CHAPTER 3
RESEARCH METHOD

3.1 Research Design

The research design in this study will use a quantitative observational analytical method with a cross-sectional approach. The observational analytical method is a research approach method that analyzes and examines the attachment between two or more variables, where the researcher only makes observations without being directly involved in the research subject. The cross-sectional approach is a research method that is carried out by measuring data on research subjects once in a certain time range. In this study, not all research subjects will be analyzed simultaneously, but each subject will be measured and observed each variable at a certain time (Ishak et al., 2023). The researcher will apply this method to analyze the factors that associated with chemotherapy treatment adherence in patients with breast cancer in the Crystal Ward at Lavalette Hospital and in the Malang Breast Cancer Community.

3.2 Population, Samples, and Sampling

3.2.1 Population

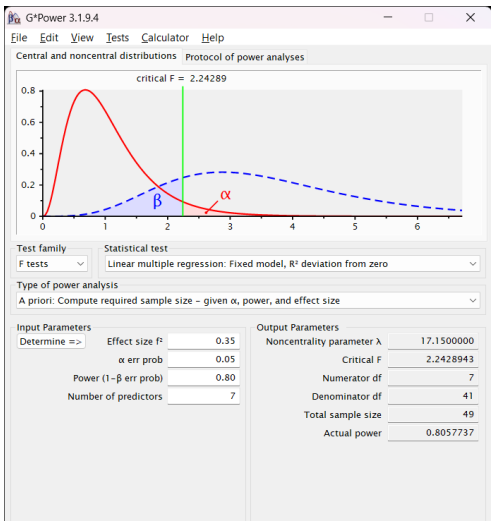
A population is a set of objects, individuals, or units that have certain characteristics that are the main focus in research (Jailani et al., 2023). According to data from the Malang City Health Service, there were 388 cases of breast cancer in 2022. In addition, there were 205 members who joined the Malang Breast Cancer

Community (MBCC) in 2025, which shows that the incidence of breast cancer is still relatively high. The population in this study is all patients who suffer from breast cancer and are undergoing chemotherapy treatment in the adult inpatient room of Lavalette Hospital.

3.2.2 Sample

A sample is a subgroup or a small portion of the population selected to participate in the study (Swarjana, 2022). The sampling method in this study will use purposive sampling, which is a method of determining samples by considering certain factors. The purposive sampling technique used in this study is based on its suitability with quantitative research that does not generalize the research subject. The participants in this study were patients who are currently undergoing or have previously undergone chemotherapy treatment for breast cancer in the Crystal Ward at Lavalette Hospital Malang and in Malang Breast Cancer Community (MBCC), and were willing to take part in the research.

The number of samples in this study was determined using the help of the GPower application with the following results:



Picture 3.1 Calculation of Minimum Sample Count with GPower Application

In the calculation of the number of research samples using the GPower application, the result was obtained that the number of samples needed is 49 respondents. This calculation is based on setting the effect size of 0.35, the level of significance (α err prob) of 0.05, the test power of 0.8, and the number of predictors 7. The number of samples is considered sufficient to meet the objectives of the study, and the duration of the research is determined by the researcher based on the inclusion and exclusion criteria that have been determined.

In the study, the sample was divided into two, namely the inclusion and exclusion sample criteria. The inclusion and exclusion criteria in this study are:

1. Inclusion Criteria
    a. Patients willing to provide information and data for research
    b. Breast cancer patients who are currently undergoing or have previously undergone chemotherapy treatment
2. Exclusion Criteria
    a. Patients with severe psychological disorders
    b. Uncooperative patients

3.2.3 Sampling

The researcher will use the purposive sampling method in this study. Purposive sampling is one of the non-probability sampling methods where researchers select samples based on certain criteria that are considered important to answer research questions or meet research objectives (Sugiyono, 2019).

3.3 Location and Time of Research

3.3.1 Research Location

This study was conducted in the adult inpatient ward, specifically in the Crystal Ward at Lavalette Hospital Malang, and included indirect interviews with members of the Malang Breast Cancer Community (MBCC).

3.3.2 Research Time

The research time was conducted on May - June 2025 in the adult inpatient ward, Crystal Ward of Lavalette Hospital and indirect interviews with members of the Malang Breast Cancer Community (MBCC).

3.4 Research Variables

Research variables are concepts or attributes that are measured or observed in a research, which function to describe the characteristics or phenomena analyzed in the research and play an important role in shaping research objectives, research questions, and in developing hypotheses to be tested (Sugiyono, 2019).

