

Effects of High Potassium Diet Rich in Spices and Herbs-Salt Substitution (HPSH-SS) on Lowering Blood Pressure by Vascular and Kidney Mechanism in Elderly: Protocol for Diet Concept and Randomized Controlled Trial

Farapti Farapti, Sheila Amara Putri, Annisaa Wulida Furqonia, Purwo S. Rejeki,
Muhammad Miftahussurur

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Effects of High Potassium Diet Rich in Spices and Herbs-Salt Substitution (HPSH-SS) on Lowering Blood Pressure by Vascular and Kidney Mechanism in Elderly: Protocol for Diet Concept and Randomized Controlled Trial

Farapti Farapti¹; Sheila Amara Putri¹; Annisaa Wulida Furqonia¹; Purwo S. Rejeki²; Muhammad Miftahussurur^{3, 4}

¹Department of Nutrition, Faculty of Public Health Universitas Airlangga Surabaya ID

²Department of Physiology, Faculty of Medicine Universitas Airlangga Surabaya ID

³Gastroentero-Hepatology Division, Department of Internal Medicine, Faculty of Medicine-Dr. Soetomo Teaching Hospital Surabaya ID

⁴Institute of Tropical Disease Universitas Airlangga Surabaya ID

Corresponding Author:

Farapti Farapti

Department of Nutrition, Faculty of Public Health

Universitas Airlangga

Rungkut

Surabaya

ID

Abstract

Background: Hypertension prevalence rises with age, primarily linked to dietary factors like high sodium and low potassium intake. Strategies salt reduction and potassium enhancement face taste acceptance challenges, especially among the elderly. The lack of potassium-focused programs hinders its intake despite its crucial role in blood pressure regulation. Phytochemical components in herbs/spices, potentially anti-hypertensive, coupled with potassium content, remain insufficiently explored. While the DASH diet has demonstrated efficacy, its application and study in Indonesia, rich in herbs/spices, remain limited.

Objective: The aims of our research are to analyse the effect of a high-potassium spices/herbs and salt substitution (HPSH-SS) diet on blood pressure in elderly and to study the molecular mechanism occurring in kidneys and blood vessels influenced by these diets.

Methods: This study is a parallel randomized controlled conducted a 14-day dietary intervention on elderly. The research divided subjects into Intervention Groups (IG) receiving a Low Sodium High Potassium (LSHP) diet enriched with spices and herbs, aiming for 3500 mg potassium and 1500 mg sodium daily. The Control Groups (CG) adhered to control diets (1500mg potassium, 2000mg sodium). The primary outcomes of the study include blood pressure assessment; serum potassium, aldosterone, F2 isoprostane, and nitric oxide plasma levels; and sodium and potassium urine levels. Confounding variables, such as age, gender, medication intake, food consumption, and specific health conditions, will be mitigated through randomization and stratified analysis.

Discussion: The mechanism of lowering blood pressure by potassium has been widely studied. However, the molecular mechanisms that occur simultant in the kidneys and blood vessels and are related to oxidative stress by giving dietary spices have not been widely studied.

Results: This study compared how a diet rich in potassium from spices/herbs and with less salt affects blood pressure in elderly people, compared to a regular diet. The intervention group ate a diet with less salt and more potassium from spices and herbs, aiming for 3500 mg potassium and 1500 mg sodium per day, while the control group followed their usual diet.

Conclusions: The mechanism of lowering blood pressure by potassium has been widely studied. However, the molecular mechanisms that occur simultant in the kidneys and blood vessels and are related to oxidative stress by giving dietary spices have not been widely studied. The protocol outlines a rigorous intervention aimed at evaluating the effectiveness of a spice-based dietary approach in managing hypertension among the elderly. By comparing this intervension diet with a regular one, the study aims to provide valuable insights into dietary strategies for blood pressure regulation in this population. Clinical Trial: Ethical approval was obtained from the Health Research Ethics Committee Universitas Airlangga School of Medicine, Surabaya,

Indonesia. (No. 35/EC/KEPK/FKUA/2023) and all subjects provided written consent. Registered on the period February 9, 2023 until February 9, 2024.

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Effects of High Potassium Diet Rich in Spices and Herbs-Salt Substitution (HPSH-SS) on Lowering Blood Pressure by Vascular and Kidney Mechanism in Elderly: Protocol for Diet Concept and Randomized Controlled Trial

Farapti Farapti¹, Sheila Amara Putri¹, Annisaa Wulida Furqonia¹, Purwo Sri Rejeki², Muhammad Miftahussurur³.

¹Department of Nutrition, Faculty of Public Health, Universitas Airlangga

²Department of Physiology, Faculty of Medicine, Universitas Airlangga

³Gastroentero-Hepatology Division, Department of Internal Medicine, Faculty of Medicine-Dr. Soetomo Teaching Hospital

³Institute of Tropical Disease, Universitas Airlangga

Corresponding Author:

Farapti Farapti

Department of Nutrition, Faculty of Public Health, Universitas Airlangga

Rungkut, Surabaya, 60115

Indonesia

Phone: +62 851 6311 1103

Email: farapti@fkm.unair.ac.id

ABSTRACT

Background: Hypertension increases with age, often due to high sodium (Na) and low potassium (K) intake. Reducing salt and increasing K intake is challenging, especially for the elderly due to taste preferences. Culinary herbs and spices, rich in K, offer a potential solution. The High Potassium Diet Rich in Spices and Herbs – Salt Substitution (HPSH-SS) diet has not yet been studied for its effectiveness in lowering blood pressure.

Objectives: This study aims to create HPSH-SS diet and analyze the effect of its diet on blood pressure in elderly and to study the molecular mechanism occurring in kidneys and blood vessels influenced by this diet.

Methods: The study consisted of two phases. The first phase involved formulating and assessing the HPSH-SS diet, tailored for the elderly with 1800 kcal/day, 3500 mg K, and 1500 mg Na for the intervention group (IG), and 1500 mg K and 2000 mg Na for the control group (CG). The diet was administered for 14 days, standardized using the Nutrisurvey program and biochemistry analysis by absorbance spectrophotometry (AAS). The second phase was a 14-day parallel randomized controlled trial (RCT) with elderly subjects divided into IG and CG. Primary outcomes included blood pressure, serum potassium, aldosterone, F2 isoprostane, nitric oxide plasma levels, and urine analysis of Na, K, and the Na/K ratio. Confounding variables were controlled through randomization and stratified analysis.

