

## **CHAPTER III**

### **RESEARCH METHODS**

#### **3.1 Type of Research**

The type of research refers to the systematic approach chosen by the researcher to achieve the objectives formulated in the study. In this research, a descriptive analytic method with a cross-sectional approach was used, which is a strategy involving data collection or observation at a specific point in time (point time approach). The purpose of this approach is to explore and analyze the relationship between independent and dependent variables simultaneously, without intervention or repeated observations over a long period. This approach is considered efficient in describing the correlation between variables in a population under actual conditions at the time of data collection.

#### **3.2 Time and Place of Research**

The research on the relationship between Interdialytic Weight Gain and intradialytic blood pressure changes in End Stage Renal Disease patients was conducted in the hemodialysis unit of Lavalette Hospital from May 5 – May 11, 2025.

#### **3.3 Population and Sample**

##### **3.3.1 Population**

A population refers to all objects or subjects to be studied, possessing specific qualities and characteristics for the researcher to examine and draw conclusions (Nurfalah Setyawati, Hartyowidi Yuliawuri,

2023). A population must have clear boundaries, which are defined using inclusion and exclusion criteria. The population for this study comprises all ESRD patients undergoing hemodialysis at Lavalette Hospital, totaling 500 patients.

### 3.3.2 Sample and Sample Size

A sample is a subset of the population that meets specific criteria determined by the researcher (Syapitri et al., 2021). In the sampling process, every individual in the population has an equal chance of being selected as a sample member. Therefore, it is crucial for the sample used in research to be representative so that the results and conclusions obtained can be generalized to the entire population. In this study, the subjects sampled were patients with End Stage Renal Disease (ESRD) undergoing hemodialysis therapy at Lavalette Hospital and meeting the established inclusion criteria. To determine the appropriate sample size, the Slovin formula was used, which allows for the estimation of sample size based on a known population while considering an acceptable margin of error.

$$n = \frac{N}{1 + Ne^2}$$

Explanation:

n : Sample size

N : population size

e : Desired critical value (margin of error) (e.g., 10% = 0,1)

$$n = \frac{500}{1 + 500 (0,1)^2}$$

$$n = \frac{500}{1 + 500 \times 0,01}$$

$$n = \frac{500}{6}$$

$$n = 83$$

Based on the sample calculation, a sample size of 83 ESRD patients undergoing hemodialysis at Lavalette Hospital was obtained.

### **3.3.3 Inclusion and Exclusion Criteria**

Sample criteria are used to set boundaries for a population in research. The sample criteria for this study are as follows:

#### **1. Inclusion Criteria**

The inclusion criteria for this study are:

- a. ESRD patients undergoing routine hemodialysis twice a week
- b. ESRD patients undergoing hemodialysis with good communication skills.

#### **2. Exclusion Criteria**

The exclusion criterion for this study is:

- a. ESRD patients undergoing hemodialysis who cannot be weighed in a standing position.

### **3.3.4 Sampling Technique**

Sampling technique refers to the procedure used to select a subset of members from a population to serve as a sample in a study (Syapitri et al., 2021). The purpose of using this technique is to ensure that the obtained sample can fully represent the characteristics of the population, thereby

making the research results valid and generalizable. In this study, the sampling approach used was non-probability sampling with the purposive sampling method, which involves selecting research subjects based on specific considerations that refer to the inclusion and exclusion criteria previously formulated by the researcher. The purposive method was chosen because only individuals with specific characteristics relevant to the research focus are considered capable of providing appropriate and in-depth information to accurately answer the research questions.

#### **3.4 Data Collection Methods**

Data collection is the most crucial stage in research. The data collection methods used by the researcher were interviews and observation. Respondents were ESRD patients undergoing hemodialysis twice a week, with a 2-day interval between the first and second hemodialysis sessions, thus data collection was conducted twice a week. The stages for collecting data in this study are as follows:

1. Data collection for meeting 1
  - a. Identifying respondents according to inclusion criteria
  - b. Explaining the research information sheet and obtaining informed consent
  - c. Measuring post-hemodialysis body weight
2. Data collection for meeting 2
  - a. Measuring pre-hemodialysis body weight
  - b. Measuring pre-hemodialysis blood pressure

- c. During the hemodialysis session, the researcher will conduct interviews regarding the duration of the patient's hemodialysis, history of previous illnesses, and types of beverages consumed by the patient during the interdialytic period.
- d. Measuring post-hemodialysis blood pressure

Data was collected from May 5 – May 11, 2025, in accordance with the patients' routine hemodialysis schedule of twice per week. Each patient meeting the inclusion criteria was observed during two consecutive hemodialysis sessions within one week.