3.4.1 Independent Variables

Independent variables or independent variables are variables that are considered to be causal factors or variables that can affect other variables (Sugiyono, 2017). These variables are factors that are manipulated or altered to see their impact on dependent variables. The independent variables in this study are factors that affect patient compliance in undergoing chemotherapy which includes physical factor, role factor, psychological factor, social factor, economy factor, and cognitive factor.

3.4.2 Dependent Variables

Dependent variables are variables that are measured or observed to see if and how changes to independent variables affect the outcome (Sugiyono, 2019). This variable is also called a bound variable because its value depends on or is bound to the variation that occurs in the independent variable. The dependent variable or bound variable in this study was the level of adherence in undergoing chemotherapy treatment in patients with breast cancer.

3.5 Operational Definition

An operational definition in a study is a clear and measurable explanation of how a variable will be measured, observed, or manipulated in the study. An operational definition provides specific instructions on how an abstract concept or variable can be transformed into something that can be observed and measured concretely.

Table 3.1 Operational Definition Analysis of Factors Associated with Chemotherapy Treatment Compliance in Patients with Breast Cancer

No.	Variable	Operational Definition	Parameters	Instruments	Scale	Score
1	**Independent** Physical Factors	Physical aspects related to the patient's body condition and biological processes that can affect how the patient responds to and follows chemotherapy treatment.	1. Side effects of chemotherapy treatment 2. The patient's general health condition 3. Patient's age 4. Decreased organ function	European Organization for Research and Treatment of Cancer Quality of Life Questionnaire - Breast Cancer Module 42 (EORTC QLQ - BR42)	Ordinal	Score criteria: 59 - 236
2	**Independent** Role Factors	Aspects related to the patient's ability to carry out social and work roles.	1. The role of the patient in the family	European Organization for Research and Treatment of Cancer Quality of Life Questionnaire - Breast Cancer Module 42 (EORTC QLQ - BR42)	Ordinal	Score criteria: 2 - 8
3	**Independent**	Mental, emotional, and	1. Anxiety and fear 2. Depression	European Organization for Research and Treatment of	Ordinal	Score criteria:

	Psychological Factors	behavioral aspects that can influence how patients respond, cope, and proceed with chemotherapy.	3. Anxiety about the prognosis 4. Refusal and distrust of treatment	Cancer Quality of Life Questionnaire - Breast Cancer Module 42 (EORTC QLQ - BR42)		14 - 56
4	**Independent** Social Factors	Various elements in the social environment that can influence the patient's decisions and ability to undergo treatment regularly.	1. Family and social support 2. Social stigma 3. Access to social support networks	European Organization for Research and Treatment of Cancer Quality of Life Questionnaire - Breast Cancer Module 42 (EORTC QLQ - BR42)	Ordinal	Score criteria: 2 - 8
5	**Independent** Economic Factors	Various economic aspects that can affect a	1. Chemotherapy treatment costs 2. Loss of income and impact on employment	European Organization for Research and Treatment of Cancer Quality of Life Questionnaire - Breast Cancer	Ordinal	Score criteria: 1 - 4

		patient's ability to access and undergo chemotherapy treatment.	3. The economic burden of the family 4. Influence on spending patterns and priorities	Module 42 (EORTC QLQ - BR42)		
6	**Independent** Cognitive Factors	Aspects related to the patient's ability to remember and concentrate.	1. Concentration 2. Memory	European Organization for Research and Treatment of Cancer Quality of Life Questionnaire - Breast Cancer Module 42 (EORTC QLQ - BR42)	Ordinal	Score criteria: 2 - 8
7	**Dependent** Medication Compliance	Patient behavior that complies with and adheres to the treatment instructions that have been given, including taking medication according to the dosage and	1. Forgot or not to take medication 2. Other reasons for not taking medication 3. Not taking medication because they feel that their condition is not improving 4. Not carrying medication while traveling 5. How often to remember to take medication	Morisky Medication Adherence Scale – 8 items (MMAS – 8)	Ordinal	Score criteria: 0 - 8

	schedule set by medical personnel beforehand.	6. Not taking medication because you feel better 7. Uncomfortable with treatment 8. How often you have difficulty remembering a treatment plan	

3.6 Data Collection Methods

3.6.1 Data Collection Procedure

The stages of the data collection procedure in this study are arranged in order, including the following steps:

1. Administrative Preparation Stage
    a. Submission of an application for permission to carry out a preliminary study to the Malang Applied Nursing Undergraduate Study Program
    b. The researcher asked for a letter of introduction from the Malang Applied Nursing Undergraduate Study Program to be given to the Training Coordinator of Lavalette Hospital
    c. Obtaining permission from the Education and Training Coordinator of Lavalette Hospital to conduct research in the adult inpatient room of Lavalette Hospital
    d. The researcher consulted with the supervisor regarding the results of the research proposal and the research instruments to be used
2. Technical Preparation Stage
    a. Preparation of research proposals
    b. Hold a proposal seminar and make improvements based on the results of the proposal seminar
    c. Submitting an Ethical Clearance to the Ethics and Training Commission of Lavalette Hospital
    d. After obtaining approval from the Ethics Commission for Education and Training of Lavalette Hospital, the researcher prepared a questionnaire sheet.