Results: Menu formulation and organoleptic assessment for the HPSH-SS diet began in mid-2022, approved by the Ethics Committee of the Faculty of Public Health, Universitas Airlangga (approval number 78/EA/KEPK/2022, May 11, 2022). The diet was standardized to achieve daily nutritional values of 1800 kcal energy, 3500 mg K, and 1500 mg Na. Analysis of K and Na content was performed using AAS from several subjects' spice diet menus. Recruitment for the RCT started in March 2023, with approval from the Health Research Ethics Committee Universitas Airlangga School of Medicine, Surabaya (approval number 35/EC/KEPK/FKUA/2023). Registered from February 9, 2023, to February 9, 2024. As of this writing, 64 participants have been recruited, with 32 subjects in both the IG and CG. Data management

is in progress, and data analysis is yet to be performed.

Conclusions: This RCT hypothesizes that the diet will increase serum K, plasma aldosterone, and nitric oxide levels, decrease plasma F2 isoprostane, increase urinary Na and K levels, lower the urinary Na/K ratio, and reduce Systolic and Diastolic Blood Pressure. If effective, it will offer valuable insights into dietary strategies for blood pressure regulation in the elderly.

Trial registration: Ethical approval was obtained from the Health Research Ethics Committee Universitas Airlangga School of Medicine, Surabaya, Indonesia. (No. 35/EC/KEPK/FKUA/2023) and all subjects provided written consent. Registered on the period February 9, 2023 until February 9, 2024.

Keywords

Sodium, Potassium, Spices and herbs, Blood pressure, Hypertension, Elderly

Introduction

Hypertension (HT) is a major public health problem worldwide because the prevalence continues to rise with increasing age. The prevalence of HT is predicted to rise around 60% by the year of 2025 with nearly 1.5 million deaths (9.4% of total deaths) annually [1,2]. Both modifiable and non-modifiable risk factors for developing HT with the focus on diet modifications as a modifiable risk factor. Risk factors of HT are closely related to dietary habits particularly excess dietary salt and potassium (K) deficiency [3]. Population studies reported that most population around the world consume less than the recommended intake of K, however, unfavorably high Na (Na) intakes remain prevalent around the world [4–6]. It is widely known that excessive Na consumption and deficit of K intake have an important role in the pathogenesis of HT and are more strongly associated with blood pressure than either Na or K alone [7,8].

Non-pharmacological therapy is the primary approach in managing HT, consisting of lifestyle changes and dietary patterns aimed at lowering blood pressure and controlling risk factors and comorbidities. Salt reduction strategies have become a cornerstone program in various countries, including Indonesia, to reduce the incidence of HT and cardiovascular diseases. Various salt reduction programs have been proven to be low-cost and effective, and some countries have successfully reduced salt consumption in their populations; however, Na or salt consumption in most of the world's population still exceeds the WHO recommendation of 5g per day [5,9–14]. Low-cost strategy in management of HT is to reduce salt in food. However, it seems that this is not easy because it is related to problems with taste and acceptance of food, especially since the elderly have a high salty taste threshold [15–17]. This can lead to decreased appetite, potentially resulting in long-term malnutrition and deteriorating health status [15,18]. Another strategy is salt substitution. Furthermore, recent studies have found a way by replacing salt with spices and it gets good results regarding taste acceptance [19]. Practices have included replacing NaCl salt with other forms such as KCl or CaCl; however, this approach has drawbacks due to its bitter taste and potential toxicity risks [16,20]. Substitution with monoNa glutamate (MSG) has also been reported. Although it has been shown to replace the function of salt without taste acceptance issues, various side effects have been reported with its use in large quantities [21,22]. Recent studies have investigated substituting salt with herbs and spices, yielding promising results in taste acceptance; however, the addition of spices may alter the taste and aroma of food, which may not be universally accepted. Studies on salt

substitution with spice blends remain limited and are generally conducted on a single type of food [17,23].

The programmes for increasing K intake at the population level are still rare and not progressive. K is a nutrient that is closely related to diet quality although the cost of the diet often may inhibit its intake [24,25] it is recommended that K should be consumed through food because of the safety and no upper limit. Therefore, presenting food sources of K that are affordable and commonly used is an important requirement [5,24,26]. Herbs and spices with their phytochemical components have been widely studied as antihypertensives [27,28]. However, the relation to K content in spices, which acts as an anti-hypertensive agent, has not been widely studied. High K and low Na diet, consuming 4-5 servings of fruit and vegetables, and low in fat, known as Dietary Approaches to Stop HT (DASH) [29,30]. These benefits of the DASH dietary pattern have been recognized by general dietary guidelines from the U.S.-based National Heart, Lung, and Blood Institute (NHLBI) and the United States, Department of Agriculture (USDA), International diabetes and The European Association for the Study of Diabetes (EASD) [31–33]. However, the study of the DASH diet is not yet fully applied and studied in Indonesia. Indonesia is the largest producer of herbs and spices in the world, Furthermore, it can easily be found in traditional markets, supermarkets, even in their own homes [27].

Kidney is the main regulator of Na and K in blood. High K intake stimulates gastrointestinal signaling, specifically enteric K sensor which increases plasma K levels and aldosterone directly. Aldosterone stimulates Aldosterone-Sensitive Distal Nephron (ASDN) and Renal Outer Medullary K Channel (ROMK) which triggers a decrease in salt and water absorption, causing diuresis and natriuresis. High K intake stimulates kaliuresis, natriuresis, and diuresis by increasing plasma K from both the aldosterone and non-aldosterone pathways through inactivation of phosphorylation of the NCC and increased ASDN and ROMK [34]. Increased K intake inhibits free radical formation from endothelial dysfunction and vascular smooth muscle cell proliferation. Increased K also inhibits platelet aggregation and arterial thrombosis where platelet oxidative stress conditions are common in the elderly, so increased K will decrease urine and plasma isoprostane F2 levels [35]. Meanwhile, increased K plasma levels improve endothelial cell stiffness and increase nitric oxide (NO) release through the mechanism of cortical actin depolarization by Cytochalasin [36,37].

Indonesia is the largest producer of herbs and spices in the world, and its consumption among elderly is familiar enough. Spices and herbs have been proven as high potassium content and can be applied to salt substitution methods, and it is not yet created become healthy diet, namely High Potassium Diet Rich In Spices And Herbs – Salt Substitution (HPSH-SS). Since the increasing K intake programs at the population level particularly in elderly are still rare and not progressive, this study aims to arrange HPSH-SS diet and analyze the effect of its diet on blood pressure in elderly and to study the molecular mechanism occurring in kidneys and blood vessels influenced by this diet. The data generated from this study will provide valuable information in developing new approaches to managing blood pressure in the elderly.