#### 1. Interdialytic Weight Gain (IDWG)

- a. Patient body weight was measured using a calibrated digital scale; the measurement results were recorded in kilograms (kg) with 2 decimal places
- b. Measurements were taken twice:
  - 1) Post HD 1 (after the first hemodialysis session)
  - 2) Pre HD 2 (before the second hemodialysis session)
- c. IDWG was calculated using the formula:

$$IDWG = \frac{BW \text{ Pre HD 2} - BW \text{ Post HD 1}}{BW \text{ Post HD 1}} \times 100\%$$

- d. IDWG results were recorded as a percentage (%)
- #### 2. Intradialytic Blood Pressure Change
- a. Systolic blood pressure was measured using a digital sphygmomanometer.

- b. Blood pressure measurements were taken on the second day and performed twice:
  - 1) Pre-HD BP: measured during the first 30 minutes of dialysis, in a supine position
  - 2) Post-HD BP: measured during the last 30 minutes of dialysis, in a supine position
- c. Blood pressure change was calculated as the difference:
$$\Delta \text{ Systolic BP} = \text{BP Post HD} - \text{BP Pre HD}$$
- d. Blood pressure measurement results were recorded in mmHg.

#### **3.4.1 Primary Data**

Primary data refers to information collected directly from research subjects without intermediaries. In the context of this study, primary data were obtained directly from patients with End Stage Renal Disease (ESRD) undergoing hemodialysis therapy at Lavalette Hospital. The information collected included personal identity data, the duration or length of time the patient had undergone the hemodialysis procedure, a history of previous medical conditions or comorbidities, and the type and amount of fluid consumed during the interdialytic period. This data was collected to provide a comprehensive overview of factors that might influence the patient's clinical condition and to support the analysis in this study.

#### **3.4.2 Secondary Data**

Secondary data refers to information collected indirectly from research subjects, typically through existing records or other available

sources. In this study, secondary data were obtained from the medical records of patients with End Stage Renal Disease (ESRD) undergoing hemodialysis at Lavalette Hospital. This data included pre- and post-hemodialysis blood pressure measurements, as well as patient body weight data measured pre-hemodialysis for the current session and post-hemodialysis for the previous session. This information was used to support the research analysis in evaluating changes in patient condition during the therapy process.

### **3.5 Data Collection Instruments**

In collecting data, researchers devise research instruments to obtain the desired data. A research instrument is a measuring tool used to collect necessary data (Syapitri et al., 2021). Several instruments used by the researcher, based on their variables, are:

#### **1. Interdialytic Weight Gain (IDWG) Variable**

##### **a. Observation sheet**

The observation sheet was used as a recording aid to systematically document patient body weight measurements. This recording is essential for calculating the weight difference that occurs during the interdialytic period, reflecting the accumulation of body fluid between two hemodialysis sessions.

##### **b. Digital body weight scale**

A digital scale serves as the primary instrument for measuring patient body weight with high accuracy. Measurements were taken

pre-hemodialysis for the current session and post-hemodialysis for the previous session. The weight difference obtained from these two measurement times serves as an indicator of Interdialytic Weight Gain (IDWG), which is important in evaluating patient adherence to fluid intake restrictions and body fluid balance control.

## 2. Intradialytic Blood Pressure Change Variable

### a. Observation sheet

The observation sheet was used to record patient blood pressure measurements in a structured manner, both pre- and post-hemodialysis procedures. This recording aims to monitor intradialytic blood pressure fluctuations, which can indicate patient tolerance to hemodialysis therapy and the potential risk of cardiovascular complications.

### b. Digital sphygmomanometer

A digital blood pressure monitor (digital sphygmomanometer) was used to automatically and accurately measure blood pressure at two time points: pre-hemodialysis and post-hemodialysis. The data obtained from this instrument are crucial for assessing blood pressure changes during the hemodialysis process and for guiding necessary medical interventions in cases of intradialytic hypotension or hypertension.