3. Implementation Stage
    a. The researcher determines respondents based on inclusion and exclusion criteria
    b. Asking respondents about their willingness to participate in research
    c. Inform respondents about the objectives, objectives, procedures, time, and location of the research
    d. Have respondents sign an information consent form if they agree to participate in the study
    e. Agree on a time contract with the respondent ranging from 10 to 15 minutes
    f. Sharing the Morisky Medication Adherence Scale – 8 items (MMAS – 8) questionnaire totaling 8 special questions that must be answered
    g. Collect all the data from the research results

3.7 Research Instruments

A research instrument is a tool or device used by researchers to collect data in a study (Hidayat, 2021). The measurement tool used in this study is a questionnaire. The questionnaire has been prepared with reference to the indicators of the research variables, which are then elaborated in detail in the form of a questionnaire of questions which are then distributed to the respondents.

1. European Organization for Research and Treatment of Cancer Quality of Life Questionnaire - Breast Cancer Module 42 (EORTC QLQ - BR42)

    The European Organization for Research and Treatment of Cancer Quality of Life Questionnaire (EORTC QLQ-C30) is a questionnaire designed to evaluate

the impact of cancer and its treatment on patients' quality of life. In addition, this questionnaire can also measure aspects related to the patient's daily life, ranging from physical, role, psychological, social, economic, and cognitive aspects.

In the use of the QLQ-C30 EORTC questionnaire, patients are asked to answer questions within a certain time span (e.g. during the past week) based on their experience regarding the symptoms and effects felt during chemotherapy. Each patient's answer was measured using the Likert scale, where a value of 1 means "not at all", a value of 2 "a little", a value of 3 "moderate", and a value of 4 "very". Higher scores on the function scale indicate a better quality of life, while higher scores on the symptom scale indicate an improvement in symptoms or problems.

Calderon et al. (2022) stated that the factors examined in the study are well-defined, replicable, and capable of providing accurate score estimates using the EORTC QLQ-30 questionnaire. Furthermore, the fidelity index reached 0.91, indicating that even simple total scores can yield accurate individual measurements for the quality of life and physical health dimensions. The questionnaire also demonstrated total reliability scores of 0.94 for quality of life and 0.86 for the physical health dimension, as evaluated using McDonald’s omega (ω).

The European Organization for Research and Treatment of Cancer Quality of Life Questionnaire - Breast Cancer Module 42 (EORTC QLQ - BR42) is a development of the EORTC QLQ-C30 questionnaire which has a more specific purpose, namely to measure the quality of life of breast cancer patients. This

questionnaire also aims to provide a complete picture of the impact of breast cancer and its treatment on aspects of patients' lives. In addition, this questionnaire can also be used to evaluate aspects related to the patient's life, such as physical, role, psychological, social, economic, and cognitive aspects.

EORTC QLQ - BR42 contains 42 questions divided into several dimensions and scales related to the breast patient experience, including physical symptoms, side effects, emotional and psychological problems, to the quality of social relationships. The measurement of the EORTC QLQ – BR42 questionnaire is the same as the EORTC QLQ-30 questionnaire, which uses a Likert scale from a value of 1 – 4 which describes the patient's quality of life.

The EORTC QLQ-BR42 is an updated version of the previous questionnaire, the EORTC QLQ-BR23. Research conducted by Bjelic-Radisic et al. (2020) indicates that the scale structure of the earlier EORTC QLQ-BR23 questionnaire remains unchanged. However, the scales in the EORTC QLQ-BR42 did not exhibit strong correlations with the earlier version, emphasizing the necessity for new subscales to capture the full range of side effects experienced by current breast cancer patients. Furthermore, all scales demonstrated values exceeding the Cronbach’s alpha threshold of 0.70, indicating that this instrument possesses strong validity and reliability.