Methods

Study Overview

Data collection was carried out at government institutional setting in Surabaya, Indonesia, namely UPTD Griya Wreda Surabaya. The study involved elderly residents at nursing home, in the year 2023 as participants in this study. The research implementation was divided into three periods: the pre-treatment period (Day-10 to Day 0), the treatment period (Day 1 to Day 14), and the post-treatment period (Day 15). A parallel RCT intervention study compared the intervention group (IG), which received a low-salt, high-K spice-enriched diet (3500 mg K and 1500 mg Na per day), with the control group (CG), which received a control diet (1700 mg K and 2000 mg Na per day) for 14 consecutive days.

The study involved almost all workers or staff members at the nursing home, including cooks, nurses, and nutrition experts during data collection of the study. As information, to be known, the institutional care did not permit to change the daily intake provided by them, so the researchers must adjust the diet concept for this study. So, the initial step of the study is observation all menus and food compositions of elderly daily intake and then we arranged and adjusted as our concept diet (3500 mg K and 1500 mg Na per day for c IG control and a control diet containing (1500 mg K and 2000 mg Na per day). We recorded specifically spices and herbs composition in their menus, and it be found that packed commercial seasoning be used in main course such as side dishes and vegetables.

Cooks in an institutional setting, as meal providers, played a crucial role in providing daily intake of elderly. They cooked daily menus as usual, the same for both groups. They received guidance and information about their involvement in this research. During the 14-day intervention period, cooks were instructed to use only commercial spices provided by institutional without adding any additional seasonings. Additionally, they were asked to reduce the salt content as instruction for the elderly's meals particularly IG. Nurses were responsible for accompanying the elderly in their daily activities to ensure their health conditions remained optimal. In this research, nurses were involved in measuring blood pressure, collecting blood samples, collecting 24-hour urine samples, and recording any health complaints from the elderly during the research activities. The involvement of dietitians as part of the research team in this study is very crucial, because of no dietitian in the nursing home. Dietitians monitored and evaluated the elderly's dietary intake. They observed the entire food preparation process, especially during cooking, and recorded all ingredients used, including seasonings, and added salt. Providing the intervention and control menus and evaluating the overall food leftovers, including main meals and intervention menus from the subjects for 14 consecutive days, was the main task of the dietitians during the intervention period.

Study design

This study consisted of two phases. First step is trials of menus formulation and organoleptic assessment of the concept of HPSH-SS diet that began in mid year 2022 and next step is application of randomized controlled trial study that recruitment started in March 2023. The intervention and data collection will take place for one year.

Phase 1: Trials of menus formulation and organoleptic assessment

Concepting HPSH-SS diet involved trials of menus formulation and organoleptic assessment, which commenced in mid-2022. We did not provide daily intake entirely since the nursing home did not permit to change its usual menus, so we adjusted the usual menu with the HPSH-SS diet concept by arranging a low-salt, high-K spice-enriched diet (3500 mg K and 1500 mg Na per day) and a control diet (1500 mg K and 2000 mg Na per day). Therefore, the initial step was to observe the elderly daily menus and the nutritional composition or nutrient content of the foods was calculated using the

Nutri survey software (version 2007).

From the nutritional values of the elderly menu, the next step was to design intervention and control menus to achieve nutritional values according to the diet concept in this study. The intervention and control menus were arranged to achieve nutritional values in line with the intervention design of this study. Both IG and CG were provided with the same energy intake of approximately 1800 kcal. However, Na and K were the main variables in this spice-enriched diet, with their roles being examined. The IG received 3500 mg of K and 1500 mg of Na, while the CG received 1500 mg of K and 2000 mg of Na. Therefore, adjustments were necessary in the daily dietary menu of the elderly at nursing home to align with the nutritional values of the designed intervention.

For each intervention menu recipe, a report on food ingredient specifications and standard operational procedures (SOP) for the production process flow had been prepared beforehand. The next step involved conducting trials and organoleptic taste evaluations for taste acceptance by a limited panel of testers and subjects, followed by biochemical laboratory examinations for K and Na nutritional values. The entire process sequence is described in Figure 1.