### **3.6 Variables**

A variable is anything (characteristic, quality, or feature) possessed by a subject or object in a study to be examined and from which information is obtained, subsequently used to draw conclusions (Syapitri et al., 2021). A dependent variable is a variable that is influenced by the independent variable. An independent variable is a variable that causes change or contributes to an outcome.

#### **3.6.1 Dependent Variable**

The dependent variable in this study is the intradialytic blood pressure change in ESRD patients undergoing hemodialysis at Lavalette Hospital..

#### **3.6.2 Independent Variable**

The independent variable in this study is Interdialytic Weight Gain (IDWG) in ESRD patients undergoing hemodialysis at Lavalette Hospital.

### **3.7 Operational Definition**

An operational definition is an explanation of the meaning of research variables and the steps that must be taken to measure those variables. An operational definition explains in detail how a variable is observed or measured (Syapitri et al., 2021). The operational definitions for this study can be seen in Table 3.1.

Table 3. 1 Operational Definition

No	Variable	Definition	Measurement Tool	Measurement Method	Measurement Scale	Measurement Result
1.	Independent variable: Interdialytic Weight Gain (IDWG)	Interdialytic Weight Gain (IDWG) is defined as the difference between a patient's pre-dialysis weight and their post-dialysis weight from the previous session. It represents the increase in fluid volume, which is manifested as an increase in body weight	1. Digital body weight scale 2. Observation sheet	IDWG is measured by completing the IDWG instrument formula $IDWG = \frac{BW_{Pre\ HD\ 2} - BW_{Post\ HD\ 1}}{BW_{Post\ HD\ 1}} \times 100\%$	Ratio	The result is expressed as a percentage (%)
2.	Dependent variable: Intradialytic blood pressure changes	Intradialytic blood pressure change is defined as the difference in systolic blood pressure between pre- and post-hemodialysis measurements	1. Digital sphygmomanometer 2. Observation sheet	Intradialytic blood pressure change is calculated using the difference in systolic blood pressure from pre- to post-hemodialysis $\Delta \text{Systolic BP} = BP_{Post\ HD} - BP_{Pre\ HD}$	Ratio	The result is numerical data, which can be positive, negative, or zero