Table 3.2 The Outline of the European Organization for Research and Treatment of Cancer Quality of Life Questionnaire - Breast Cancer Module 42 (EORTC QLQ - BR42)

No.	Aspects	Items	Total
1.	Physical factors	1, 2, 3, 4, 5, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, 29, 30, 31, 32, 33, 34, 35, 36, 37, 38, 47, 48, 49, 50, 51, 52, 53, 54, 55, 56, 57, 58, 59, 60, 61, 62, 63, 64, 65, 66, 67, 68, 69, 70	51
2.	Role factors	6, 7	2
3.	Psychological factors	21, 22, 23, 24, 39, 40, 41, 42, 43, 44, 45, 46, 71, 72	14
4.	Social factors	26, 27	2
5.	Economic factors	28	1
6.	Cognitive factors	20, 25	2

2. Morisky Medication Adherence Scale – 8 items (MMAS – 8)

MMAS – 8 is a measuring tool used to assess a patient's level of medication adherence, especially in patients undergoing long-term treatment such as chemotherapy. The MMAS – 8 questionnaire has 8 questions with yes/no answers designed to evaluate the extent to which the patient adheres to the given treatment instructions. Research by Zhang et al. (2021) reported a Cronbach's α value of 0.625 for the MMAS-8 questionnaire. Although a Cronbach's α value

of ≥ 0.8 is recommended, a value of ≥ 0.6 is considered acceptable according to previous studies by Robinson et al. (1991) as cited in Zhang et al. (2021). The relatively low Cronbach's α value may be attributed to patient characteristics, including age, differences in diseases, and the repetition of questions within the questionnaire.

Table 3.3 Morisky Medication Adherence Scale – 8 items (MMAS – 8)

No.	Question	Answer
1.	Do you sometimes forget to follow your treatment or take your medication?	Yes/No
2.	People sometimes fail to follow their treatment or take their medication for reasons other than forgetting. Thinking about the last two weeks, have there been days when you did not follow your treatment or take your medication?	Yes/No
3.	Have you ever reduced or stopped following your treatment or taking your medication without informing your doctor because you felt worse when taking it?	Yes/No
4.	When traveling or leaving home, do you sometimes forget to bring your medication?	Yes/No
5.	Do you follow your treatment or take your medication as scheduled last time?	Yes/No
6.	When your symptoms feel under control, do you sometimes stop following your treatment or taking your medication?	Yes/No
7.	Taking medication every day can be inconvenient for some people. Have you ever felt bothered by following your treatment plan?	Yes/No

8.	Do you have trouble remembering to follow your treatment or take all of your medications?	Yes/No

Each answer given in MMAS – 8 has a specific value that is calculated to determine the patient's level of compliance. A score of 0 – <6 indicates a low level of compliance, a score of 6 – <8 indicates a moderate level of compliance, and a score of 8 indicates a high level of compliance. The total score is calculated by adding the answer scores of each question, the higher the total score indicates the better the patient's level of medication compliance.

Table 3.4 The Outline of the Morisky Medication Adherence Scale – 8 items (MMAS – 8)

No.	Aspects	Items	Total
1.	Forgetting to take medication	1	1
2.	Compliance in the last two weeks	2	1
3.	Reducing or stopping medication without consultation	3	1
4.	Forgetting to take your medication with you	4	1
5.	Adherence to treatment schedule	5	1
6.	Stop taking medication when there are no symptoms	6	1
7.	Discomfort following a treatment plan	7	1
8.	Difficulty remembering to take medication	8	1

3.8 Data Processing

Data processing is a set of methods and procedures used to collect, compile, analyze, and interpret data (Yasin et al., 2023). Data processing aims to transform raw data into more meaningful information, which can be used for decision-making or other purposes in research. The researcher uses the SPSS data processing application to process the data that has been obtained from the respondents which includes the editing, entry, and cleaning stages.

The researcher first conducts an editing stage which aims to check and correct errors or inconsistencies in the data that has been collected before further analysis. Then it was continued with the coding stage to classify the answers to the questionnaire that had been filled out by the previous respondents. After that, the researcher entered the data into the SPSS program and continued with the cleaning process to check whether there were variables or data that did not match.

3.9 Data Analysis

3.9.1 Univariate Analysis

Univariate analysis is an approach used to describe in detail each variable that is the focus of the research by paying attention to the distribution of data frequencies (Nursalam, 2015). The researcher grouped the general characteristics of the respondents such as age, occupation, gender, and education as categorical variables. These data are analyzed using descriptive statistics, namely frequency distributions described in the form of percentages of each variable.

3.9.2 Bivariate Analysis

Bivariate analysis is a data analysis approach involving two variables. This analysis method is used on two variables, namely dependent and independent variables that are suspected of having an attachment or relationship (Notoatmodjo, 2018). Bivariate analysis in this study was carried out to identify factors that affect chemotherapy treatment adherence in patients with breast cancer.