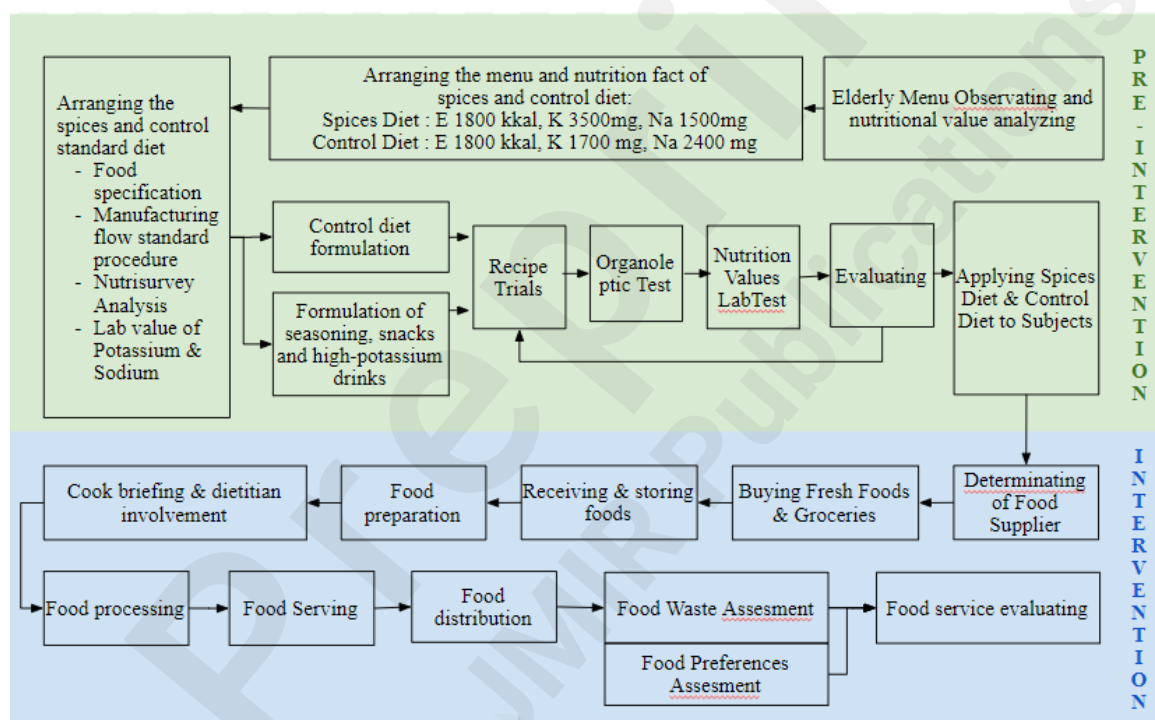


Figure 1. The flowchart of intervention (HPSH-SS) diet and monitoring evaluation

Phase 2: Randomized controlled trial study

The randomized controlled trial study was implemented with recruitment commencing in March 2023 until end year 2023. This study is a parallel randomized controlled feeding trials testing the effect of two dietary patterns on blood pressure by analyzing serum K levels, plasma aldosterone, plasma isoprostane F2, and plasma NO, urinary Na, urinary K, Urinary Na/K ratio changes in the elderly with HT for 14 consecutive days. Both IG and CG were provided with the same energy intake of approximately 1800 kcal. The IG received 3500 mg of K and 1500 mg of Na, while the CG received 1700 mg of K and 2000 mg of Na.

Study Population and Participants

Population is elderly registered residents at institutional nursing home in Surabaya, Indonesia. The sample size for each

group is set at minimal 28 subjects. The sample size calculation utilized the formula by Lemeshow et al., 1990. Based on standard deviation calculation by Geleijnse et al., 2018, sample size yielded a minimum of 25 participants for each group. Accounting for a 10% dropout rate, the minimal sample size for each group became 28 individuals, resulting in a total sample size of 56 participants for this study. Inclusion criteria was elderly residents aged ≥ 60 years in the nursing home and the condition is active and not bedridden, and did not suffer infectious disease, taste disorders, and dementia. Another thing as subject in this study is blood pressure measurements indicating a SBP ≥ 130 mmHg and/or DBP ≥ 85 mmHg. Exclusion criteria involved individuals with impaired kidney function (creatinine serum levels > 1.2 mmol/L), uncontrolled diabetes mellitus (fasting Blood Sugar (GDP) > 126 mg/dL), obesity (BMI ≥ 30 kg/m²), active smoking, or suffering from memory impairment and depressive conditions.. Additionally, subjects declining continued participation, requiring intensive hospital care, or experiencing persistent vomiting and diarrhea will be excluded from the intervention.

Study's variables

The variables of this study included independent, dependent, mediating, controllong, and confounding variables. Independent variables were the HPSH-SS diet and the control diet. Dependent variables included SBP and DBP. Meanwhile, mediating variables were serum K level, plasma aldosterone, urine Na, urine K, plasma F2 isoprostane, and plasma nitric oxide. Furthermore, controlling variables consisted to duration of intervention, timing and method of treatment, timing and method of evaluation, subject's criteria, laboratory examination of outcome results, equal energy content of both diets, sources of food ingredients and commercial seasonings containing spices and herbs used in both group, cooks involved in food preparation and presentation. Finally, confounding variable consisted of age, gender, consumption of antihypertensive medications, amount of diet consumed during the intervention period, occurrence of mild nausea and vomiting during the intervention period, other metabolic diseases such as dyslipidemia and hyperuricemia. The randomization process is a method used to control confounding variables (age, gender, and consumption of antihypertensive drugs) between two groups to ensure that subject characteristics are evenly distributed among both groups.

