Protocol title:

EFFECT OF WHITE TEA (*Camellia sinensis* L.) BEVERAGES ON ANTHROPOMETRIC, HEMATOLOGICAL, BIOCHEMICAL AND FIRST LINE ANTIOXIDANT ENZYMES ACTIVITY OF HEALTHY HUMAN (SUPEROXIDE DISMUTASE, CATALASE, AND GLUTATHIONE PEROXIDASE)

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Archiving samples and raw data	Sample archiving will be placed in a locked cabinet in the Pharmacology Laboratory, Faculty of Pharmacy, Padjadjaran University.

1. PROTOCOL RESUME

1.1. Protocol Resume

Protocol title:

Effect of White Tea (*Camellia sinensis* L.) Beverages on Anthropometric, Hematological, Biochemical and First Line Antioxidant Enzymes Activity of Healthy Human (Superoxide Dismutase, Catalase, and Glutathione Peroxidase)

Research aims:

Understanding the potential of white tea for human health in terms of anthropometry (body weight, body mass index and waist circumference), blood pressure and biochemistry (lipid profile, blood glucose levels and antioxidant enzyme activity). Furthermore, the safety of white tea products will be evaluated by means of haematological parameters (red blood cells, haematocrit, haemoglobin, mean corpuscular volume (MCV), and mean corpuscular haemoglobin (MCH)), liver parameters (alanine aminotransferase (ALT) and aspartate aminotransferase (AST)), and renal parameters (creatinine levels, estimated glomerular filtration rate (eGFR), and blood urea nitrogen) following a 14-day period of white tea consumption.

Study design:

This study will combine a pilot study with a pre-post quasi-experimental design.

Specific aims

1. Determine the effect of white tea consumption on the anthropometry of healthy subjects based on body weight, body mass index, waist circumference, and blood pressure.
2. Determine the effect of white tea consumption on the biochemical parameters of healthy subjects based on blood glucose, lipid profile (total cholesterol, low-density lipoprotein (LDL), high-density lipoprotein (HDL), and triglycerides), alanine aminotransferase (ALT), aspartate aminotransferase (AST), serum creatinine levels, estimated glomerular filtration rate (eGFR), and urea nitrogen levels.
3. Determine the effect of white tea consumption on blood parameters in healthy subjects based on red blood cell count, haemoglobin, haematocrit, mean corpuscular haemoglobin (MCH), and mean corpuscular volume (MCV).
4. Determine the effect of white tea consumption on the activity of first-line antioxidant enzymes (superoxide dismutase, catalase, and glutathione peroxidase) in healthy subjects.

Pre-post quasi-experimental study design

The present study was conducted over a period of 14 days with the aim of observing the effects of white tea consumption on anthropometric parameters, blood pressure, haematology, biochemistry, and antioxidant enzymes activity. Prior to the intervention, subjects were instructed to undergo a washout phase. During the washout phase, subjects were instructed to refrain from consuming vitamins, herbal drinks containing spices (turmeric, ginger, and galangal), fruits with high flavonoid content (grapes, apples, oranges, and their processed products), and products containing high levels of tannins (coffee, other types of tea, and chocolate). This approach was adopted to mitigate potential bias and to avert the occurrence of anemia or other forms of toxicity.

Subsequently, a series of anthropometric, blood pressure, complete haematology, and biochemistry tests are conducted to ascertain which subjects meet the criteria to proceed to the research stage. Subjects who meet the specified criteria will then be educated on the art of tea-making and instructed to consume it for a period of 14 days. During the administration stage of white tea, subjects are instructed to refrain from using the products that they abstained from during the washout stage. Anthropometric measurements, blood pressure, complete haematology, and biochemistry tests will be performed again on day 15 and the day after last day white tea administration. Subsequently, all subjects will undergo a period of post-intervention monitoring (the observation phase) for a duration of seven days. The purpose of this monitoring is to ensure that no deleterious effects result from the white tea intervention.

Sample Size Calculation

This study is a pilot study, and the minimum sample size calculation will be performed using the thumb method through an NCT approach with 90% power and a significance value of 5%. The calculation indicated that, given a 20% attrition rate, a sample size of 19 subjects was required for the study.

Subject:

The total number of subjects included in the study was 19, with an age range of 20-35 years (excluding women who were either unmarried or sexually inactive). These subjects resided in the vicinity of Padjadjaran University and had provided written consent by signing an informed consent form. The subjects must be in good health, have not been active smokers for a period of less than five years, and have no history of anaemia, cardiovascular disease, or liver and kidney disorders. The exclusion criteria employed are outlined below:

a. Participants were required to take certain medications or vitamin supplements.
b. The subjects reported experiencing discomfort during the administration of the product.
c. Prior to the initiation of treatment, biochemical results were found to be outside the normal range.

Consent to Respondents

Informed consent will be requested by the research team before the washout period begins. Consent will be given in writing in the form of a signed consent form by the respondents.

Respondents Recruitment

The patient recruitment process was executed through the dissemination of advertisements utilising Google Forms, which were subsequently propagated via social media WhatsApp groups and Instagram. Following an initial screening process based on the information provided in the Google Forms by prospective research subjects, the research team made a selection based on inclusion criteria to obtain patients who met the specified criteria.

Test Product

The test product provided was 4 grams of white tea, packaged in a tea bag. The respondents were instructed to brew one tea bag in 200 mL of hot water for 10 minutes. The ingestion of the white tea should be scheduled for one hour prior to or two hours after breakfast.

Monitoring During Intervention
During the white tea intervention process, subjects will be monitored for food and beverage intake and daily activities. Please refer to Appendix 1 for a comprehensive overview of the daily data.

Research Duration
The research is estimated to take 28 days, including the first seven days for the washout phase, the second 14 days for the intervention phase, and the last seven days for the observational stage. This is to ensure that the subjects do not experience any serious effects as a result of the research.

Data Collection
All data pertaining to the study will be stored on CRFs/individual screening sheets. The data will be recorded in both soft and hard file formats on a daily basis.

Evaluation Criteria
Anthropometric measurements, blood pressure, haematology, and biochemistry tests will be conducted before the intervention and one day after the last intervention (day 0 and day 15). Anthropometric measurements, blood pressure, and blood sampling will be conducted at the Faculty of Pharmacy, Padjadjaran University. The biochemical examinations will be carried out at the clinical laboratory of the Bandung City Health Office, while the complete haematology and antioxidant enzyme examinations will be carried out at the Biomedical Laboratory of the Faculty of Medicine, Padjadjaran University. The results of the examinations conducted before and after the white tea intervention will be analyzed to ascertain the effect of white tea consumption over a period of 14 days. The types of food and beverages consumed by the research subjects and their daily activities were recorded in the CRF for a period of 28 days (from the wash-out phase to the observational phase).