### 3.8 Operational Framework

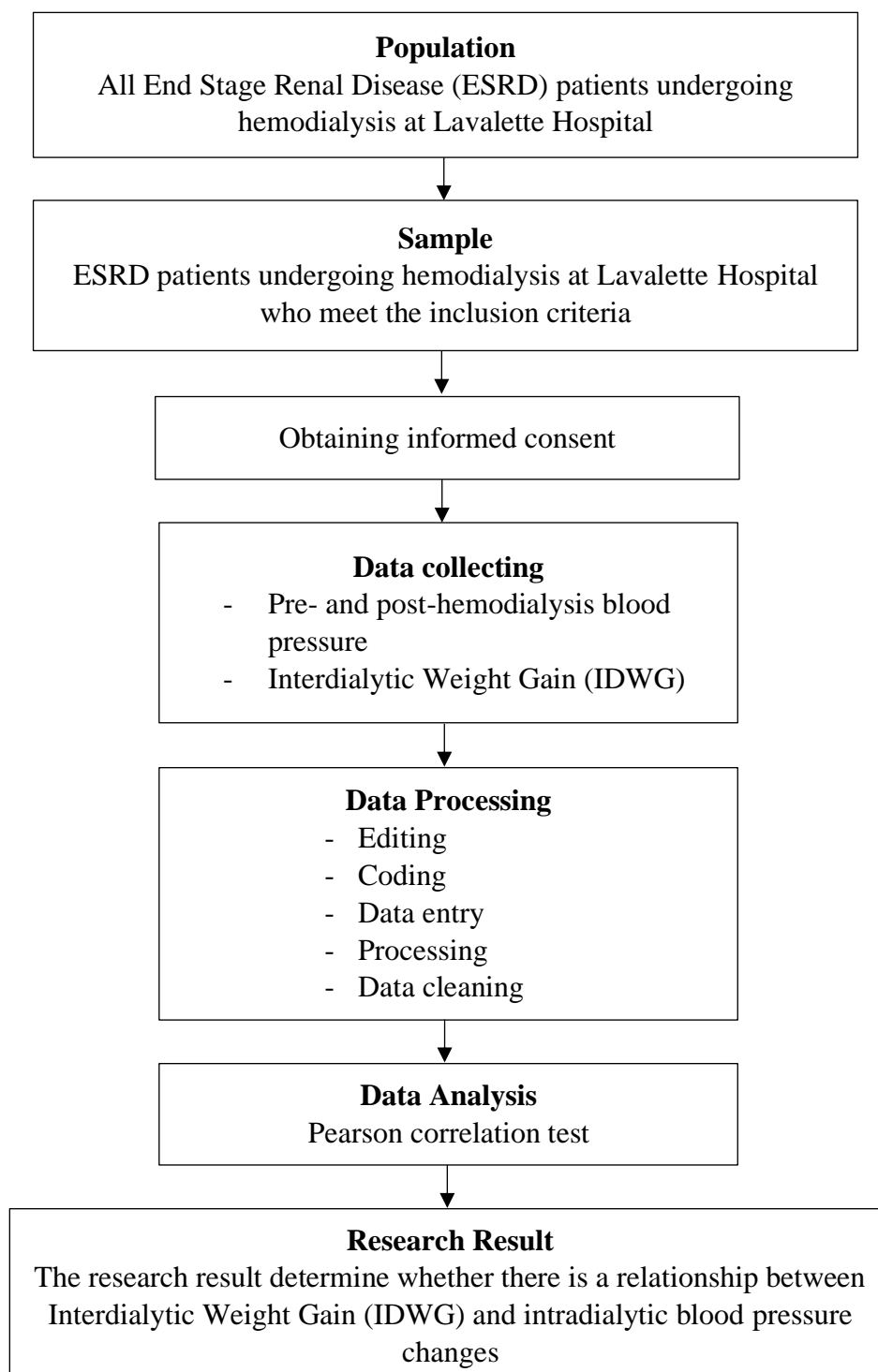


Figure 3. 1 Operational Framework

### **3.9 Data Processing and Analysis Methods**

#### **3.9.1 Data Processing**

Data processing is the transformation of collected data into necessary output information. Raw data, once gathered, will be processed and analyzed to produce information (Syapitri et al., 2021). Data processing can be done manually or with software applications. The data processing flow utilized in this research is as follows:

1. Editing

Editing or data curation is the process of reviewing the completeness of collected data. It's crucial to examine the gathered data to identify and correct any inaccuracies or errors, as well as to fill in any missing information.

2. Coding

Coding is the process of converting data, originally in the form of sentences or letters, into numerical data. This is done to facilitate the researcher's analysis of frequency distributions and crosstabulations.

The code breakdown used is as follows:

- a. Categories of Interdialytic Weight Gain (IDWG):

- 1) 1 = Mild (IDWG <4%)
- 2) 2 = Moderate (IDWG 4 – 6%)
- 3) 3 = High (IDWG >6%)

b. Categories of intradialytic blood pressure changes:

- 1) 1 = Intradialytic hypotension ( $\Delta$  Systolic BP =  $\leq -20$  mmHg)
- 2) 2 = Stable ( $\Delta$  Systolic BP =  $-19$  mmHg to  $+9$  mmHg)
- 3) 3 = Intradialytic hypertension ( $\Delta$  Systolic BP =  $\geq +10$  mmHg)

### 3. Data entry

Data entry involves populating columns within a computerized system.

The researcher enters two types of data: original data (uncoded data) and coded data. The uncoded data is used for normality testing and hypothesis testing.

### 4. Processing

Processing refers to the stage where the data, having been entered into the columns of the data processing application on the computer, is then analyzed. This data is processed using the SPSS (Statistical Package for Social Sciences) version 27 program.

### 5. Data cleaning

Data cleaning is the process of re-examining the entered data for any errors or incompleteness. The researcher checks for missing data by reviewing the frequency distribution of each variable.