Operational Framework

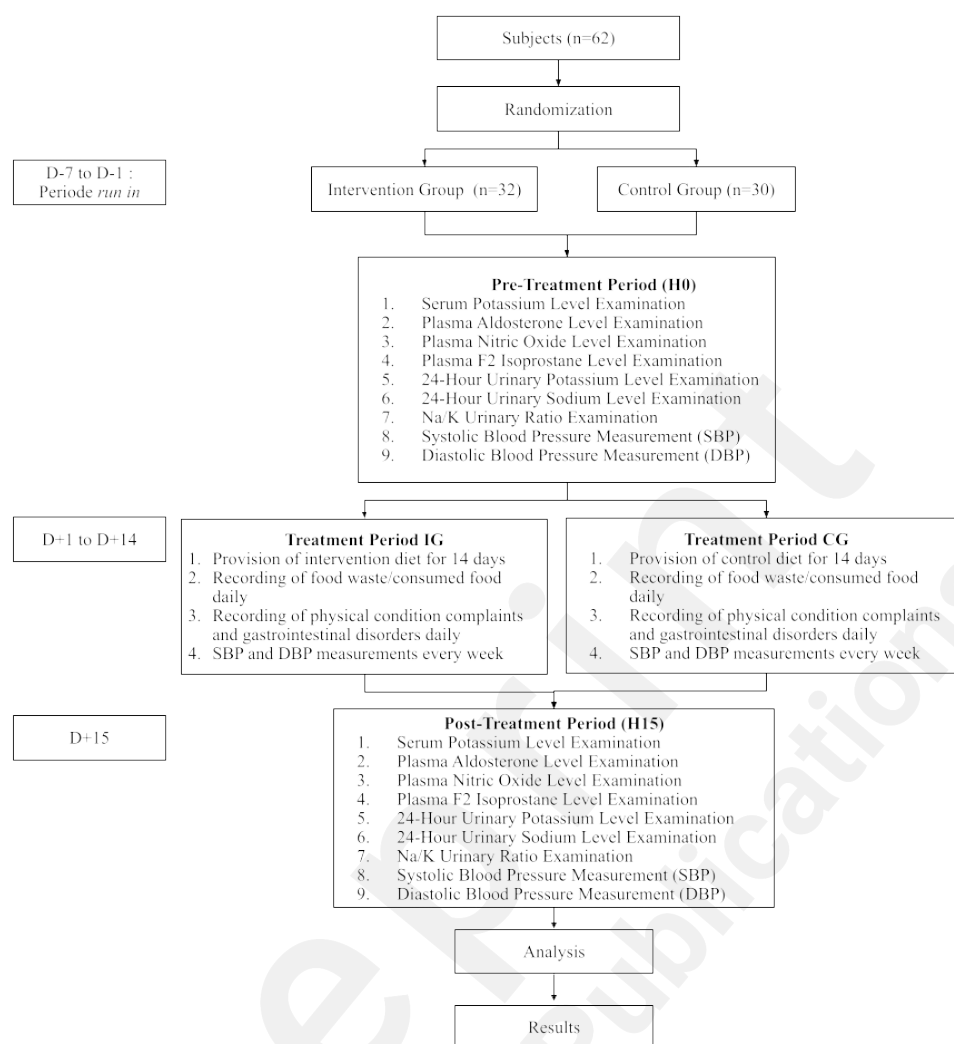


Figure 2. Operational Framework

The research implementation is divided into three periods as shown in the operational framework in Figure 2: the pre-treatment period, treatment period, and post-treatment period. Pre-treatment Period (Day-10 to Day 0) consisted of giving information and explanations about the purpose and benefits of the research, and finally, interviews were conducted to obtain baseline data (age, medical history, and medication consumption), and anthropometric measurements including body weight and height, blood pressure measurements, as well as screening for kidney function and serum K levels were performed. Subjects who met the research criteria were divided into two groups, namely IG and CG, through randomization. Starting from Day-7, subjects entered a seven-day run-in period to standardize food intake and physical activity. The elderly were educated not to change their usual eating patterns or activities. Both groups consumed meals provided only by the institution. On Day -1, subjects were informed and briefed on the treatment they would receive, namely receiving a new menu to be consumed for 14 consecutive days, and the evaluation and various examinations that would be conducted. Finally, on Day 0, SBP and DBP measurements were taken, and serum K levels, plasma aldosterone, urine Na and K levels, plasma F2 isoprostane levels, and plasma nitric oxide (NO) were examined.

Treatment Period (Day +1 to Day +14) consisted of consumption of the diet every day for 14 days consecutively. Every mealtime, subjects were asked and assessed about taste acceptance and food waste form for the food served. The elderly

were informed that uneaten food should not be discarded and should be kept on the plate for recording in the form by the research team. In the middle day of intervention (Day +8) in the morning, SBP and DBP measurements were conducted by trained nurses following standardized measurement procedures. Moreover, during the intervention, any complaints of health disturbances experienced by the elderly, especially those related to digestive problems such as nausea, vomiting, or diarrhea, were noted and addressed by providing medication to reduce and treat the complaints. Finally, on the post-treatment Period (Day +15 SBP and DBP measurements were taken again, and serum K levels, plasma aldosterone, urine Na and K levels, plasma F2 isoprostane levels, and plasma nitric oxide (NO) were examined.

Research hypotheses of this study is whether a high potassium spice diet and salt substitution in elderly with a history of hypertension can increase serum potassium levels, increase plasma aldosterone levels, increase plasma nitric oxide (NO) levels, decrease plasma F2 isoprostane levels, increase urinary sodium (Na) levels, increase urinary potassium (K) levels, decrease urinary sodium to potassium (Na/K) ratio, decrease Systolic Blood Pressure (SBP) and Diastolic Blood Pressure (DBP).

Statistical Analysis

All statistical calculations were conducted with Statistical Package for Social Science (SPSS) version 21, and p value <0.05 was considered significant. Saphiro-Wilk test was used to check normality data. In normal distributions for continuous variables, the mean and standard deviation were applied, meanwhile in abnormal distributions, the median and minimum - maximum were used. Data classified as categorical variables were summarized as numbers and percentages. Bivariate analysis to analyze the difference outcome between two groups (IG and CG) used t-test or Mann-Whitney. Meanwhile to compare ratio data between pre and post test applied paired tes or Wilcoxon.

Ethics Approval and Informed Consent

The trials of menus formulation and organoleptic assessment to concept of HPSH-SS diet began in mid year 2022 with ethics approved by the Ethics Committee of the Faculty of Public Health, Universitas Airlangga, with approval number 78/EA/KEPK/ 2022, on May 11, 2022. The application of randomized controlled trial study started in March 2023. The ethical approval was obtained from the Health Research Ethics Committee at Universitas Airlangga School of Medicine, Surabaya, Indonesia (No. 35/EC/KEPK/FKUA/2023) for the study titled 'The Mechanism of Lowering Blood Pressure in Elderly with Diet of Spice and Herb High Potassium and Salt Substitution,' registered on February 9, 2023. All procedures performed in this study involving human participants were conducted in accordance with the ethical standards outlined by the committee. The data collection procedure was initiated by seeking approval from the head of institutional nursing home and the subjects directly. The research commenced with a preliminary socialization process. The subjects sign an informed consent after receiving a detailed and clear explanation about the study, including the research title, the benefits of being a research subject, and the research procedures.

RESULTS

The concept of HPSH-SS diet

The initial step before arranging diet menus was observing the elderly daily menus in nurisng home and analysing its

nutritional value. Table 1 shows the nutritional values of the master menu providing approximately 1321 kcal of energy, which meets around 73% of the energy requirement, 1661 mg of Na, and 130 mg of K, accounting for only about 30% of the recommended intake.

Table 1. Nutritional Values of Master Menu at Griya Werdha Surabaya

Nutritional Values	Energy kcal	Protein g	Fat g	Carb g	Fiber g	Na mg	K mg	Calcium mg
Daily Average	1321 ± 109.59	47 ± 5.79	53 ± 10.18	168 ± 18.94	7 ± 1.82	1661 ± 363.92	1305 ± 211.39	289 ± 100.67
RDA	1800	65	50	275	25	1500	4700	1200
% Fulfillment	73%	73%	106%	61%	28%	111%	28%	24%

From the nutritional values of the elderly menu, the next step was to design intervention and control menus to achieve nutritional values according to the diet concept in this study. The energy content was arranged to meet the nutritional needs of the elderly, consisting of 1800 kcal/day, so both groups (IG and CG) were provided with the same energy intake. The IG received 3500 mg of K and 1500 mg of Na, while the CG received 1500 mg of K and 2000 mg of Na daily. Therefore, adjustments were necessary in the daily dietary menu of the elderly at nursing home to align with the nutritional values of the designed intervention.

Since researchers did not been permitted to change its usual menus applied by nursing home, the main meals of breakfast, lunch, and dinner were still same as usual, however, we added combination of fried onion and garlic and reduction of salt in main meals. Furthermore, to fulfill K and Na nutrient of both diets, we added snacks and beverage. Additional food menus for both groups were created with similar appearance although different nutrients content.