Statistical Analysis
The effect of white tea administration will be compared before and after treatment using a t-test analysis.

1.2. Proposal Summary

Background

In the contemporary era, there is a general consensus that individuals have the capacity to procure a wide variety of goods and services with ease. A pertinent example of this phenomenon is the accessibility of food. A significant proportion of the population may be unconsciously adopting unhealthy lifestyles, characterised by the consumption of junk food in place of healthy foods, and an insufficient amount of exercise and rest, potentially attributable to their demanding workloads. These factors are supported by rapid industrial development, which also contributes to increased pollution, thereby increasing the production of free radicals in the human body. It is evident that the excessive and protracted generation of free radicals will exert a substantial influence on the onset of degenerative diseases, including cardiovascular disease, diabetes mellitus, cancer, and other grave pathologies.

The objective of the present study is to assess the antioxidant potential of white tea, with a view to providing the public with a reference point for high-antioxidant products that are more convenient and safer to consume. White tea has been shown to be effective in other countries, such as China, but the potential of white tea produced in Indonesia has not yet been extensively investigated. Geographical differences in the cultivation of tea have been demonstrated to result in discrepancies in content and effects. In the event of efficacy being demonstrated, it would be beneficial to conduct further testing of its potential in other, more specific diseases. Patients who meet the specified criteria will be instructed to consume white tea for a period of 14 consecutive days, while ensuring that they avoid the consumption of products that are rich in antioxidants, such as vitamins, herbal drinks (turmeric, ginger, and galangal), fruits with high flavonoid content (grapes, apples, oranges and their processed products), and products containing high tannin compounds (coffee, other types of tea, and chocolate). During the white tea consumption phase, subjects will be asked to report their daily food and beverage intake, as well as their daily activities. Clinical examinations will be conducted in two phases: the first prior to the administration of white tea, and the second after a 14-day period of white tea consumption. The data will be examined and compared before and after the administration of white tea to analyze the effects of white tea on human health. Should the study demonstrate a satisfactory degree of potential, it may be utilised as a point of reference to ascertain its broader potential for the treatment of specific diseases.

Metodologi

This study will analyze the potential effects of consuming white tea for 14 consecutive days. During the 7 days prior to white tea consumption (wash-out stage) and the 14 days during white tea consumption (treatment stage), all research subjects were instructed to avoid consuming products high in flavonoids, such as vitamins, herbal drinks containing spices (turmeric, ginger and kencur), fruits high in flavonoids (grapes, apples, oranges and their processed products), and products containing high levels of tannins (coffee, other types of tea, and chocolate). This was done to avoid excessive flavonoid intake, which can trigger anaemia and the formation of pro-oxidants. In addition, the presence of other strong antioxidants can also cause errors in the test (leading to bias) due to the influence of other antioxidant products. Furthermore, all respondents will be asked to drink white tea (made by brewing 4 grams of white tea in 200 mL of hot water) every morning one hour before eating or two hours after eating. To ensure the compliance of the research subjects, we will ask respondents to send videos of themselves consuming white tea, monitor and record the food and drinks consumed by all subjects in the CRF.

White tea is a type of tea that is believed to have better antioxidant content than other types of tea due to its high content of flavonoid compounds, especially catechins. If regular consumption of white tea for 14 days is proven to have a positive effect on anthropometric parameters, lipid profile, blood sugar levels and increases antioxidant enzyme activity, and is proven to be safe when reviewed from haematological parameters, ALT, AST, serum creatinine levels and eGFR, then this product can be further developed as a product for adjuvant therapy in various types of diseases. This study was conducted as an initial test of the potential of white tea for health before further exploration for application to a specific disease.

1.3. List of Abbreviations and Definitions

ALT : Alanine aminotransferase
APOB : Apolipoprotein B
AST : Aspartate aminotransferase
BMI : Body mass index
CAT : Catalase
CRF : Case Report Form
EDTA : Ethylene Diamine Tetra acetic Acid
EGCG : Epigallocatechin Gallate
EGC : Epigallocatechin
eGFR : estimated Glomerular Filtration Rate
GPx : Glutathione Peroxidase
Hb : Hemoglobin
HCT : Hematocrit
HDL : High-density Lipoprotein
LDL : Low-density Lipoprotein
LDLR : Low-density Lipoprotein Receptor
MCV : Mean Corpuscular Volume
MCH : Mean Corpuscular Hemoglobin
MTTP : Microsomal Triglyceride Transfer Protein
RBC : Red Blood Cells
ROS : Reactive Oxidative Stress
SOD : Superoxide Dismutase

2. Introduction

2.1. Background

Reactive oxygen species (ROS) are natural products of oxygen metabolism in living cells (1–3). Excessive ROS production triggers oxidative stress in the human body (4, 5). The long-term exposure to oxidative stress has been demonstrated to be a contributing factor to the development of several degenerative diseases, including cardiovascular disease, cancer and various other chronic conditions. These diseases currently represent the leading causes of mortality in the human population (6–8). In 2019, the global mortality rate was 28% higher than in 2000. The number of cardiovascular disease cases in Indonesia reached 2,784,064, while diabetes mellitus cases reached 16 million (9). The World Health Organization (WHO) also reports cancer as the leading cause of death worldwide, with 10 million deaths in 2020 (10, 11).

The prevalence of degenerative diseases in contemporary society is attributable to a multitude of factors, chief among which is an unhealthy lifestyle that engenders excessive ROS formation. Antioxidants are vital for neutralizing and reducing ROS production in the body. White tea (Camellia sinensis) is one such antioxidant whose potential for exploration is significant (12). Catechins and polysaccharides have been identified as the bioactive compounds responsible for the wide range of biological activities exhibited by white tea, which include hypoglycemic, hypolipidemic, and antioxidant properties (13). Previous studies have reported that EGCG and EGC are capable of regulating gene expression in cholesterol metabolism, such as low-density lipoprotein receptor (LDLR), microsomal triglyceride transfer protein (MTTP), and apolipoprotein B (APOB) (14). Supported by other studies, white tea has been shown to suppress the adipogenesis process by increasing lipolytic activity (15). It has been documented that white tea has the capacity to reduce creatinine and blood urea nitrogen levels in female rats afflicted with kidney disorders induced by cisplatin (16). As demonstrated in our preceding preclinical research, a dose-response relationship has been observed between white tea consumption and several parameters, including ALT, AST, lipid profile, red blood cells, haematology, and haematocrit, in healthy rats. It was hypothesised that the most significant increase in ALT and AST values would occur at higher doses. This hypothesis was tested, and it was concluded that 0.072 mg/day of white tea (equivalent to a human dose of 4 g/day) was more effective than 0.144 mg/day (equivalent to a human dose of 8 g/day). This phenomenon may be attributable to the production of pro-oxidants, a consequence of the elevated antioxidant content present in high concentrations of white tea. The objective of this study was twofold: firstly, to analyze the effectiveness of a 4 g/day dose in humans on human health parameters; and secondly, to ensure the safety of using this dose for 14 days.