## 3.9.2 Data Analysis

Data analysis is the process that follows data processing, involving the organization of data based on patterns, categories, or basic descriptions to formulate derived hypotheses. This research employs two types of data analysis:

## 1. Univariate Analysis

Univariate analysis involves processing data for a single variable without examining its relationship with other variables. This type of analysis simplifies or summarizes a collection of research data, transforming it into useful information. In this study, univariate analysis will describe the demographic characteristics of respondents, including age, gender, duration of hemodialysis, medical history, type and amount of fluid consumed during the interdialytic period, Interdialytic Weight Gain (IDWG), and intradialytic blood pressure changes.

## 2. Bivariate Analysis

Bivariate analysis involves processing data by connecting two variables. The aim of bivariate analysis is to determine whether a relationship exists between two variables. In this study, bivariate analysis will investigate the relationship between the independent variable (IDWG) and the dependent variable (intradialytic blood pressure changes) using the Pearson Product-Moment Correlation test. This test is suitable for examining the relationship between two variables measured on a ratio scale.

A prerequisite for conducting the Pearson Product-Moment Correlation test is that the data must be normally distributed. Before performing the Pearson Product-Moment Correlation test, a Kolmogorov-Smirnov normality test was conducted, which is appropriate for large sample sizes. Based on the normality test, the

significance value was found to be  $0.200 > 0.05$ , indicating that the data are normally distributed.

Once the normality test is performed and the results confirm that the data are normally distributed, hypothesis analysis can proceed using the Pearson Product-Moment Correlation test. This test is used to measure the strength and direction of the linear relationship between two numerical variables. There are three approaches used as the basis for decision-making in interpreting the results of the Pearson correlation test:

1. Based on the significance value (Sig. 2-tailed)

If the significance value (Sig. 2-tailed) is less than 0.05, it indicates a statistically significant relationship or correlation between the two variables tested. Conversely, if the significance value is greater than 0.05, there is no significant correlation found between the variables.

2. Based on the calculated r-value (pearson correlation)

The correlation between two variables is considered significant if the calculated r-value is greater than the r-table value at a given significance level. However, if the calculated r-value is smaller than the r-table value, there is no significant relationship between the variables.

3. Based on asterisks (\*) in SPSS output

In SPSS output, the presence of one asterisk (\*) or two asterisks (\*\*) next to the Pearson correlation value indicates that the correlation between the two variables is significant at a certain confidence level (typically  $p < 0.05$  for one asterisk and  $p < 0.01$  for two asterisks). If no asterisks are present, the correlation is considered not significant.

### **3.10 Research Ethics**

Research involving human subjects must undergo an ethical review by an Institutional Review Board (IRB) or Ethics Committee. For this study, the ethical review was submitted to the KEPK Poltekkes Kemenkes Malang and was declared ethically sound with letter number No.DP.04.03/F.XXI.30/00350/2025. Research involving human subjects is obligated to adhere to the following ethical principles:

#### **1. Principle of Beneficence**

This principle emphasizes the obligation to maximize potential benefits to individuals and society while minimizing harm. In this study, beneficence is upheld by ensuring no suffering is inflicted upon subjects, and no interventions are imposed on respondents. The research design actively works to avoid any form of harm to participants, and the researchers have meticulously assessed both the potential negative and positive impacts to prioritize the well-being of the subjects. The focus is on generating valuable knowledge without causing detriment.

#### **2. Principle of Respect for Persons**

This principle underscores the importance of acknowledging the autonomy and dignity of every individual. In this research, respondents retain the fundamental right to decide voluntarily whether to participate. This autonomy is supported by providing them with comprehensive and detailed information about the study's purpose, procedures, potential implications, and their right to withdraw at any time without penalty. This ensures their participation is based on informed choice and free will.

### 3. Principle of Non-Maleficence

This principle asserts the duty to do no harm. Researchers are committed to considering both the potential negative and positive impacts of the study. Proactive measures are taken to anticipate and mitigate any foreseeable risks that could potentially harm the research subjects. This involves careful planning and execution to ensure that participation in the study does not lead to any adverse physical, psychological, social, or economic consequences for the individuals involved.

### 4. Principle of Justice

This principle demands that all research subjects be treated fairly and equitably. In this study, every participant will receive equal treatment throughout all phases of the research: before, during, and after their involvement. This means that burdens and benefits of the research are distributed fairly, and no group or individual is unfairly excluded or subjected to disproportionate risks or advantages.