Table 2. Additional Foods for Intervention and Control Menus

Meal Time	HPSH-SS Menus	Control Menus
07:00 (Breakfast)	Herbal tea	Tea bag
10:00 (Morning Snack)	Cinnamon spinach pudding	Sweet milk pudding
14:00 (Afternoon Snack)	Mung bean <i>Kampferia galanga</i>	Coconut milk dawet
19:00 (Evening Snack)	Spices potato schotel	Tofu noodle schotel
Additional Treatments	Onions (10g) and garlic (5g) in every main meal. Reduction of salt amount in cooking.	

Analysis of K and Na nutrients were examined using atomic absorbance spectrophotometry (AAS) from additional foods in both groups. Table 3 and Table 4 presented nutrients of the HPSH-SS Menus and the control menus.

Table 3. Nutrients of HPSH-SS Menus

Menu	E	K	Na
	kcal	mg	mg
Ginger Tea	79.0	402.8	3.4
Cinnamon Spinach Pudding	64.4	336.0	15.7
Mung Bean <i>Kaempferia Galanga</i>	182.1	600.0	21.3
Spiced Potato Schotel	147.9	780.0	62.2

Fried onion and garlic	75.0	75.0	50.0
Nutritional Values of Intervention Menu	548.4	2193.8	152.5
Master menus' elderly	1321	1661	1305
Total Intake	1869	3555	1563

Table 4. Nutrients of Control Menus

Menu	E	K	Na
	kcal	mg	mg
Tea 400 ml	109.0	0.6	12.0
Milk Pudding	66.2	11.4	2.7
Dawet Coconut Milk 400 ml	286.5	87.2	24.1
Tofu Schotel 80 g	139.5	89.6	394.5
Nutritional Values of Control Menu	601.2	188.8	433.3
Total Intake	1922	1494	2094

Equal energy content of both diets, sources of food ingredients and commercial seasonings containing spices and herbs used in both groups, cooks involved in food preparation and presentation were controlled variables accurately. For all menu recipes applied standard operational procedures (SOP) for the production process, including the evaluating process of taste acceptance and food taste. This is an example of composition of one of the menu items.

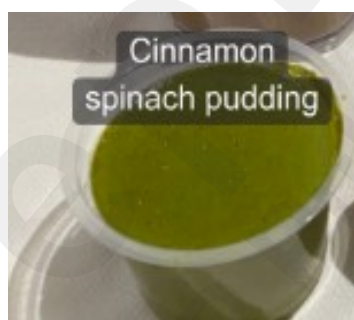


Figure 3. Cinnamon Spinach Pudding

Figure 3 shows the cinnamon spinach pudding, a snack of HPSH-SS diet consumed by IG in the morning every day during the intervention periode. It contained some ingredients with specifications such as 125 g Agar-agar, 25 g Nutrijell, 30 g Spinach, 35 g Cinnamon, 75 g Milk, 14 g Sugar, 75 ml water. We applied spinach and cinnamon as K source foods. Moreover, cinnamon was chosen as spices and herbs that high K content.

Randomized controlled trial study

The recruitment of randomized controlled trials started in March 2023. The study was approved by the Health Research Ethics Committee Universitas Airlangga School of Medicine, Surabaya, with approval number 35/EC/KEPK/FKUA/2023 and all subjects provided written consent. Registered on the period February 9, 2023, until February 9, 2024. The intervention and data collection will take place for one year. As of this writing, 64 participants have already been recruited for the study; each of 32 subjects were distributed in the IG and CG. Data management and analysis is still in progress, so data analysis has not yet been performed.

Discussion

A high prevalence of hypertension (HT) in elderly still becomes major public health problem worldwide and excessive Na or salt consumption and low intake of K have an vital role in the pathogenesis of HT and cardiovascular disease [7,39]. Comprehensive strategies to reduce salt and increase K intake simultaneously is needed since both Na and K are the essential nutrition working at the cellular complementary and more strongly associated with blood pressure than either Na or K alone [40]. This study aims to create a diet containing high K and low Na intake and analyze the effects of its diet on blood pressure in elderly. This parallel randomized controlled trial (RCT) intervention study compares IG receiving a high-K spice diet (3500 mg K and 1500 mg Na per day) with the CG receiving a control diet (1500 mg K and 2000 mg Na per day) for 14 consecutive days. This study applied and controlled standard operational procedures (SOP) for the production process of the diet, including the evaluation process of taste acceptance and food waste at every food menu eaten by elderly. This RCT will prove hypothesis whether the HPSH-SS diet is effective on lowering blood pressure by examining some markers of vascular and kidney in elderly .

Na or salt consumption reduction has become a major health program in various countries worldwide to reduce the incidence of HT and cardiovascular diseases [41]. Epidemiological studies highlight excessively high dietary intake of sodium at the community level in most parts of the world [41]. Several countries have applied salt-reduction strategy programs and already successfully established to limit dietary salt in their populations [10,42]. However, in the elderly, this seems challenging due to issues related to high salt taste threshold and taste preference, which can lead to overall reduced intake [38]. According to WHO recommendations, Na intake should not exceed 2g/day, and extremely low Na consumption is not recommended, as both too low and too high intakes potentially increase the risk of mortality, especially when applied to the elderly [43,44]. Therefore, this study provided Na intervention at 1500 mg for the IG and 2000 mg for the CG. Analysis Na intake of elderly menus in nursing home showed their Na intake were not too high, it was only 1661 mg and fulfilled 111% of the recommended dietary allowance (RDA). So, we reduced salt in the cooking process until 1500 mg for IG, meanwhile, the addition of Na intake until 2000 mg came from additional foods of control menus. We did not apply Na intake less than 1500 mg since reducing salt intake can influence taste and cause deficiency elderly intake totally and trigger undernutrition for long time [45,46]. Moreover, giving Na intake more than 2000 mg might cause harmful effects in elderly and unethical to individuals with raising blood pressure [47,48].

Most populations consume less than the requirement of K and still fail to reach the recommended levels, emphasizing the urgent need for dietary interventions. Unlike salt-reduction strategy programs that low cost and effective [6], increasing K intake and achieving the recommended daily K intake of 4700 mg seems challenging, particularly for low socioeconomic groups, as K-rich foods such as fruits, vegetables, legumes, and dairy products are associated with food costs [19,24]. Low potassium intake is generally due to low fruit and vegetable intake particularly a systematic review study showed almost Indonesian people consume inadequate fruit and vegetable [49]. Furthermore, the previous study demonstrated potassium intake is associated with nutritional quality, so increasing K intake will improve diet quality and reduce BP [24]. Specifically, for K intake, we did not apply the Indonesian RDA to 4700 mg/d since K intake among elderly in the nursing home only 1300 mg or 28% of the requirement [50]. Furthermore, the administration of 3500 mg of K in this study is in line with the WHO recommendation for a minimum daily K intake of 3500 mg, primarily obtained from food sources rather than supplementation [6].