The researcher conducted a bivariate analysis using the simple multiple logistic regression method. Multiple logistic regression is used to model the relationship between one dependent variable and one or more independent variables. This study was carried out using a predictive model. The aim of this modeling is to obtain a model consisting of independent variables that are considered most influential in predicting the occurrence of the dependent variable. Then, the researcher conducted a bivariate analysis between the dependent variable and each existing independent variable. If the test results show a p < value of 0.25, then the variable can be included in the multivariate model. However, if the test results show a p value > 0.25, then the variable can still be included in the multivariate model if it is considered important in substance. If the results of data show that there is only one factor that most influences breast cancer patient compliance in undergoing chemotherapy treatment, then data processing will not be continued to multivariate analysis.

3.9.3 Multivariate Analysis

Multivariate analysis is used to determine the relationship between more than one independent variable and one dependent variable. In this study, a double logistic regression test was used as a statistical test to find out which independent variables had a closer relationship with patient compliance in undergoing chemotherapy treatment.

After the variables that are the modeling candidates in the multivariate analysis are obtained, the next stage is to perform a double logistic regression test using the backward method. If the test results show a p-value > 0.05, then the variable must be excluded from the modeling. The double logistic regression test was carried out gradually until there were no variables that had a p-value > 0.05. The expenditure of variables with p-value is not done simultaneously, but gradually starts from the variable that has the largest p-value.

After that, the researcher identified the linearity of numerical variables by grouping the variables into 4 groups based on their quartile values. Then the researcher conducted a logistical analysis and calculated the OR value. If the OR value of each group of variables shows a straight line shape, then a numerical variable can be used, but if the results show a fault, then the researcher can consider changing the variable into a categorical form.

If the researcher has obtained a model that contains important variables, then the researcher must examine the possibility of interaction between variables into the model through substantive logical considerations. If the variable has a

meaningful value, then the interaction variable must be incorporated into the modeling.

3.10 Data Presentation

In the process of preparing this research report, the presentation of data is intended to facilitate a clearer understanding and more accurate analysis of the collected information, thereby supporting the attainment of the research objectives. The data obtained from each participant are systematically presented in tabular format, followed by descriptive explanations in the form of narrative text, to provide a comprehensive interpretation of the research findings.

3.11 Research Ethics

This research involves human participation as a subject, so a feasibility test or ethical clearance is needed to be in accordance with ethical norms and to protect the rights and safety of respondents (Komorowski & Trappel, 2023). Before the research was carried out, the researcher submitted an ethical feasibility standard test to the Ethics Commission of the Malang Ministry of Health. Ethical principles in research can be distinguished into 3 types, namely the principle of respecting human rights, the principle of benefits, and the principle of justice (Nursalam, 2015).

1. Principles of Respect for Human Rights
    a. Informed Consent

        Informed consent is a process in which research participants are given sufficient and clear information about the objectives, procedures, potential

risks, and benefits of the research being followed, so that respondents can make a conscious and voluntary decision to participate. Informed consent is a basic principle in research ethics to protect the rights and welfare of respondents. This process also helps to ensure that the research conducted is transparent and fair, and to avoid exploitation or abuse of respondents.

b. Right to Full Disclosure

It is the right of every research participant to be treated fairly, with dignity, and free from exploitation, discrimination, or unnecessary harm. This right ensures that any respondent will not be exposed to adverse or unethical treatment during the research process.

c. Right to Self Determination

It is the right of each individual to choose voluntarily whether the respondent is willing to participate in the research or not, without any coercion or pressure. This right is one of the basic principles in research ethics that respects the freedom and autonomy of respondents.

2. Principle of Benefits

a. Free from exploitation

The research process must be carried out by avoiding unfortunate events for respondents. Researchers must provide confidence that the participant's participation and personal information are not misused for things that can be detrimental in any form.

b. Free from suffering

During the research process, all actions must be taken to avoid suffering to the respondents, especially when providing a special intervention.

c. Risks (benefits ratio)

The research must pay attention to and take into account the benefits and risks that can be felt by the respondents during the research process or the provision of interventions.

3. Principles of Justice

a. Right to Privacy

The research process must provide confidentiality rights for each respondent for each data and information that has been obtained during the research process. Maintaining data confidentiality is a key element in maintaining respondents' trust and ensuring that research is conducted with respect for each individual's right to privacy.

b. Right in Fair Treatment

It is the right of participants to be treated fairly and equally in research, especially regarding access to benefits or medical treatment that should be received without discrimination or adverse treatment.