2.2. Product Dosage

The dosage employed in the clinical trials pertains to in vivo studies conducted on both normal Wistar rats and CCl4-induced rats, with varying doses of white tea ranging from 0.072 to 0.144 milligrams per kilogram of body weight, administered over a period of 14 days. In consideration of the findings and the outcomes of an analysis of numerous parameters, including complete haematology (RBC, Hb, Hct, MCV and MCH), biochemistry (ALT, AST, total cholesterol, LDL, HDL and triglycerides), and antioxidant enzyme activity (SOD, CAT, and GPx), it was determined that a dose of 0.072 mg/kg BW exhibited the most efficacious and secure effect on these parameters. The 0.072 mg/kg BW dose for rats was adopted from the conversion of a 4 gram/day

human dose. The present study will utilize a dosage of 4 grams of white tea in 200 millilitres of water, to be consumed on a daily basis for a period of 14 days.

2.3. Known Risks and Potential Health Benefits of White Tea Consumption

Possible risks associated with drinking white tea that have been studied:

- White tea contains theophylline and caffeine (17). Theophylline has been demonstrated to induce acid reflux, a factor which can precipitate the development of erosive oesophagitis. Consequently, the burning sensation experienced by the subject may be attributable to elevated levels of theophylline entering the body. The presence of caffeine in white tea has been demonstrated to induce adverse effects, including symptoms such as nausea and vomiting.
- Caffeine, a stimulant compound found in tea, has been observed to induce calcium release, thereby facilitating increased muscle contractions. Furthermore, it has been demonstrated that caffeine can induce the secretion of stimulatory agents such as prostaglandin, adenosine triphosphate, acetylcholine and nitric oxide from the urothelium, thereby stimulating augmented urine production in the bladder (18).
- Catechins, a type of polyphenol found in white tea, have been shown to possess therapeutic benefits in treating various diseases. However, in excessive doses, they have the potential to cause excessive pro-oxidant effects, triggering inflammatory reactions, necrosis and steatosis in the liver (18).
- The high polyphenol content of white tea has been demonstrated to have a potential inhibitory effect on iron absorption, which may consequently result in iron deficiency and the subsequent development of anaemia (19–21).

Benefits associated with drinking white tea that have been studied:

- Catechins and polysaccharides are believed to be responsible for the broad biological activity exhibited by white tea, which includes hypoglycaemic, hypolipidaemic, and antioxidant properties (13).
- The ingestion of green tea (Camellia sinensis) for a period of two months has been demonstrated to engender favourable outcomes in elderly subjects afflicted with metabolic syndrome. These outcomes encompass a reduction in weight, BMI, and waist circumference (22).
- The administration of three cups of green tea infusion (7.5 g/day) has been demonstrated to enhance the lipid profile in patients with T2DM nephropathy, without compromising renal function (23).
- It has been demonstrated that EGCG, a polyphenol compound found in green tea, possesses the ability to regulate glucose homeostasis by promoting glucose uptake in adipocytes, reducing insulin resistance, and decreasing blood glucose levels (24).
- Green tea (600 mL/day) for 4 weeks was reported to maintain the health of healthy respondents. This was evidenced by no significant changes in haematological profile (RBC, Hb, Hct, MCV, and MCH), serum creatinine, eGFR, and serum urea (25).
- The ingestion of three cups of green tea (100 mL per cup) per day has been demonstrated to enhance the activity of superoxide dismutase (SOD), catalase (CAT), glutathione (GSH), and glutathione peroxidase (GPx) in chronic smokers(26).

3. REASONS AND OBJECTIVES OF THE RESEARCH

3.1. Justification for Study

A plethora of studies conducted in various countries, including China, Japan, and Turkey, have demonstrated the health benefits of white tea, including its potential as an anticancer, anti-obesity, antihyperlipidemic, and antidiabetic agent. Geographical differences in the countries where Camellia sinensis tea is cultivated will affect its chemical composition. A review of the extant literature reveals a paucity of studies exploring the potential of white tea from Indonesia for human health. The present study will examine the antioxidant capacity of white tea, with a view to providing new references for the public regarding white tea products as antioxidants that can be used as products to improve public health.

3.2. Research objectives

The objectives of this study are:

1. Determine the effect of white tea consumption on the anthropometry of healthy subjects based on body weight, body mass index (BMI), waist circumference, and blood pressure.
2. Determine the effect of white tea consumption on biochemical parameters in healthy subjects based on blood sugar levels, complete lipid profile (total cholesterol, low-density lipoprotein, high-density lipoprotein, and triglycerides), liver function activity (based on liver enzyme function including alanine aminotransferase and aspartate aminotransferase), and kidney function (through measurement of creatinine levels, estimated glomerular filtration rate, and urea nitrogen levels).
3. Determine the effect of white tea consumption on hematology profile parameters associated with anaemia, including total red blood cell count, haemoglobin, haematocrit, mean corpuscular haemoglobin (MCH), and mean corpuscular volume (MCV).
4. Determine the effect of white tea consumption on the first line antioxidant enzymes activity of healthy subjects, such as superoxide dismutase, catalase, and glutathione peroxidase.

4. STUDY DESIGN

The present study adopts a quasi-experimental design, conducted as a pilot study, with the objective of ascertaining the effect of white tea consumption on several human health parameters. These parameters include anthropometry, blood pressure, haematology, biochemistry, and antioxidant enzyme activity. The study is divided into three stages. Firstly, a washout stage is conducted over the first seven days. This is followed by an intervention/treatment stage for 14 days, which is conducted one day after blood sampling. Finally, an observation stage is conducted for the last seven days to ensure that the subjects are in good condition after the intervention.

5. RESEARCH LOCATION

The research will be conducted in several locations, including:

1. Faculty of Pharmacy, Padjadjaran University.
2. Biomedical Laboratory, Faculty of Medicine, Padjadjaran University.
3. Clinical Laboratory, Bandung City Health Office, Bandung, West Java.

6. TARGET POPULATION AND SAMPLE SIZE

The population utilised in this study comprised healthy subjects residing at Padjadjaran University and its environs who had completed the recruitment form on Google Forms. The respondents' data that had been entered underwent preliminary screening based on the following inclusion and exclusion criteria.

Inclussion criteria

a. Participants are members of the Padjadjaran University community and surrounding areas aged 20-35 years (excluding women who were either unmarried or sexually inactive).
b. Participants must not have been smokers for less than 5 years.
c. Participants must not have a history of anaemia, liver or kidney disease.

Exclussion criteria

a. Participants were required to take certain medications or vitamin supplements.
b. The subjects reported experiencing discomfort during the administration of the product.
c. Prior to the initiation of treatment, biochemical results were found to be outside the normal range.