This study provided Na intervention at 1500 mg for the IG and 2000 mg for the CG. Furthermore, Na/K ratio of 1 is considered beneficial for health and it is important to note that the Na/K ratio was much above the recommended level. Therefore, achieving effective ways to lower this ratio in the population by reducing Na consumption while

promoting dietary K consumption is very important [4,7]. Our study showed Na/K ratio in HPSH-SS diet was 1500/3500 mg (less than 1), meanwhile its control diet was 2000/1500 mg (more than 1). Interventions involving K intake and Na restriction have been carried out both through supplementation and in the form of food or dietary intake. High-K, low-Na diets, including 4-5 servings of vegetables and fruits per day, and low-fat diets known as the Dietary Approaches to Stop HT (DASH), have been proven effective in reducing blood pressure [29]. DASH diet studies with varying K contents and Na-restricted diets have been studied. However, the development of a DASH diet with the main addition of spices has not been reported. Since spices as a source of K have also been less studied, a recent study by Singh in 2023 examined the K, Na, and their ratio in 45 commercial cultivars of onions in India. The results of this study demonstrated that onions are a potential source of K and low Na [51]. Strategies involving salt reduction face challenges, particularly regarding taste acceptance, especially among the elderly. Replacing salt with spices has shown potential in addressing taste acceptance issues while potentially benefiting blood pressure management. A recent study by Farapti et al., 2024, demonstrated that the use of herbs and spices is an effective method for salt substitution in food that is acceptable in terms of taste preference and taste acceptance by the elderly [52]. However, the implementation study of a spice diet in daily food menus for reducing blood pressure has not been reported, and it is the novel aspect of this study. However, the detail mechanism of reducing BP in older subjects is complicated. This study only evaluated the effectiveness of HPSH-SS diet on lowering blood pressure by vascular and kidney mechanism, not including sympathetic nerves that might explain comprehensive mechanism of reducing BP. The result of this study might not be applied in general population particularly elderly with impaired kidney function and suffered other diseases.

Indonesia is the world's largest producer of spices and herbs with a contribution of around 21.06% of the total world market [53], and moreover, its consume among elderly in Indonesia is enough high, so the HPSH-SS diet is expected greatly accepted. This study introduced food sources of K that nutritional quality, affordable price, available products, and easy to food processing daily. So, the diet can be applied to fulfill the daily K intake. Furthermore, it also presents the innovation of functional foods from spices and herbs that contain high K for lowering BP. If proven effective, it will provide valuable insights into dietary strategies for blood pressure regulation particularly in older population and can contribute to improve their health status.

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Authors' contributions

FF: Conceptualization, Methodology, Formal analysis, Investigation, Writing original draft, review & editing, SAP and AWF: Data collection, Formal analysis and table preparation, Writing manuscript, PSR and MM: Investigation and Supervision. All authors participated in the writing and revision of the manuscript and approved the final version.

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Availability of data and material

All data that will be used or analyzed in the study will be supplied upon reasonable request. Data supporting the findings of this study are included in the manuscript. Personal data are not publicly accessible due to ethical considerations, but they can be obtained from the corresponding author upon request.

Ethics approval and consent to participate

Ethical approval was obtained from the Ethics Committee of the Faculty of Public Health, Universitas Airlangga, with approval number 78/EA/KEPK/ 2022, on May 11, 2022, and the Health Research Ethics Committee at Universitas Airlangga School of Medicine, Surabaya, Indonesia (No. 35/EC/KEPK/FKUA/2023) for the study titled 'The Mechanism of Lowering Blood Pressure in Elderly with Diet of Spice and Herb High K and Salt Substitution,' registered on February 9, 2023.

Consent for publication

Informed consent materials are attached as supplementary materials.

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Abbreviations

AAS: Atomic Absorption Spectrometry

ASDN: Aldosterone-Sensitive Distal Nephron

CG: Control Groups

DASH: Dietary Approaches to Stop Hypertension

DPB: Diastolic Blood Pressure

EASD: European Association for the Study of Diabetes

ELISA: Enzyme-Linked Immunosorbent Assay

HPSH-SS: High-Potassium Spices/Herbs and Salt Substitution

HT: Hypertension

IG: Intervention Groups

K: Kalium (Potassium)

LSHP: Low Sodium High Potassium

MSG: Mono Sodium Glutamate

NCC: Natrium-Chloride Cotransporter

NHLBI: National Heart, Lung, and Blood Institute

NO: Nitric Oxide

Na: Natrium (Sodium)

ROMK: Renal Outer Medullary K Channel

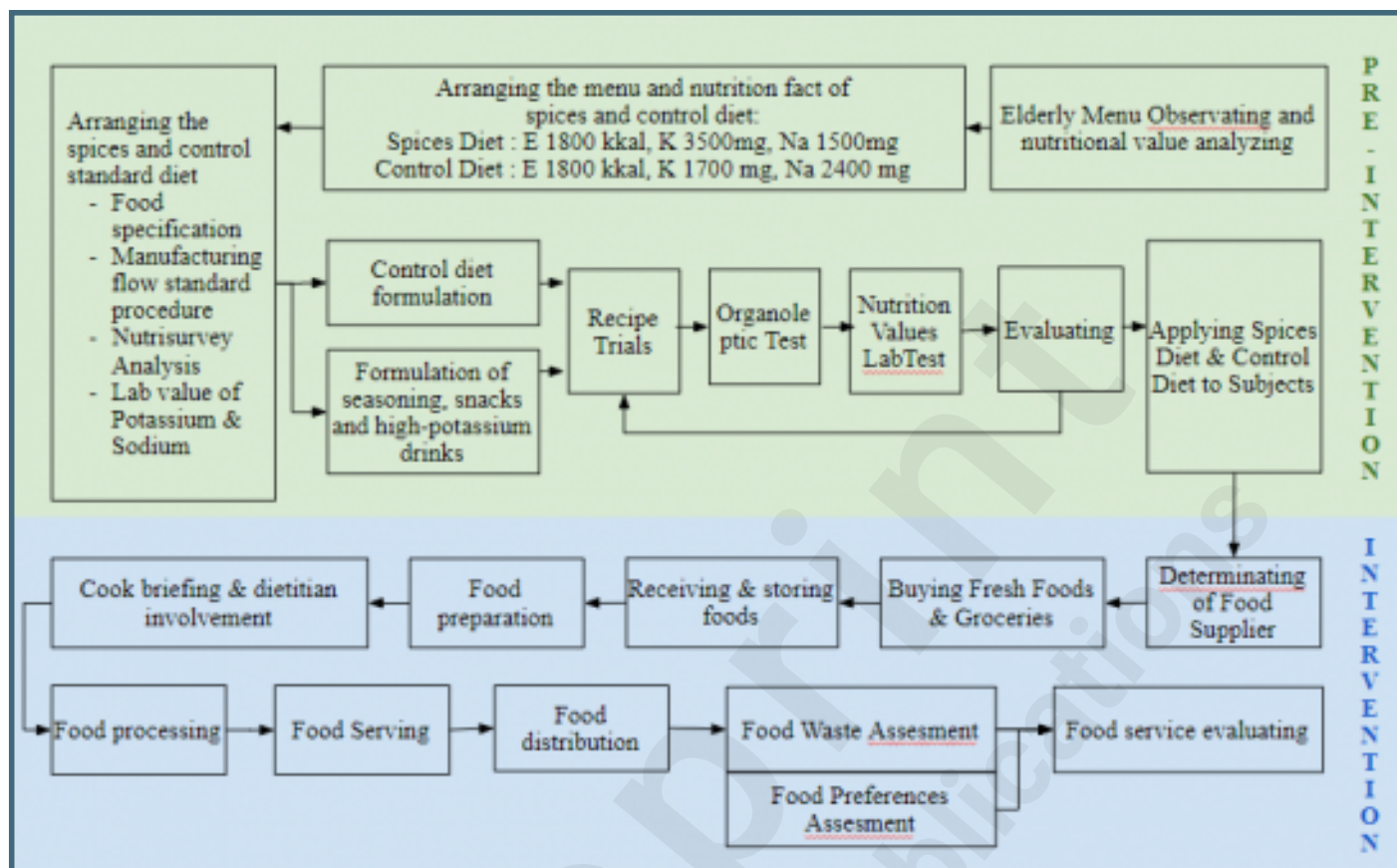
SBP: Systolic Blood Pressure

USDA: United States Department of Agriculture

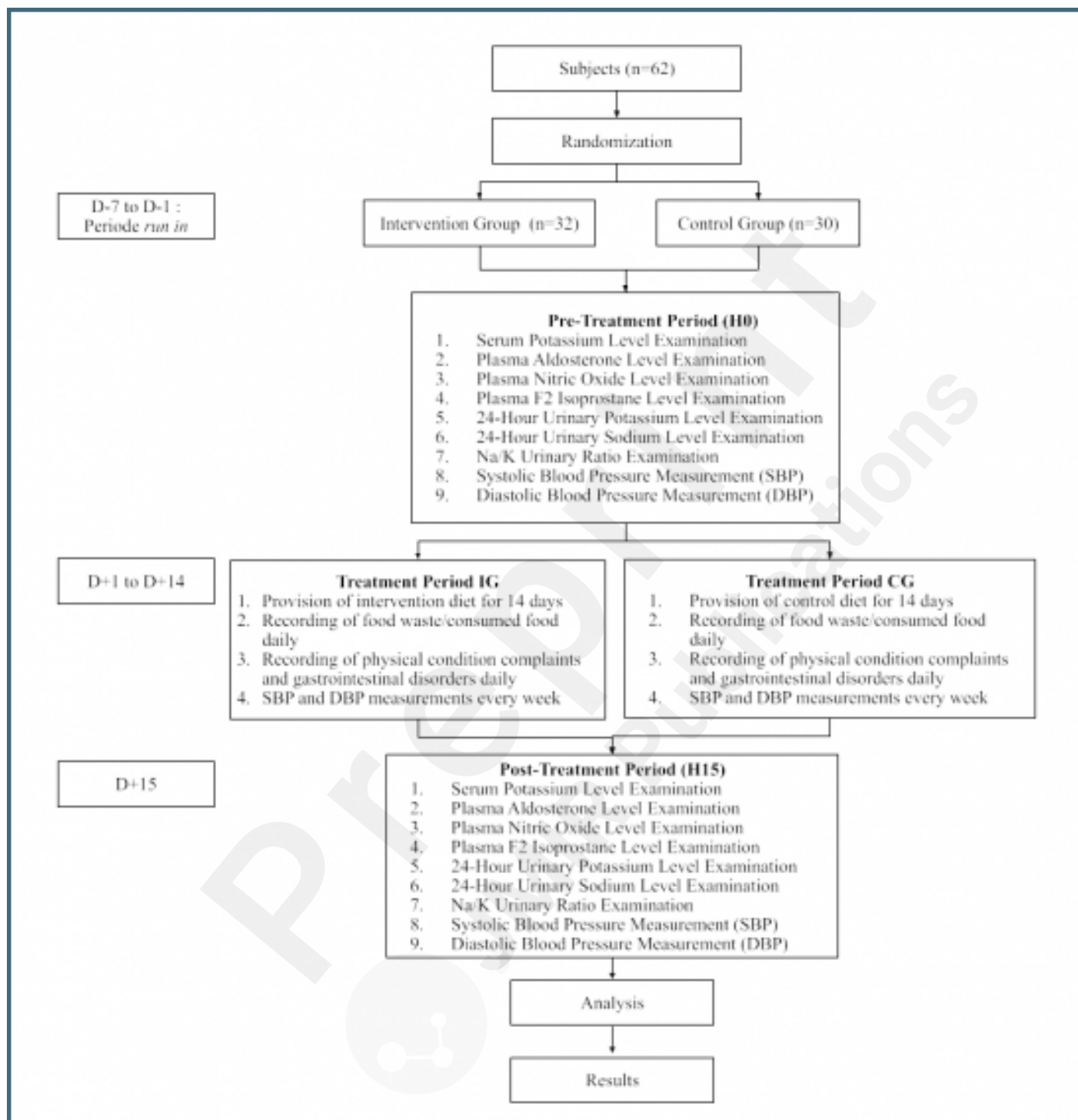
Supplementary Files

Figures

The flowchart of intervention (HPSH-SS) diet and monitoring evaluation.



Operational Framework.



Cinnamon Spinach Pudding.

