data type. All study data were obtained from internal sources through primary data collection conducted directly from the participants.

4. *Cleaning*

   The *cleaning* process involved rechecking all data entered into the computerized database to identify *missing data* through a *listing* procedure. The researcher also verified the accuracy and consistency of the dataset by reviewing coding accuracy, identifying potential entry errors, and ensuring that all values were entered correctly.

5. *Processing dan Tabulating*

   After verification, the data were categorized, evaluated, and analyzed using IBM SPSS Statistics Version 26. Statistical analyses were conducted according to the study objectives and variable characteristics. Subsequently, the processed data were tabulated and presented in tables to facilitate interpretation and reporting of the study findings.

6. *Saving*

   After completing the *processing* and *tabulating* stages, all datasets were securely stored in both electronic and printed formats. Electronic files were saved on the researcher's personal laptop and maintained in a password-protected storage drive accessible only to the researcher to ensure data confidentiality and security.

G. Data Analysis

Data analysis is a fundamental stage of the research process that involves examining, organizing, interpreting, and synthesizing the collected data to establish meaningful relationships among variables and to achieve a comprehensive understanding of the research findings. This process also entails systematically evaluating the data based on empirically testable assumptions, thereby providing a scientific basis for interpreting the study results in a clear, valid, and meaningful manner (Adiputra *et al*., 2021).

This study employed both univariate and bivariate data analyses. The procedures for each analytical approach are described as follows:

1. Univariate Analysis

The data analysis began with univariate analysis to describe the baseline characteristics of the study sample and the variables under investigation before conducting further statistical analyses (Nasir *et al*., 2019). In this study, univariate analysis was performed to summarize the characteristics of the respondents and the main study variables using descriptive statistical methods. The results are presented in tables showing the distribution of the sample characteristics.

Categorical variables, including vascular access type (arteriovenous fistula [AVF] and catheter double lumen [CDL]), fatigue severity category, sex, age category, hemoglobin level category, duration of hemodialysis category, interdialytic weight gain (IDWG) category, sleep quality category based on the Pittsburgh Sleep Quality Index (PSQI), and comorbidities, were summarized using frequencies (n) and percentages (%). Continuous variables, including fatigue severity scores, age, hemoglobin levels, duration of hemodialysis, percentage of IDWG, and PSQI scores, were summarized using measures of central tendency and dispersion, including the *mean*, standard deviation (SD), median (for non-normally distributed data), minimum and maximum values (range), and the 95% confidence interval (CI) for the *mean*. In addition, univariate analysis was performed as a preliminary step to provide a descriptive overview of the distribution, normality, and homogeneity of the study variables before conducting inferential statistical analyses.

According to Arikunto (2021), percentage values may be interpreted using the following categories:

0% = None of the observed events occurred.
1%-25% = A small proportion of the observed events occurred.
26%-49% = Nearly half of the observed events occurred.
50% = Half of the observed events occurred.

51%-69% = More than half of the observed events occurred.

70%-90% = Most of the observed events occurred.

91-100% = Almost all observed events occurred.

2. Bivariate Analysis

Bivariate analysis was performed to test the research hypothesis and examine the relationship between the study variables (Nasir *et al*., 2019). The alternative hypothesis (*Ha*) stated that there is a difference in the *mean* fatigue severity between patients undergoing maintenance hemodialysis using an arteriovenous fistula (AVF) and those using a catheter double lumen (CDL) as vascular access at the Hemodialysis Units of Dr. M. Yunus Regional General Hospital, Bengkulu Province, and Harapan and Doa Regional General Hospital, Bengkulu City.

To ensure the validity of the comparative analysis before testing the primary hypothesis, homogeneity testing was first performed during the univariate analysis to assess the equivalence of respondents' baseline characteristics. The categorical variables included sex, age group, hemoglobin level category, duration of hemodialysis category, comorbidities, interdialytic weight gain (IDWG) category, and sleep quality category measured using the Pittsburgh Sleep Quality Index (PSQI). The homogeneity of these characteristics between the AVF and CDL groups was evaluated using the Chi-square test. The results demonstrated no statistically significant differences between the two groups ($p > 0.05$), indicating that the respondents' baseline characteristics were comparable. These findings suggest that any observed difference in fatigue severity between the AVF and CDL groups was unlikely to be influenced by differences in respondents' characteristics.

In addition, the distribution of fatigue scores in both groups was assessed for normality during the univariate analysis. Because each study group consisted of more than 50 participants, the Kolmogorov–Smirnov test was used to evaluate the normality of the fatigue score distribution. The results indicated that fatigue scores in both groups were normally distributed

($p > 0.05$). Subsequently, the homogeneity of variances was examined using Levene's test, which demonstrated that the variance of fatigue scores was homogeneous between the two groups, as indicated by a non-significant Levene's test result ($p > 0.05$).

Since all assumptions of normality and homogeneity of variance were satisfied, the primary hypothesis was tested using the Independent Samples *t*-test to compare the *mean* fatigue scores between the two independent groups. The analysis revealed a statistically significant difference in *mean* fatigue severity between patients undergoing maintenance hemodialysis using an arteriovenous fistula (AVF) and those using a catheter double lumen (CDL) as vascular access ($p < 0.05$). Therefore, the alternative hypothesis (*Ha*) was accepted, indicating that the observed difference in fatigue severity was statistically significant and was not attributable to differences in respondents' baseline characteristics.

H. Research Flowchart

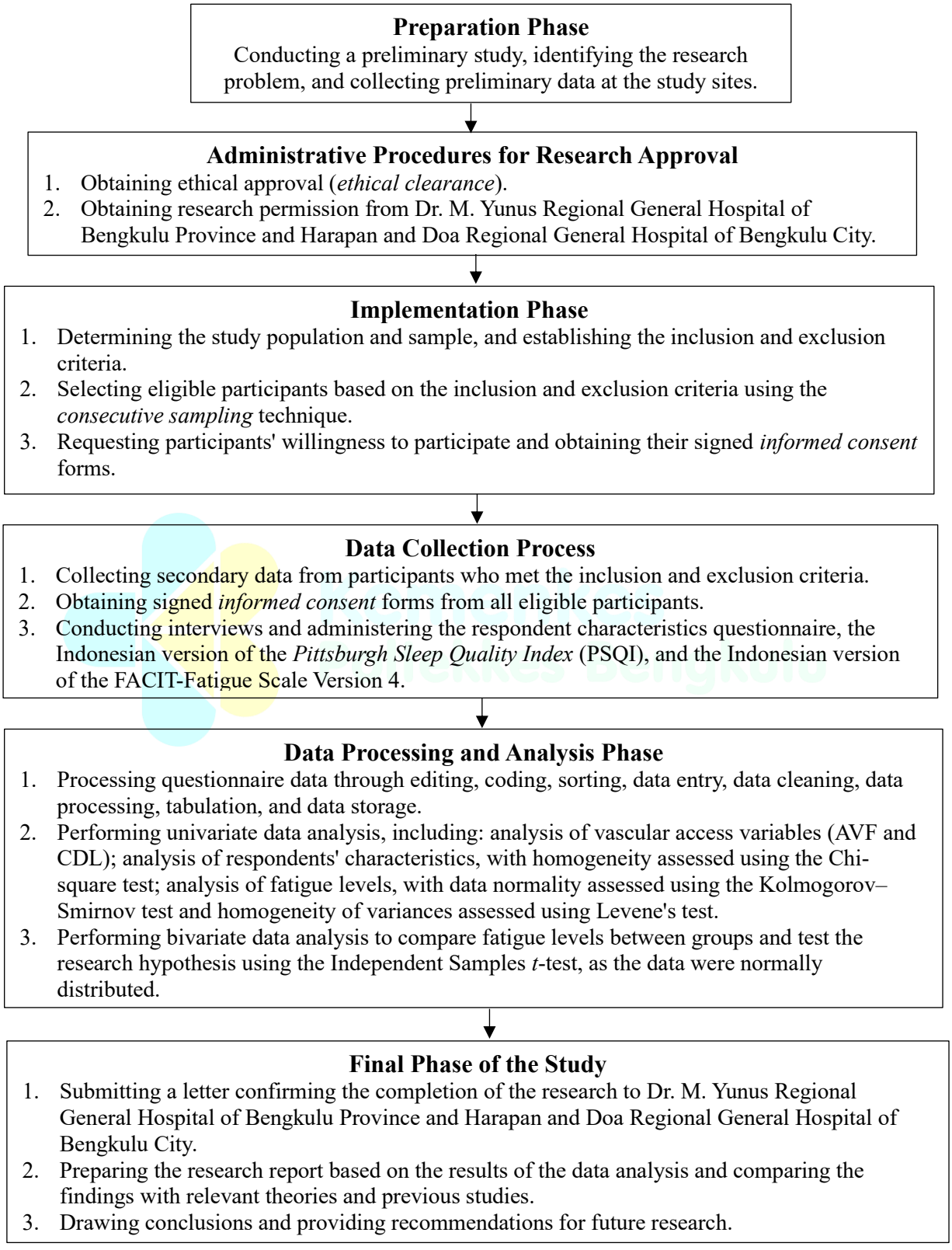

Diagram 4.2 Research Flowchart

I. Research Ethics

This study adhered to ethical principles and legal standards for health research based on the *International Ethical Guidelines for Health-related Research Involving Humans* developed by the Council for International Organizations of Medical Sciences (CIOMS, 2016), which are internationally recognized as a fundamental ethical framework for research involving human participants (Masriadi *et al*., 2022). In accordance with these guidelines, health research involving human participants should uphold the fundamental ethical principles of voluntary participation, protection of participants' privacy and confidentiality, and the use of scientifically appropriate and safe research methods (Bahri, 2023).

Prior to data collection, ethical approval was obtained from the Health Research Ethics Committee (*Komite Etik Penelitian Kesehatan* [KEPK]) of Poltekkes Kemenkes Bengkulu. The study was reviewed and approved in accordance with the seven WHO ethical standards (2011) under Ethical Approval No. KEPK.BKL/791/12/2025. Throughout the study, the following fundamental ethical principles were strictly observed:

1. *Informed Consent*

   Participation in this study was entirely voluntary. Before providing written informed consent, all participants received clear and comprehensive information regarding the study objectives, procedures, potential risks, and expected benefits. Participants were also given sufficient time and opportunity to ask questions and to decide freely whether to participate without coercion.

2. *Respect for Person*

   The principle of *respect for persons* requires researchers to recognize and protect the dignity, autonomy, and rights of all participants. Researchers carefully considered the potential risks and the possibility of misuse of the research findings. Furthermore, participants who were considered vulnerable received additional protection throughout the research process.

3. *Anonymity* and Confidentiality

   Protecting participants' privacy and maintaining the confidentiality of research data were fundamental ethical obligations in this study. All participant information was securely stored and accessible only to authorized researchers. To ensure anonymity, participants were identified using coded numbers and initials rather than their full names. Signatures were recorded exclusively on the written informed consent forms and were not linked to the research dataset.

4. *Beneficence*

   The principle of *beneficence* requires that research maximize potential benefits while minimizing possible risks or harm to participants. Accordingly, the study was carefully designed to ensure the safety, well-being, and welfare of all participants throughout the research process.

5. *Non-Maleficence*

   The principle of *non-maleficence* obliges researchers to avoid causing harm to participants. Potential risks associated with the study were carefully assessed in advance, and appropriate measures were implemented to prevent or minimize any foreseeable physical, psychological, or social harm.

6. *Justice*

   The principle of *justice* requires that all participants be treated fairly and equitably without discrimination. Participant selection was conducted objectively, and the distribution of the potential benefits and risks of the research was considered fair and balanced for all participants, including physical, psychological, and social aspects.

J. Research Schedule

This study was conducted according to a structured and systematic research schedule. The schedule was designed to facilitate the implementation of the research and to ensure that each stage of the study was completed efficiently and in a timely manner. The research schedule is presented in the following table.

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												