This study utilised a pilot study, and the minimum sample size calculation was performed using the thumb method with a non-central t-distribution (NCT) approach. Whitehead stated that the minimum sample size for a power (β) value of 90% and a significance (α) value of 5% is 15 for each group. Considering a 20% possibility of dropouts, we used 19 subjects in the study. The following table provides a reference for the calculation of the sample size, as outlined by Whitehead et al. (2016) (27).

Table 8. Estimated stepped rules of thumb for required pilot trial sample size per treatment arm when the NCT approach will be used to calculate the main trial sample size.

Standardised difference	80% powered main trial	90% powered main trial
Extra small ($\delta < 0.1$)	50	75
Small ($0.1 \leq \delta < 0.3$)	20	25
Medium ($0.3 \leq \delta < 0.7$)	10	15
Large ($\delta \geq 0.7$)	10	10

7. RESEARCH PROCEDURE

7.1. Recruitment of Respondents and Initial Screening

The data collected from respondents will undergo a review and selection process, with this being based on predetermined inclusion and exclusion criteria. A proportion of respondents who meet the specified criteria will be directed to undergo a 7-day washout period. The purpose of this procedure is to prevent bias in the initial screening process. During this phase, subjects are instructed to avoid the consumption of vitamins, herbal drinks containing spices (turmeric, ginger and galangal), fruits with high flavonoid content (grapes, apples, oranges and their processed products), and products containing high levels of tannins (coffee, other types of tea, and chocolate).

7.2. Procedures for Requesting Permission from Research Subjects

Patients who are deemed to be eligible will be provided with an explanation of the research process and will be requested to provide their voluntary consent. As the population under study consists of adults in good health, consent must be obtained directly from the participant via a process of signing the consent form after receiving an

explanation (informed consent). The signing process will be initiated subsequent to the subject being deemed to have comprehended the explanation pertaining to the research. The signing process will be carried out by the respondent, the researcher, and a witness who will observe the consent process.

7.3. Respondents Selection

Patients who have been declared eligible during the preliminary screening and have signed the consent form will be provided with instructions on how to prepare the tea. It is imperative that the CRF be completed in a manner that is both legible and exhaustive.

7.4. Provision of Test Products

Following the endorsement of the consent form, each subject will be furnished with a set of fourteen tea bags, each containing four grams of white tea. These tea bags will be accompanied by comprehensive instructions detailing the optimal preparation of the tea. Subjects are instructed to brew one tea bag in hot water for 10 minutes. The tea must be consumed one to two hours after breakfast for a period of 14 days.

Product Storage

White tea products should be stored in a sealed container at room temperature.

Guarantee of research subject compliance

Subject compliance will be monitored each morning by asking subjects to send a video of themselves drinking the beverage product every day.

7.5. Respondent Monitoring

Monitoring of anthropometry and blood pressure

The subjects of the research will undergo physical monitoring, including weight, height, BMI, waist circumference and blood pressure, by research team on days 0 and 15 (one day before and one day after the last day of the white tea intervention).

Laboratory monitoring

Laboratory monitoring was conducted on days 0 and 15 (one day before and one day after the last day of the white tea intervention) on blood samples from subjects in order to determine the effects of drinking tea for a period of 14 days. Should the preliminary investigative results pertaining to haematological parameters (RBC, HB, HCT, MCV and MCH), ALT, AST, serum creatinine levels, eLFG and urea nitrogen levels demonstrate abnormality, the subject will be withdrawn from the study for reasons of safety. Haematological tests are performed to ensure that the subject is not anaemic. ALT and AST tests are performed to ensure that there is no liver dysfunction, while serum creatinine, eGFR, and urea nitrogen tests are performed to ensure that the subjects do not have kidney dysfunction. In summary, the parameters employed in this study to observe the effects of white tea consumption are outlined as follows:

a. Hematology profile
b. Lipid profil
c. Fasting blood glucose
d. ALT dan AST
e. Serum creatinine level, urea nitrogen level and eGFR
f. First line antioxidant enzymes (SOD, CAT dan GPx).

Monitoring consumption and daily activities

In order to ensure that respondents adhere to the prescribed dietary regime, researchers will ensure that subjects abstain from the consumption of particular products that must be avoided during the course of the research process. Researchers will record all food and beverages consumed, the subjects' daily activities, and any complaints that may be experienced by the subjects, whether related or unrelated to the administration of white tea products.

7.6. Discontinuation of Respondent Involvement in Research

Research subjects may withdraw from participation in the study, and researchers may also terminate a subject's involvement in the study if there is a deviation from the protocol. If a research subject is terminated for medical reasons, the researcher will ensure that their health is monitored until their condition improves.

7.7. Anthropometric Measurement

Measurements of body weight, height, and waist circumference for the study will be taken on day 0 (one day before the intervention) and day 15 (one day after the last day of the white tea intervention). Participants are advised to wear light clothing and remove their shoes before weight and height measurements. BMI values will be calculated using an online BMI calculator based on weight (kg) and height (cm) (nhlbi.nih.gov/health/education/lose_wt/BMI/bmi-m.htm).

7.8. Blood Pressure Measurement

Concurrently, blood pressure assessments will be conducted on the day of blood sampling. The protocol for conducting blood pressure tests is outlined as follows:

a. Participants are asked to rest for 5 minutes before blood pressure measurement without talking during the rest period.
b. Participants are asked to sit upright with their back against the chair, ensuring that both feet are flat on the floor.
c. Blood pressure measurement will be taken in a sitting position with the sleeve of the shirt open.
d. The sphygmomanometer is placed on the right or left arm approximately 3 cm above the elbow crease. The arm cuff should not be too tight or too loose.
e. The start button on the sphygmomanometer monitor is pressed. Blood pressure measurements will be taken three times, with a 1-minute interval between each measurement.
f. The systolic and diastolic pressure results are recorded.

7.9. Hematology Profile Measurement

Haematological analysis will be conducted at the clinical laboratory of the Bandung District Health Office. Blood samples were collected on day 0 (one day before the intervention) and day 15 (one day after the last day of the white tea intervention). The samples were stored in EDTA tubes and analyzed using an Erba H360 automatic haematology analyzer.

7.10. Biochemical Measurement

The investigation involved the performance of a comprehensive array of analytical procedures, including lipid profile, blood glucose, blood urea nitrogen, serum creatinine, ALT and AST tests. These were conducted at the Bandung District Health Office clinical laboratory, employing the utilisation of a Cobas C 311 biochemical automatic analyzer.

7.11. estimated Glomerular Filtration Rate Value Measurement

The creatinine level obtained will be used to calculate the eGFR value. The eGFR value will be calculated using an online calculator based on creatinine level, age, and gender. (https://kidney.org.au/health-professionals/egfr-calculator).

7.12. Antioxidant Enzymes Analysis

Antioxidant enzyme activity testing will be conducted at the Biomedical Laboratory, Faculty of Medicine, Padjadjaran University. Enzyme activity analysis will be performed on human blood serum collected on days 0 and 15. The analysis of antioxidant enzyme activity encompasses the assessment of superoxide dismutase (SOD), catalase (CAT) and glutathione peroxidase (GPx) activity. The analysis procedure will refer to the manual guideline in the Elabscience KIT.

8. STATISTICAL ANALYSIS

The mean data before and after treatment will be tested for homogeneity and normality. In order to draw parallels between the two data sets, parametric measurements will be considered using the T-test for data with normal distribution, while data with abnormal distribution will be analyzed using a non-parametric test, namely the Wilcoxon test. The statistical analysis of all data will be conducted using SPSS version 20.0.

9. STORAGE OF FILES AND DATA

9.1. Data Collections

Paper-based CRFs (hard files) will be used to record data, with copies being made in the form of scanned files and stored in the researcher's personal Google Drive, with access restricted to the principal investigator. It is imperative that all CRFs are completed for each research subject. In order to reduce errors in filling out the forms and inconsistencies between the data in the CRF and the database, the data manager will validate the data as follows: by entering the numerical data twice into the database (double data entry), by rereading the comments written, or by entering the data once with 100% Quality Control (QC). In the event of any discrepancies, the resolution process will be initiated through the utilisation of a data clarification form, which must be signed by the researcher. It is imperative to note that the clarification sheet will be attached to the original CRF, thus serving as a crucial instrument for the rectification of any data that may be found to be inconsistent.

9.2. Source Document

Source documents encompass all clinical information, laboratory results (in their original form or as certified copies), observations or other clinical activities deemed necessary for the reconstruction and evaluation of clinical trials. It is imperative that all source documents are retained by the investigator. It is incumbent upon the investigator to ensure that auditors, ethics committees and other officials are permitted to view source documents when required.

9.3. File Management in Clinical Trial Sites

Researchers have an obligation to ensure that files are stored in accordance with GCP and ethical guidelines.

9.4. Data and File Storage

It is incumbent upon the principal investigators to retain research files and data for security purposes, as well as for the purposes of audit and inspection following the completion of the research. It is imperative that essential documents be retained for a period of no less than five years.

10. QUALITY CONTROL AND ASSURANCE

10.1. Procedures at the Research Site

Standard Operating Procedures will be established for all relevant clinical and laboratory activities to ensure the quality of the research. Subject compliance will be monitored throughout the study to ensure adherence to the established inclusion and exclusion criteria. Researchers are obliged to sign and date all examination results, thereby confirming that said results have been reviewed. Researchers may appoint assistants to assist with the execution of research and the supervision of research assistants. Nevertheless, the onus for the research remains with the researcher.

Prior to the initiation of the research process, ethical approval will be sought. Researchers must ensure that all personnel have been adequately briefed and trained on SA GCP, ICH-GCP, protocols and all procedures for research purposes.

10.2. Research Supervision

The principal investigator will be responsible for the validity of the data collected. The purpose of monitoring is threefold: firstly, to ensure that the human rights of research subjects are protected; secondly, to ensure that research data is accurate, complete and verifiable against source data; and thirdly, to ensure that clinical trials are conducted in compliance with protocols and do not violate the ethical principles as stated in the Declaration of Helsinki.

The supervisor will inquire with the researcher about any missing or unclear data. All questions are to be addressed without delay. The supervision notes will document the findings during the supervision process, the reasons for the visit, and the signatures of the supervisor and research team.

10.3. Management of Research Data

The management of research data will adhere to rigorous protocols. All research data obtained will be entered into a screening form in hard copy format, which will then be meticulously compiled into a folder for each research subject. Subsequent to the entry of data, the screening form will undergo scanning on the same day and uploading to Google Drive as a soft copy, with the objective of minimising data loss. It is imperative to note that access to Google Drive is strictly limited to the primary research team, a measure that is crucial to ensure the strict confidentiality of the research data.

10.4. Audit

The audit process will be carried out by the principal investigator to assess compliance with the protocol, GCP guidelines and ethical principles. The objective of the audit is to evaluate the quality of data in terms of accuracy, adequacy and consistency, and to ascertain whether the research has been conducted in accordance with existing guidelines. As stipulated by Good Clinical Practice (GCP), a comprehensive review of all documentation pertaining to the research will be conducted as part of the audit. The audit will involve a comparison of the source documents with the CRF, with the objective

of ensuring the accuracy and adequacy of the recorded information. This process will include the verification of any side effects that may have occurred.

11. ETHICS AND RESPONSIBILITY

11.1. Basic Principles

This research will be conducted in accordance with the ethical principles set out in the Declaration of Helsinki.

11.2. Independent Ethics Committee Assessment

This research protocol will be reviewed by the Ethics Committee, which is an independent institution, and the Ethics Committee's assessment notes will be kept by the research team. Researchers will ensure the accuracy and completeness of the notes to be submitted to the Ethics Committee.

11.3. Informed Consent

Prior to the initiation of the study, written consent will be obtained from the subject, subsequent to the provision of a comprehensive explanation of the study.

Prior to participation, the researcher will furnish the subject with comprehensive information regarding the study. Subsequent to the communication of salient information and the determination of the subject's comprehension of the explanation, the informed consent form can be endorsed by the subject, the researcher, and a witness.

It is incumbent upon the researcher to ensure that each subject is provided with a full explanation of the research. The Ethics Committee must undertake a thorough evaluation of both the research participation consent form and information sheet, prior to their approval.

The original informed consent form is retained in the CRF, with a copy being provided to the patient. An additional copy is maintained in the patient's medical records.

Compensation for research subjects' expenses during the study:
The researcher will assume financial responsibility for all costs associated with care, laboratory tests and medication.

12. CONFIDENTIALITY

The confidentiality of subjects involved in this study will be guaranteed by the research team and field doctors involved. Only the study number and initials will be written in the CRF. All correspondence related to subjects will use the study number and initials. The informed consent form will include a statement allowing the research team to view the source data for review purposes.

13. PUBLICATION POLICY

The results of this study are to be submitted for publication upon completion of the research, in the form of a joint publication with clinical researchers.

14. IMPROVEMENT POLICY FOR PRODUCTIVITY

It is imperative that any amendments to the protocol that occur during the research process are submitted in the form of protocol amendments and submitted to the Ethics Committee prior to implementation, particularly those that affect the safety, well-being,

and comfort of research subjects. It is imperative that any such changes be subject to approval by both the researchers and the ethics committee.

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APPENDIX 1. SCREENING FORM FOR SUBJECTS

SAMPEL

Research Number:	**Respondent's initials: [___|___|___]**

SCREENING 1 – PERSONAL DATA

PERSONAL DATA			**Officer**
Date of data collection	:	[__|__] / [__|__] / [__|__] (DD/MM/YY)	
Name / inisial	:	[___|___|___]	
Place and Date of Birth			
Age	:	Tahun	
Gender	:	Pria / Wanita *	
Job	:		( )
Adress	:		
Contact	:		

Note: The first two boxes in the initials are filled in with the first two letters of the two words of the name, and the third box is filled in with the date of birth. If the date of birth contains two numbers, use only one of them.
Example: Name: Lidya Cahyo Bawono, Date of Birth: Januari 8th → [L|C|8].

MEDICAL HISTORY

History	Yes	No	Unknown
Have you ever had anaemia within the last 5 years?			
Do you have a history of kidney disorder?			
Do you have a history of stomach ulcers or GERD?			
Do you have a history of liver disorder?			
Are you an active smoker < 5 years?			
Are there any family members who smoke?			
Are you undergoing any medical treatment? Please specify!			

Signature of officer after filling out form: Initials: Date:

SAMPEL

Research Number:	Respondent's initials: [___|___|___]

SCREENING 2 – ANTHROPOMETRY AND BLOOD PRESSURE

ANTHROPOMETRIC EXAMINATION (PRE)	
Body weight : kg	Body height : cm
BMI : kg/m^2	
Waist Circumference: cm	
BLOOD PRESSURE MEASUREMENT (PRE)	
Blood pressure:	

ANTHROPOMETRIC EXAMINATION (POST)	
Body weight : kg	Body height : cm
BMI : kg/m^2	
Waist Circumference: cm	
BLOOD PRESSURE MEASUREMENT (POST)	
Blood pressure:	

Signature of officer after filling out form: Initials: Date:

SAMPEL

Research Number:	Respondent's initials: [___|___|___]

SCREENING 3 – BLOOD AND BIOCHEMICAL TESTS

a. Initial Screening

Parameters	Test Date/Time	Result	Status
Hematology Profile	[__|__] / [__|__] / [__|__|__|__] (DD/MM/YY) [__|__] . [__|__] WIB	RBC : 10^6/uL HB : g/dL HCT : % MCV : fL MCH : pg	☐ Eligible ☐ Not Eligible
Lipid Profile	[__|__] / [__|__] / [__|__|__|__] (DD/MM/YY) [__|__] . [__|__] WIB	TC : mmol/L HDL : mmol/L LDL : mmol/L Tg : mmol/L	☐ Eligible ☐ Not Eligible
Fasting Blood Glucose	[__|__] / [__|__] / [__|__|__|__] (DD/MM/YY) [__|__] . [__|__] WIB	mmol/L	☐ Eligible ☐ Not Eligible
ALT	[__|__] / [__|__] / [__|__|__|__] (DD/MM/YY) [__|__] . [__|__] WIB	µkat/L	☐ Eligible ☐ Not Eligible
AST	[__|__] / [__|__] / [__|__|__|__] (DD/MM/YY) [__|__] . [__|__] WIB	µkat/L	☐ Eligible ☐ Not Eligible
Creatinine	[__|__] / [__|__] / [__|__|__|__] (DD/MM/YY) [__|__] . [__|__] WIB	µmol/L	☐ Eligible ☐ Not Eligible
eGFR	[__|__] / [__|__] / [__|__|__|__] (DD/MM/YY) [__|__] . [__|__] WIB	mL/min/ $1.73m^2$	☐ Eligible ☐ Not Eligible
Ureum	[__|__] / [__|__] / [__|__|__|__] (DD/MM/YY) [__|__] . [__|__] WIB	mmol/L	☐ Eligible ☐ Not Eligible
Antioxidant enzymes	[__|__] / [__|__] / [__|__|__|__] (DD/MM/YY) [__|__] . [__|__] WIB	SOD: CAT: GPx:	☐ Eligible ☐ Not Eligible

Signature of officer after filling out form: Initials: Date:

SAMPEL

Research Number:	Respondent's initials: [___|___|___]

b. Final Screening

Parameters	Test Date/Time	Result	Status
Hematology Profile	[__|__] / [__|__] / [__|__|__|__] (DD/MM/YY) [__|__] . [__|__] WIB	RBC : 10^6/uL HB : g/dL HCT : % MCV : fL MCH : pg	☐ Eligible ☐ Not Eligible
Lipid Profile	[__|__] / [__|__] / [__|__|__|__] (DD/MM/YY) [__|__] . [__|__] WIB	TC : mmol/L HDL : mmol/L LDL : mmol/L Tg : mmol/L	☐ Eligible ☐ Not Eligible
Fasting Blood Glucose	[__|__] / [__|__] / [__|__|__|__] (DD/MM/YY) [__|__] . [__|__] WIB	mmol/L	☐ Eligible ☐ Not Eligible
ALT	[__|__] / [__|__] / [__|__|__|__] (DD/MM/YY) [__|__] . [__|__] WIB	µkat/L	☐ Eligible ☐ Not Eligible
AST	[__|__] / [__|__] / [__|__|__|__] (DD/MM/YY) [__|__] . [__|__] WIB	µkat/L	☐ Eligible ☐ Not Eligible
Creatinine	[__|__] / [__|__] / [__|__|__|__] (DD/MM/YY) [__|__] . [__|__] WIB	µmol/L	☐ Eligible ☐ Not Eligible
eGFR	[__|__] / [__|__] / [__|__|__|__] (DD/MM/YY) [__|__] . [__|__] WIB	mL/min/ $1.73m^2$	☐ Eligible ☐ Not Eligible
Ureum	[__|__] / [__|__] / [__|__|__|__] (DD/MM/YY) [__|__] . [__|__] WIB	mmol/L	☐ Eligible ☐ Not Eligible
Antioxidant enzymes	[__|__] / [__|__] / [__|__|__|__] (DD/MM/YY) [__|__] . [__|__] WIB	SOD: CAT: GPx:	☐ Eligible ☐ Not Eligible

Signature of officer after filling out form: Initials: Date:

SAMPEL

Research Number:	Respondent's initials: [___|___|___]

SKRINING 4 – MAKANAN, MINUMAN, KEGIATAN HARIAN DAN KELUHAN

Day-	Food Intake	Beverages / Supplement	Daily activity/ Complaint
1	Breakfast: Lunch: Dinner:	☐ **Fruit juice:** Yes / No* Indicate yes if applicable: ☐ **Vitamin** Yes / No* Indicate yes if applicable:	Sleep duration: Activity: Are you experiencing any of the following? (Please indicate when the symptoms began.) ☐ Nausea ☐ Vomiting ☐ Constipation ☐ Weakness ☐ Loss of appetite ☐ Fever ☐ Excessive fatigue
2	Breakfast: Lunch: Dinner:	☐ **Fruit juice:** Yes / No* Indicate yes if applicable: ☐ **Vitamin** Yes / No* Indicate yes if applicable:	Sleep duration: Activity: Are you experiencing any of the following? (Please indicate when the symptoms began.) ☐ Nausea ☐ Vomiting ☐ Constipation ☐ Weakness ☐ Loss of appetite ☐ Fever ☐ Excessive fatigue
3	Breakfast: Lunch:	☐ **Fruit juice:** Yes / No* Indicate yes if applicable: ☐ **Vitamin** Yes / No*	Sleep duration: Activity: Are you experiencing any of the following? (Please indicate when the symptoms began.) ☐ Nausea

Signature of officer after filling out form: Initials: Date:

SAMPEL

Research Number:	**Respondent's initials: [___|___|___]**

	Dinner:	Indicate yes if applicable:	☐ Vomiting ☐ Constipation ☐ Weakness ☐ Loss of appetite ☐ Fever ☐ Excessive fatigue
4	Breakfast: Lunch: Dinner:	☐ **Fruit juice:** Yes / No* Indicate yes if applicable: ☐ **Vitamin** Yes / No* Indicate yes if applicable:	Sleep duration: Activity: Are you experiencing any of the following? (Please indicate when the symptoms began.) ☐ Nausea ☐ Vomiting ☐ Constipation ☐ Weakness ☐ Loss of appetite ☐ Fever ☐ Excessive fatigue
5	Breakfast: Lunch: Dinner:	☐ **Fruit juice:** Yes / No* Indicate yes if applicable: ☐ **Vitamin** Yes / No* Indicate yes if applicable:	Sleep duration: Activity: Are you experiencing any of the following? (Please indicate when the symptoms began.) ☐ Nausea ☐ Vomiting ☐ Constipation ☐ Weakness ☐ Loss of appetite ☐ Fever ☐ Excessive fatigue
6	Breakfast:	☐ **Fruit juice:** Yes / No* Indicate yes if applicable:	Sleep duration: Activity: Are you experiencing any of the following? (Please

Signature of officer after filling out form: Initials: Date:

SAMPEL

Research Number:	**Respondent's initials: [___|___|___]**

	Lunch: Dinner:	☐ **Vitamin** Yes / No* Indicate yes if applicable:	indicate when the symptoms began.) ☐ Nausea ☐ Vomiting ☐ Constipation ☐ Weakness ☐ Loss of appetite ☐ Fever ☐ Excessive fatigue
7	Breakfast: Lunch: Dinner:	☐ **Fruit juice:** Yes / No* Indicate yes if applicable: ☐ **Vitamin** Yes / No* Indicate yes if applicable:	Sleep duration: Activity: Are you experiencing any of the following? (Please indicate when the symptoms began.) ☐ Nausea ☐ Vomiting ☐ Constipation ☐ Weakness ☐ Loss of appetite ☐ Fever ☐ Excessive fatigue
8	Breakfast: Lunch: Dinner:	☐ **Fruit juice:** Yes / No* Indicate yes if applicable: ☐ **Vitamin** Yes / No* Indicate yes if applicable:	Sleep duration: Activity: Are you experiencing any of the following? (Please indicate when the symptoms began.) ☐ Nausea ☐ Vomiting ☐ Constipation ☐ Weakness ☐ Loss of appetite ☐ Fever ☐ Excessive fatigue
9	Breakfast:	☐ **Fruit juice:** Yes / No*	Sleep duration: Activity:

Signature of officer after filling out form: Initials: Date:

SAMPEL

Research Number:	**Respondent's initials: [___|___|___]**

	Lunch: Dinner:	Indicate yes if applicable: ☐ **Vitamin** Yes / No* Indicate yes if applicable:	Are you experiencing any of the following? (Please indicate when the symptoms began.) ☐ Nausea ☐ Vomiting ☐ Constipation ☐ Weakness ☐ Loss of appetite ☐ Fever ☐ Excessive fatigue
10	Breakfast: Lunch: Dinner:	☐ **Fruit juice:** Yes / No* Indicate yes if applicable: ☐ **Vitamin** Yes / No* Indicate yes if applicable:	Sleep duration: Activity: Are you experiencing any of the following? (Please indicate when the symptoms began.) ☐ Nausea ☐ Vomiting ☐ Constipation ☐ Weakness ☐ Loss of appetite ☐ Fever ☐ Excessive fatigue
11	Breakfast: Lunch: Dinner:	☐ **Fruit juice:** Yes / No* Indicate yes if applicable: ☐ **Vitamin** Yes / No* Indicate yes if applicable:	Sleep duration: Activity: Are you experiencing any of the following? (Please indicate when the symptoms began.) ☐ Nausea ☐ Vomiting ☐ Constipation ☐ Weakness ☐ Loss of appetite ☐ Fever ☐ Excessive fatigue

Signature of officer after filling out form: Initials: Date:

SAMPEL

Research Number:	**Respondent's initials: [___|___|___]**

12	Breakfast: Lunch: Dinner:	☐ **Fruit juice:** Yes / No* Indicate yes if applicable: ☐ **Vitamin** Yes / No* Indicate yes if applicable:	Sleep duration: Activity: Are you experiencing any of the following? (Please indicate when the symptoms began.) ☐ Nausea ☐ Vomiting ☐ Constipation ☐ Weakness ☐ Loss of appetite ☐ Fever ☐ Excessive fatigue
13	Breakfast: Lunch: Dinner:	☐ **Fruit juice:** Yes / No* Indicate yes if applicable: ☐ **Vitamin** Yes / No* Indicate yes if applicable:	Sleep duration: Activity: Are you experiencing any of the following? (Please indicate when the symptoms began.) ☐ Nausea ☐ Vomiting ☐ Constipation ☐ Weakness ☐ Loss of appetite ☐ Fever ☐ Excessive fatigue
14	Breakfast: Lunch: Dinner:	☐ **Fruit juice:** Yes / No* Indicate yes if applicable: ☐ **Vitamin** Yes / No* Indicate yes if applicable:	Sleep duration: Activity: Are you experiencing any of the following? (Please indicate when the symptoms began.) ☐ Nausea ☐ Vomiting ☐ Constipation ☐ Weakness ☐ Loss of appetite

Signature of officer after filling out form: Initials: Date:

SAMPEL

Research Number:	**Respondent's initials: [___|___|___]**

			☐ Fever ☐ Excessive fatigue
15	Breakfast: Lunch: Dinner:	☐ **Fruit juice:** Yes / No* Indicate yes if applicable: ☐ **Vitamin** Yes / No* Indicate yes if applicable: ☐	Sleep duration: Activity: Are you experiencing any of the following? (Please indicate when the symptoms began.) ☐ Nausea ☐ Vomiting ☐ Constipation ☐ Weakness ☐ Loss of appetite ☐ Fever ☐ Excessive fatigue
16	Breakfast: Lunch: Dinner:	☐ **Fruit juice:** Yes / No* Indicate yes if applicable: ☐ **Vitamin** Yes / No* Indicate yes if applicable: ☐	Sleep duration: Activity: Are you experiencing any of the following? (Please indicate when the symptoms began.) ☐ Nausea ☐ Vomiting ☐ Constipation ☐ Weakness ☐ Loss of appetite ☐ Fever ☐ Excessive fatigue
17	Breakfast: Lunch:	☐ **Fruit juice:** Yes / No* Indicate yes if applicable: ☐ **Vitamin** Yes / No* Indicate yes if applicable:	Sleep duration: Activity: Are you experiencing any of the following? (Please indicate when the symptoms began.) ☐ Nausea ☐ Vomiting

Signature of officer after filling out form: Initials: Date:

SAMPEL

Research Number:	**Respondent's initials: [___|___|___]**

	Dinner:	☐	☐ Constipation ☐ Weakness ☐ Loss of appetite ☐ Fever ☐ Excessive fatigue
18	Breakfast: Lunch: Dinner:	☐ **Fruit juice:** Yes / No* Indicate yes if applicable: ☐ **Vitamin** Yes / No* Indicate yes if applicable: ☐	Sleep duration: Activity: Are you experiencing any of the following? (Please indicate when the symptoms began.) ☐ Nausea ☐ Vomiting ☐ Constipation ☐ Weakness ☐ Loss of appetite ☐ Fever ☐ Excessive fatigue
19	Breakfast: Lunch: Dinner:	☐ **Fruit juice:** Yes / No* Indicate yes if applicable: ☐ **Vitamin** Yes / No* Indicate yes if applicable: ☐	Sleep duration: Activity: Are you experiencing any of the following? (Please indicate when the symptoms began.) ☐ Nausea ☐ Vomiting ☐ Constipation ☐ Weakness ☐ Loss of appetite ☐ Fever ☐ Excessive fatigue
20	Breakfast: Lunch:	☐ **Fruit juice:** Yes / No* Indicate yes if applicable: ☐ **Vitamin**	Sleep duration: Activity: Are you experiencing any of the following? (Please

Signature of officer after filling out form: Initials: Date:

SAMPEL

Research Number:	**Respondent's initials: [___|___|___]**

	Dinner:	Yes / No* Indicate yes if applicable: ☐	indicate when the symptoms began.) ☐ Nausea ☐ Vomiting ☐ Constipation ☐ Weakness ☐ Loss of appetite ☐ Fever ☐ Excessive fatigue
21	Breakfast: Lunch: Dinner:	☐ **Fruit juice:** Yes / No* Indicate yes if applicable: ☐ **Vitamin** Yes / No* Indicate yes if applicable: ☐	Sleep duration: Activity: Are you experiencing any of the following? (Please indicate when the symptoms began.) ☐ Nausea ☐ Vomiting ☐ Constipation ☐ Weakness ☐ Loss of appetite ☐ Fever ☐ Excessive fatigue
22	Breakfast: Lunch: Dinner:	☐ **Fruit juice:** Yes / No* Indicate yes if applicable: ☐ **Vitamin** Yes / No* Indicate yes if applicable: ☐	Sleep duration: Activity: Are you experiencing any of the following? (Please indicate when the symptoms began.) ☐ Nausea ☐ Vomiting ☐ Constipation ☐ Weakness ☐ Loss of appetite ☐ Fever ☐ Excessive fatigue
23	Breakfast:	☐ **Fruit juice:** Yes / No*	Sleep duration: Activity:

Signature of officer after filling out form: Initials: Date:

SAMPEL

Research Number:	**Respondent's initials: [___|___|___]**

	Lunch: Dinner:	Indicate yes if applicable: ☐ **Vitamin** Yes / No* Indicate yes if applicable: ☐	Are you experiencing any of the following? (Please indicate when the symptoms began.) ☐ Nausea ☐ Vomiting ☐ Constipation ☐ Weakness ☐ Loss of appetite ☐ Fever ☐ Excessive fatigue
24	Breakfast: Lunch: Dinner:	☐ **Fruit juice:** Yes / No* Indicate yes if applicable: ☐ **Vitamin** Yes / No* Indicate yes if applicable: ☐	Sleep duration: Activity: Are you experiencing any of the following? (Please indicate when the symptoms began.) ☐ Nausea ☐ Vomiting ☐ Constipation ☐ Weakness ☐ Loss of appetite ☐ Fever ☐ Excessive fatigue
25	Breakfast: Lunch: Dinner:	☐ **Fruit juice:** Yes / No* Indicate yes if applicable: ☐ **Vitamin** Yes / No* Indicate yes if applicable: ☐	Sleep duration: Activity: Are you experiencing any of the following? (Please indicate when the symptoms began.) ☐ Nausea ☐ Vomiting ☐ Constipation ☐ Weakness ☐ Loss of appetite ☐ Fever ☐ Excessive fatigue

Signature of officer after filling out form: Initials: Date:

SAMPEL

Research Number:	**Respondent's initials: [___|___|___]**

26	Breakfast: Lunch: Dinner:	☐ **Fruit juice:** Yes / No* Indicate yes if applicable: ☐ **Vitamin** Yes / No* Indicate yes if applicable: ☐	Sleep duration: Activity: Are you experiencing any of the following? (Please indicate when the symptoms began.) ☐ Nausea ☐ Vomiting ☐ Constipation ☐ Weakness ☐ Loss of appetite ☐ Fever ☐ Excessive fatigue
27	Breakfast: Lunch: Dinner:	☐ **Fruit juice:** Yes / No* Indicate yes if applicable: ☐ **Vitamin** Yes / No* Indicate yes if applicable: ☐	Sleep duration: Activity: Are you experiencing any of the following? (Please indicate when the symptoms began.) ☐ Nausea ☐ Vomiting ☐ Constipation ☐ Weakness ☐ Loss of appetite ☐ Fever ☐ Excessive fatigue
28	Breakfast: Lunch: Dinner:	☐ **Fruit juice:** Yes / No* Indicate yes if applicable: ☐ **Vitamin** Yes / No* Indicate yes if applicable: ☐	Sleep duration: Activity: Are you experiencing any of the following? (Please indicate when the symptoms began.) ☐ Nausea ☐ Vomiting ☐ Constipation ☐ Weakness ☐ Loss of appetite

Signature of officer after filling out form: Initials: Date:

SAMPEL

Research Number:	Respondent's initials: [___|___|___]

			☐ Fever ☐ Excessive fatigue

***cross out what is unnecessary**

Signature of officer after filling out form: Initials: Date: