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Impact of a Randomized Controlled Trial with Salt Control H in dietary salt intake, dietary behavior and blood pressure

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Personal contribution in research work in this thesis

I collaborated in defining the objectives of the thesis, carried out the work of collecting data in the field, coding, analyzing and interpreting the results and writing the works resulting from studies II to IV. I collaborated in the writing of study I.

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Abstract/Resumo

Abstract

Aim: The aim of this thesis was to analyze successful interventions to reduce salt intake and to assess the impact of an intervention using Salt Control H (innovative salt dosage equipment) on salt intake, eating behavior and blood pressure.

Its specific objectives were: 1) to carry out a review of successful interventions to reduce salt intake in adults; 2) to assess the impact of an intervention using Salt Control H on urinary excretion of sodium, potassium and on the sodium-potassium ratio; 3) to assess the impact of an intervention using Salt Control H on blood pressure; 4) to analyze changes in behavior and knowledge regarding salt after an intervention using Salt Control H and 5) to analyze changes in the main sources of salt intake after an intervention using Salt Control H.

Methods: To carry out the review regarding successful interventions to reduce salt intake, a search was carried out in the PubMed, Web of Science and Scopus databases. Studies published in the last 10 years were included; randomized trials, pilot interventions without a control arm, or experimental studies; adult participants; and interventions that successfully reduced salt intake. Study quality was assessed.

The impact of the intervention with Salt Control H to reduce salt consumption was evaluated through an 8-week randomized clinical trial with 114 workers at a public university. The participants were evaluated four times: first at baseline, then two times during the intervention (week 4 and week 8, at end of intervention) and 6 months after the end of the intervention. The intervention group (n = 57) used the equipment to monitor and control the use of salt during cooking (Salt Control H) and the control group continued with the usual routine. The main outcome of this analysis was the 24-h urinary sodium excretion, which was used as a proxy for salt intake. Changes in 24-h urinary potassium excretion, sodium/potassium ratio and blood pressure were also analyzed.

To assess knowledge and behavior in relation to salt, the WHO STEPwise questionnaire was used, and the main sources of salt were obtained from the 24-hour dietary recall and 24-hour urinary sodium excretion.

Results: The review included 21 studies, 16 randomized and five non-randomized studies. Eleven interventions described health and nutrition education, seven interventions described nutrition education plus other interventions, and three studies used salt meters to reduce sodium intake.

In assessing the impact of the intervention with the Salt Control H to reduce salt, it was found that there was a decrease in sodium intake in the intervention group, but without statistical significance. When analyzing the results by sex and hypertension status, there was a reduction in sodium (−1009 mg (−1876 to −142), p=0.025) and in the sodium potassium (Na:K) ratio (−0.9 (−1.5 to −0.3), p=0.007) in hypertensive men within the intervention group. Diastolic blood pressure decreased in both groups.

Regarding knowledge, attitudes and behaviors, after the intervention, participants in the intervention group reported a decrease in the addition of salt when cooking (p=0.037), avoided processed foods (from 54.2% to 83.3%, p=0.001), analyzed the amount of salt on food labels (from 18.8% to 39.6%, p=0.013), and bought low-salt food alternatives (from 43.8% to 60.4%, p=0.039). After the intervention, there were no statistically significant differences in the contribution of different food groups to salt consumption. Although in the intervention group, added salt decreased by 5%, in the salty snacks and pizzas group it decreased by 7% and in the meat, fish and eggs group it increased by 4%.

Conclusions: Health and nutrition education alone, nutrition education as a complement to other interventions, and interventions that used salt meters to reduce sodium intake have all shown success in reducing salt intake in the review article. There is no evidence that one type of intervention analyzed is more effective than another in reducing salt consumption. It is fundamental to customize the intervention according to the individuals or subpopulations to optimize the results.

Intervention with Salt Control H equipment to measure added salt during food preparation and cooking may be a valid approach in individual salt reduction strategies, especially in hypertensive men.

Furthermore, with the use of the equipment, it is possible to change some consumer behaviors in relation to salt.

Keywords: salt reduction; behavior change; hypertension; dietary intervention; cardiovascular disease

Resumo

Objetivo: O objetivo desta tese foi analisar intervenções bem-sucedidas para reduzir a ingestão de sal e avaliar o impacto de uma intervenção usando o Salt Control H (um equipamento inovador para dosear o sal) no consumo de sal, no comportamento alimentar em relação ao sal e na pressão arterial. Os objetivos específicos foram os seguintes: 1) a realização de uma revisão com intervenções bem-sucedidas para reduzir a ingestão de sal em adultos; 2) avaliar o impacto de uma intervenção com o Salt Control H na excreção urinária de sódio, potássio e na relação sódio-potássio; 3) avaliar o impacto de uma intervenção com o Salt Control H na pressão arterial; 4) analisar alterações no comportamento e conhecimento em relação ao sal numa intervenção com o Salt Control H e 5) analisar as alterações nas principais fontes de sal após a intervenção com o Salt Control H.

Métodos: Para a realização da revisão sobre intervenções com sucesso para reduzir a ingestão de sal procedeu-se a uma pesquisa nas bases de dados PubMed, Web of Science e Scopus. Foram incluídos estudos publicados nos últimos 10 anos; ensaios randomizados, intervenções piloto sem braço controle ou estudos experimentais; participantes adultos; e intervenções que reduziram com sucesso a ingestão de sal. A qualidade dos estudos foi avaliada.

O impacto da intervenção com o Salt Control H para reduzir o consumo de sal foi avaliada através de um estudo clínico randomizado de 8 semanas com 114 trabalhadores de uma universidade pública. Os participantes foram avaliados quatro vezes: na avaliação *baseline*, duas vezes durante a intervenção (semana 4 e semana 8, no final da intervenção) e 6 meses após o final da intervenção.

O grupo intervenção (n = 57) utilizou o equipamento Salt Control H para controlar o uso de sal durante a preparação e confeção de alimentos e o grupo controlo continuou com a sua rotina habitual. O resultado principal desta análise foi a excreção urinária de sódio de 24 h, que foi usada como proxy da ingestão de sal. Também foram analisadas as alterações na excreção urinária de potássio de 24 h, na razão sódio/potássio (Na:K) e na pressão arterial.

Para avaliar o conhecimento e comportamento em relação ao sal foi utilizado o questionário STEPwise da OMS, e as principais fontes de sal foram obtidas pelo recordatório alimentar de 24 horas e a excreção urinária de sódio de 24 horas.

Resultados: No estudo de revisão foram incluídos 21 estudos, 16 randomizados e cinco estudos não randomizados. Onze intervenções descreveram educação em saúde e nutrição, sete intervenções descreveram educação nutricional com o complemento de outras intervenções e três estudos usaram medidores de sal para reduzir a ingestão de sódio.

Na avaliação do impacto da intervenção com o Salt Control H para reduzir o sal verificou-se que houve diminuição da ingestão de sódio após a intervenção, mas sem significância estatística. Ao analisar os resultados por sexo e estado de hipertensão, houve redução do sódio (−1009 mg (−1876 a −142), p = 0,025) e da relação Na:K (−0,9 (−1,5 a −0,3), p = 0,007) em homens hipertensos dentro do grupo intervenção. A pressão arterial diastólica diminuiu em ambos os grupos.

Relativamente aos conhecimentos, atitudes e comportamentos, após a intervenção, os participantes do grupo de intervenção reportaram diminuição da adição de sal ao cozinhar (p=0,037), evitaram alimentos processados (de 54,2% para 83,3%, p=0,001), viram a quantidade de sal no rótulo dos alimentos (de 18,8% a 39,6%, p=0,013) e compraram alternativas de alimentos com baixo teor de sal (de 43,8% a 60,4%, p=0,039). Após a intervenção não se verificou diferenças estatisticamente significativas no contributo para o consumo sal nos diferentes grupos de alimentos. Embora no grupo de intervenção, o sal adicionado diminuiu 5%, no grupo de snacks, salgados e pizzas diminuiu 7% e no grupo de carne, pescado e ovos aumentou 4%.

Conclusões: Educação em saúde e nutrição, educação nutricional com o complemento de outras intervenções e intervenções que estimam a ingestão de sal mostraram sucesso na redução do consumo de sal no artigo de revisão. Não há evidências de que um tipo de intervenção analisado seja mais eficaz do que outro na redução do consumo de sal. É fundamental personalizar a intervenção de acordo com os indivíduos ou subpopulações para otimizar os resultados.

A intervenção com o equipamento Salt Control H para dosear o sal adicionado durante a preparação e confeção dos alimentos pode ser uma abordagem válida

em estratégias individuais de redução de sal, especialmente em homens hipertensos.

Com o uso do equipamento é possível mudar o comportamento do consumidor em relação ao sal.

Palavras chave: redução de sal; mudança de comportamento; hipertensão; intervenção dietética; doença cardiovascular

List of abbreviations

CVD – Cardiovascular disease

KAB – Knowledge, attitudes and behavior

Na:K ratio – sodium potassium ratio

WHO – World Health Organization

General introduction

High blood pressure is one of the main causes of cardiovascular disease (CVD), by reducing salt consumption, it lowers blood pressure and therefore decreases CVD which is the main cause of morbidity and mortality worldwide [1].

In 2017, 3 million of deaths and 70 million of disability-adjusted life years were attributed to high salt intake. According to estimates obtained for Portugal, within the scope of the Global Burden of Diseases study, the risk factors that most contribute to disability-adjusted life years in the Portuguese population are inadequate eating habits (15.8%) [2]. Excessive salt (sodium chloride) consumption is estimated to be the avoidable food risk factor that most contributes to the loss of years of healthy life [3].

In Portugal, in 2011/2012 the Portuguese Society of Hypertension evaluated the consumption of salt in a representative sample of Portuguese adults, concluding that the consumption was on average of 10.7g/day of salt, approximately double than that is recommended by the World Health Organization (WHO) [4]. According to data from the national food and physical activity survey, in 2015/2016 added salt was the main source of dietary salt consumed by the Portuguese population [5].

In 2022, excessive salt consumption remains a public health problem and it is essential to find effective measures and strategies to control salt consumption.

With this thesis we intend to contribute and be part of the solution to reduce salt consumption.

The aim of this thesis was to review successful interventions to reduce salt intake and to assess the impact of an intervention using Salt Control H (innovative dosage device) on dietary salt intake, dietary behavior and blood pressure.

Salt Control H is a patented device (INPI, No. 20191000033265)[6] that measures the doses of salt for cooking according to age and number of the consumers.

The following studies are included in this thesis:

I. Gonçalves, C.; Silva-Santos, T.; Abreu, S.; Padrão, P.; Graça, P.; Oliveira, L.; Esteves, S.; Norton, P.; Moreira, P.; Pinho, O. Innovative equipment to monitor and control salt usage when cooking at home: iMC SALT research protocol for a randomised controlled trial. *BMJ open* **2020**, *10*, e035898, doi:10.1136/bmjopen-2019-035898.

II. Silva-Santos, T.; Moreira, P.; Rodrigues, M.; Padrão, P.; Pinho, O.; Norton, P.; Ndrio, A.; Gonçalves, C. Interventions That Successfully Reduced Adults Salt Intake-A Systematic Review. *Nutrients* **2021**, 14, doi:10.3390/nu14010006.

III. Silva-Santos, T.; Moreira, P.; Pinho, O.; Padrão, P.; Abreu, S.; Esteves, S.; Oliveira, L.; Norton, P.; Rodrigues, M.; Ndrio, A.; Gonçalves, C. Impact of an Innovative Equipment to Monitor and Control Salt Usage during Cooking at Home on Salt Intake and Blood Pressure-Randomized Controlled Trial iMC SALT. *Nutrients* **2021**, 14, doi:10.3390/nu14010008.

IV. Silva-Santos, T.; Moreira, P.; Pinho, O.; Padrão, P.; Norton, P.; Gonçalves, C. Salt-related knowledge, attitudes and behavior in an intervention to reduce added salt. (submitted, under review).

Chapter I – Background

1. Salt in health and disease

Sodium is an essential mineral nutrient for maintaining the body's homeostasis. The human population has demonstrated the ability to adapt and survive in extreme conditions in terms of sodium intake, from the consumption of 200mg of sodium per day by the Yanomami Indians in Brazil to 10300mg of sodium per day by the Japanese [7].

Sodium is essentially consumed through salt, which is made up of 40% sodium and 60% chloride [1]. Salt or sodium chloride is the main osmotically active anion in the extracellular fluid, contributes to the maintenance of fluid and electrolyte balance, and is also an important constituent of gastric juice [1]. Most ingested sodium chloride is excreted in the urine (90 to 95%), except when sweating is excessive [8].

The human body needs a very small amount of dietary salt to maintain fluid balance and cellular homeostasis. Under normal conditions, the body adapts to different levels of sodium intake by changing the amount that is excreted through urine and/or sweat. However, with aging or the development of certain chronic diseases, the function of the renal system may decrease, limiting sodium excretion. Thus, in situations of excessive sodium consumption, plasma volume can increase, causing overload of the cardiovascular system and induction of hypertension [9].

The WHO recommends a salt intake below 5g per day (2000 mg/day of sodium) [10] and a potassium intake above 3500mg/day [11]. The dietary reference intakes from institute of medicine indicate that adequate intake in adults is 3.75 g/day of salt (1500 mg/day of sodium) and adequate potassium intake is 3400 mg/day in men and 2600 mg/day in women [12].

The relationship between sodium intake and high blood pressure became a focus of investigation when Dahl in 1960 published a paper with extensive evidence of a positive relationship between sodium intake and high blood pressure during the 20th century. Dahl compared this relationship in various populations and concluded that in societies that usually had a low-salt diet, approximately less than 5g per day, hypertension was not frequent. On the contrary, hypertension was common in populations that ingested high amounts of salt, 10 to 15g per day [13].

A vast and diverse body of evidence has consistently shown a causal relationship between salt intake and blood pressure [14]. Consequently, three million deaths were attributed to high salt consumption in 2017 [2].

The INTERSALT study, the first large international salt study evaluated 10,079 adults from 32 countries using standardized methods for measuring blood pressure and collecting 24-hour urine. The study demonstrated a direct association between blood pressure and salt intake [15].

Another study evaluated more than 102,000 adults from 18 countries and showed that an increase of 1 g of sodium daily increased blood pressure by 2.11/0.78 mmHg. It found that the positive association between sodium intake and blood pressure was stronger in elderly, hypertensive, and low-potassium intake subjects [16]. In the TOHP-II study, a sodium reduction study with 2382 participants with 36 months of follow-up, the mean sodium intake achieved was 3.1 g/day at 18 months and 3.2 g/day at 36 months, consequently, blood pressure values improved and the prevalence of hypertension in the intervention group decreased over time [17].

The relationship between blood pressure and salt consumption has been described by other large epidemiological studies [18,19] and several meta-analyses of randomized trials of salt reduction [1]. Two highly successful examples demonstrating that reducing salt, even in small amounts, lowers blood pressure are the case of Finland and the United Kingdom [20,21]. In Finland, salt consumption in 1972 was 14 g/day and decreased to 9 g/day in 2002. Blood pressure decreased by 10 mmHg and cardiovascular mortality by 75%. During this period obesity and alcohol consumption increased, suggesting a key role for sodium restriction [21]. In the UK, salt consumption in 2003 was 9.5 g/day and decreased to 8.1 g/day in 2002. Systolic blood pressure decreased by 2.7 mmHg and mortality from stroke and ischemic heart disease decreased by 36% [20].

A recent meta-analysis found a significant linear relationship between sodium intake and the risk of CVD, for every 1 g of sodium intake, the risk of CVD increased by up to 6% [22]. Worldwide, a 10% reduction in salt consumption over

10 years is projected to avoid approximately 5.8 million DALYs per year related to CVD [23].

In addition to CVD, there is evidence that excessive salt intake is associated with other health conditions, such as kidney disease, kidney stones, osteoporosis, obesity, stomach cancer, [1,14], dementia [24] and microbiota change [25]. Recent rodent data demonstrate that dietary sodium disrupts intestinal microbial homeostasis as the composition of the gut microbiota changes with manipulation of dietary sodium [25]. Also, some human and animal studies have found evidence of a link between high salt intake and cognitive impairment and Alzheimer's, either due to salt's effect on blood pressure or through blood pressure-independent mechanisms [24,26-28].

Excessive salt intake has been linked to many risk factors for chronic kidney disease, such as proteinuria, blood pressure, endothelial dysfunction and oxidative stress [29]. Reducing salt intake may slow the progression of chronic kidney disease [30]. A high salt intake also increases the risk of kidney stones by causing increased urinary calcium excretion [31].

In recent years sodium intake has been positively associated with obesity [32]. A high salt diet appears to increase fasting ghrelin in healthy subjects, which may be a new underlying mechanism of obesity [33]. In addition, salty food may be an addictive substance that stimulates the opiate and dopamine receptors at the center of reward and pleasure of the brain being "tasty", while the preference for salty foods, craving and hunger may be manifestations of opiates withdrawal [34]. Salt intake is also positively associated with body fat percentage and waist circumference [35]. A recent study concluded that salt intake assessed by urinary sodium excretion was associated with a higher body mass index (BMI), higher waist circumference and a higher prevalence of obesity and central adiposity [32].

Potassium has a protective effect on CVD. In 1928, Addison was the first to suggest that increasing potassium intake can lower blood pressure through its natriuretic effect [36]. The data from the INTERSALT study were very important, confirming that potassium intake was an independent determinant of blood pressure in the population. They found that a 30 mmol increase in potassium was associated with a mean reduction in systolic blood pressure of 2 to 3 mmHg [37].

Lower potassium intake was associated with hypertension [37] and stroke [38]. Therefore, higher levels of consumption may be protective against these risk factors [39].

Elevated Na:K ratio in urine is an indicator of higher sodium intake and lower potassium intake [40,41]. Several epidemiological studies have shown that the Na:K ratio is associated with blood pressure [42]. The TOHP study reported a direct association between urinary Na:K ratio and CVD [43-45] and showed that a higher Na:K ratio was associated with a higher risk of CVD, which was higher than for Na or K alone [43]. The WHO recommends a Na:K molar ratio of approximately 1.00 based on recommendations for sodium and potassium intake [10].

2. Salt consumption

It is estimated that for several million years the diet of human ancestors contained less than 0.25g of salt per day. When the Chinese, about 5000 years ago, discovered that salt could be used to preserve food, allowing to preserve food during the winter, salt became a valuable commodity traded around the world, reaching the peak of consumption around 1870. After the industrial revolution with the invention of the refrigerator and freezer, salt consumption decreased, however in recent years with the increase in the consumption of highly processed foods and discretionary salt, salt consumption has increased to levels close to those of the year 1870, approximately 9 to 12 g per day [15,46].

There are populations that for generations have consumed foods without any added salt, namely the Eskimos, Northwest American Indians and African Masai Indians. When analyzing the diet of these populations, it was found that when consuming only food in its natural state, the maximum consumption of salt is less than 5g per day, with individuals consuming less than 1g per day, except in regions where drinking water has high salinity [13].

A systematic analysis of the 2010 Global Burden of Disease study with 187 countries showed that the average salt intake in adults globally was 10.06 g of salt per day. In Western Europe, it was estimated that average sodium intake values ranged from 8.2 g per day (Denmark) to 11.1 g per day (Italy). In the Netherlands, Belgium, Germany and Iceland, consumption varied between 8.3 g and 9.0 g per day, in another 12 Western European countries, between 9.05 g per day (Switzerland) and 10.1 g per day (Spain) and in Cyprus, Luxembourg, Malta, Portugal and Italy between 10.15 to 11.1 g/day. In North Africa/Middle East, sodium consumption was estimated to range from 7.8 g per day (Lebanon) to 13.4 g per day (Bahrain). In sub-Saharan Africa, the highest estimated consumption was in Mauritius (13.6 g/day). In the United States the estimated average consumption was 9.0 g per day and in Canada 9.3 g per day [47].

A more recent review updated data from the Global Burden of Disease study, identifying studies that measured salt intake through 24-hour urinary excretion in a nationally representative population. Salt intake in the identified studies ranged from 6.75 g/d in Barbados to 10.66 g/d in Portugal. In seven countries, the population's average salt intake has changed since the 2010 review. Average salt intake was lowest in Canada (-0.6 g/d), Barbados (-1.94 g/d), England (-1.11 g/d) and Italy (-1.41 g/d)/d). On the other hand, mean salt intake was higher in Benin (2.96 g/d), Fiji (3 g/d) and Samoa (2.39 g/d). Estimates of salt consumption from the other remaining countries were similar, including Portugal. All countries had a level of salt intake above the WHO recommendations [48].

Although the practice of adding salt to foods is ancient, until relatively few centuries ago, its widespread use as a condiment was uncommon. Currently, the practice is widespread, and salt can be added before, during or after food processing, as well as being added at all stages of handling. The ancient appreciation of salt as a precious commodity may have contributed to the modern notion that it is necessary or even beneficial to add salt to food [13].

Sodium is found naturally in a wide variety of foods, such as milk, meat and seafood. Although it is found in greater amounts in processed foods and in many condiments, namely soy and sauces [10]. Processed foods contain high concentrations of sodium due to the addition of sodium as an additive during processing, and those that contain the greatest amount, mainly under the form of salt is charcuterie, hot dogs, canned vegetables, processed cheese, potato chips, and sauces such as beef broth, which are often used to enhance the flavor of foods [7]. The addition of salt in food is intended to improve the taste, however it can also have a functional role, for example, in bread making it is essential to add salt to the yeast dough, in addition to helping to control the growth of unwanted bacteria and mold [49]. Salt is also added to frozen foods to preserve texture and to decrease the water activity of foods, thus helping to control the growth of pathogenic bacteria. Other food additives that contain sodium, notably sodium benzoate, work as a preservative in processed foods to extend shelf life and control microbial growth [7].

A recent review of major sources of salt included thirty-three studies that contained information on discretionary salt intake. The average salt intake among adults in these studies ranged from 5.2 to 15.5 g/day. Countries that demonstrated that discretionary salt contributed more than 50% to total salt intake were populations in China, Brazil, Guatemala, Costa Rica, Mozambique, Japan, India, Romania, and Benin. Countries that demonstrated that discretionary salt contributed between 25% and 50% of total intake were populations in Portugal, Jordan, Taiwan, South Korea, and Turkey. Populations of Australia, Canada, Austria, Finland, Denmark, the United Kingdom, New Zealand and the United States of America discretionary salt accounted for less than 25% of daily salt intake [50].

In Portugal, the national food and physical activity survey estimated in 2015/2016 that added salt was the biggest contributor (29.2%) of the total daily sodium intake, followed by the group of cereals, derivatives and tubers (20.6%), the group of meat, fish and eggs (18.2%) and dairy products (8.5%)[5].These data are in agreement with several countries and continents, where the group of breads, bakery products, cereals and grains, the meat group and dairy products seems to be the most significant foods for the daily intake of salt [50].

The reduction of population salt consumption was identified as one of the five major priority interventions to prevent non-communicable diseases based on criteria such as health effects, cost-effectiveness, low implementation costs, and political and financial viability. The goal is to reduce world salt consumption to less than 5g (2000mg sodium) per person per day until 2025 [51].

By 2014, 75 countries with national salt reduction strategies were identified, more than double the 32 reported in 2010. In all regions, consumer education was the most commonly used strategy. Educational interventions provide consumers with information, education, or skills to reduce salt intake changing salt-related behavior by strengthening salt knowledge and its effects and adverse abilities to help reduce salt intake. Most programs are multifaceted and also include industry involvement to reformulate products, setting salt content targets for foods, front-of-pack labeling schemes, taxation on salty foods and interventions in public institutions [52].

In addition to interventions to reduce salt at the national level, there are others interventions that focus on individuals or communities. Interventions such as changing consumer behavior at an individual [53,54] or family level [55,56] and changing the environment, such as canteens or schools [57,58].

A review analyzed interventions to reduce salt in canteens. Interventions that reduced salt included changes to the menus, training of cooks (by a cook or nutritionist), replacing added salt with spices, holding food education sessions for consumers and reducing the number of pre-packaged meals with a salt content above 200 mg/portion provided by canteens [57]. Also in the canteens, a pilot study used innovative equipment to gradually reduce the salt added to meals by 30%. The intervention canteen achieved a reduction of more than 30% in salt added to the fish dish (-41.1% per 100 g), soup (-34.3% per 100 g) and meat dish (-48.0% per 100 g). In addition, there was a significant increase in satisfaction with the main dish and there was no decrease in consumer global satisfaction. No significant differences were found in food waste either. The use of equipment that allows the gradual reduction of salt seems to be a good strategy for adequate salt consumption in canteens [58].

At the family level, an educational intervention on the harmful effects of salt and how to reduce salt intake in regular school health education classes for children was successful in reducing salt consumption in children and their families. The intervention was carried out with children who had the mission of transmitting the message of salt reduction to their families. The mean effect on salt intake for intervention versus control group was -1.9 g/day in children and -2.9 g/day in adults [59].

In a study of 291 patients on antihypertensive treatment, the intervention to reduce salt was a low-sodium diet prescribed by a nutritionist. After two months, the intervention group showed a significant decrease in sodium excretion (from 153.1 to 133.5 mEq/24h) and in systolic and diastolic blood pressure (from 134.16 to 126.5 mm Hg and from 80. 59 for 75.9 ± 8.72 mm Hg, respectively) [53]. Individual dietary advice is another important strategy to reduce sodium intake. The health professional-patient encounter provides an opportunity for health professionals to promote changes in lifestyle and behavior. The effectiveness of the health professional in this role can be improved through their greater knowledge [60]. A cross-sectional analysis from the iMC SALT evaluated the association between adherence to the Mediterranean diet and excretion of sodium and potassium. In logistic regression analysis, urinary excretion tertiles of sodium, potassium, and Na:K ratio were not associated with adherence to the Mediterranean diet, even after adjusting for confounders. That is, high adherence to the Mediterranean diet was not associated with lower sodium excretion or high potassium excretion, or their proportion [61]. This traditional healthy eating pattern recommended by health professionals does not seem to be the solution to reducing salt intake and increasing potassium intake. Hence the importance of health professionals having the knowledge to make recommendations based on evidence.

The large and growing number of salt reduction strategies is encouraging, although an inconsistent assessment approach and methodology provides uncertainty about the elements most important to success. It is essential to find solutions on successful strategies and interventions with good methodological bases.

3. Aims

The aim of this thesis was to review successful interventions to reduce salt intake and to assess the impact of an intervention using salt control H on dietary salt intake, eating behavior and blood pressure.

This thesis is organized by studies according to the following specific objectives:

I. To review of successful interventions to reduce adults salt intake (study 2).
II. To implement one randomized controlled trial to reduce salt intake through the use of one innovative dosing device during cooking at home (Salt Control H) (study 1)
III. To assess the impact of the intervention on urinary excretion of sodium, potassium and sodium-to-potassium ratio (study 3).
IV. To assess the impact of the intervention on blood pressure (study 3).
V. To determine changes in behavior, attitudes and knowledge towards salt of the subjects with the intervention (study 4).
VI. To analyze the main sources of salt before and after the intervention (study 4).

Chapter II – Methods

1. Summary of the characteristics of the studies

The characteristics of each study of this thesis are presented in Table 1. The complete description of the methods is presented in the corresponding article in the methods section. The description of the entire randomized controlled trial is described in study 1.

Table 1. Summary of the characteristics of the studies integrated in the thesis.

Study	Type	Main variables	Sample size	Age (years)	Major statistics
Study 1 Innovative equipment to monitor and control salt usage when cooking at home: iMC Salt research protocol for a randomized controlled trial	Protocol	Not applicable	Not applicable	Not applicable	Not applicable
Study 2 Review of successful interventions to reduce adults salt intake	Systematic review	Interventions that successfully reduced salt intake estimated by urinary measurements	21 studies: 16 randomized intervention trials 5 nonrandomized intervention studies	Adullts	Not applicable
Study 3 Impact of an Innovative Equipment to Monitor and Control Salt Usage during Cooking at Home on Salt Intake and Blood Pressure-Randomized Controlled Trial iMC SALT	Randomized controlled trial	One 24-hour urinary sodium and potassium excretion, Na:K ratio and blood pressure at baseline, during the intervention, at the end of the intervention, and at follow-up.	57 Intervention group 57 Control group	47 ± 10 49 ± 11	Independent t test Mann-Whitney U test χ2 test for categorical Linear mixed models with an intention-to-treat approach A per-protocol analysis
Study 4 Salt-related knowledge, attitudes and behavior in an intervention to reduce added salt	Randomized controlled trial	WHO STEPwise tool, module salt One 24-hour urinary sodium excretion at baseline and two 24-hour urinary sodium excretion during intervention One 24-hour dietary recall at baseline and two 24-hour dietary recall during intervention	48 Intervention group 49 Control group	46 ± 10 50 ± 10	Independent t test Mann-Whitney U test χ2 test Wilcoxon test McNemar test Spearman's correlation

Study 1 – Innovative equipment to monitor and control salt usage when cooking at home: iMC Salt research protocol for a randomized controlled trial

BMJ Open

Innovative equipment to monitor and control salt usage when cooking at home: iMC SALT research protocol for a randomised controlled trial

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ABSTRACT

Introduction Excessive salt intake is a public health concern due to its deleterious impact on health. Most of the salt consumed come from those that are added when cooking. This study will improve knowledge on the effectiveness of interventions to reduce salt consumption among consumers.

Methods and analysis In this randomised clinical trial, we will be evaluating the efficacy of an intervention—the Salt Control H, an innovative prototype equipment to monitor and control use of salt when cooking—among workers from a public university, with the aim of reducing their dietary salt intake. We will randomly select 260 workers who meet the eligibility criteria and who are enrolled to an occupational health appointment and randomise them into one of the two arms of the study (either control or intervention), with matched baseline characteristics (sex and hypertension). The intervention will last for 8 weeks, during which the participants will use the equipment at home to monitor and control their use of salt when cooking. The main outcome will be 24-hour urinary sodium excretion at baseline, at fourth and eighth weeks of intervention, and at 6 months after intervention.

Ethics and dissemination Ethical approval for the study has been obtained from the Ethics Committee of the Centro Hospitalar Universitário São João. The results of the investigation will be published in peer-reviewed scientific papers and presented at international conferences.

Trial registration number NCT03974477

Equipment provisional patent number Registered at INPI: 20191000033265.

Strengths and limitations of this study

- ► A researcher independent of the recruitment and intervention process will perform stratified randomisation.
- ► Laboratory analysis will be performed by technicians who are unaware of the origin of the samples for analysis (control or intervention group).
- ► Dietary salt consumption will be assessed by 24-hour urine collection.
- ► Statistical analyses will be carried out by an independent researcher.
- ► Double-blinded study design is not possible in the current study.

INTRODUCTION

Dietary salt intake has been causally linked to high blood pressure and increased risk of cardiovascular problems.[1] Cardiovascular diseases, including coronary heart diseases and cerebrovascular diseases, are the main causes of morbidity and mortality in the European Union, including Portugal.[2] In 2014, inadequate dietary habits were the major risk factors that contributed to the total disability adjusted life years in the Portuguese population. Low fruit intake and eating salty food were particularly the main factors responsible for the loss of years of healthy life.[3]

Excessive salt intake is one of the greatest risks to public health in Portugal,[4–6] making it urgent to propose measures to reduce its intake. Small reductions in consumption can bring great benefits to the health of the population, not only in terms of cardiovascular diseases, but also in relation to other chronic diseases prevalent in Portugal.[7]

In European countries, a large proportion of salt ingested by consumers come from food prepared outside home and which are added during food production (75%–85%), while around 10%–12% come from food prepared at home.[7,8] In the Portuguese population, the main source of salt consumption is the salt that are added during food preparation and cooking (29%).[9]

Despite it being naturally present in some foods, a large majority of salt are added to food during processing or cooking.[10] The quantity of sodium ingested could vary greatly depending on the food product that a person chooses to eat.[7 11] A study that analysed sodium content present in vegetable soups served in several canteens concluded that the mean salt content varies greatly between canteens, with no clear pattern with regard to the amount of salt added when cooking.[12] In fact, most chefs recognise that even when cooking meals for children they use an arbitrary amount of salt based on flavour.[13] The difference in salt content found in food at the market-place and at restaurants makes it difficult for consumers to meet dietary guidelines.

Salt is a learnt taste preference. With exposure to consistently high levels of salt in food, high levels of salt become appetising and so people start to choose food with higher salt content. Research suggests that the preferred level of salt in food is dependent on the level of salt consumed, and that this preferred level can be lowered when sodium intake is reduced.[14]

The reduction of salt intake has been recognised by the WHO as a priority,[15 16] and recommends that daily sodium intake should be less than 2000 mg/day (5 g/day).[17] In 2013, all WHO member states committed to reaching the target reduction in salt intake of 30% by 2025, aiming a target of 5 g per day in the adult population.[18]

In 2015, the Portuguese government assumed that salt reduction was imperative to public health and promoted the creation of an interministerial working group,[19] which elaborated on a consensus document[20] that highlights the necessity to set quantifiable reduction targets and monitor salt consumption.

Almost all countries have failed to reduce the quantity of salt added to catered food as well as during food preparation at home. The development of a quick and user-friendly instrument to monitor and control salt added to food when cooking is a potential solution. This study will provide important evidence on salt reduction and its sustainability, which can then help policymakers design as well as reformulate effective strategies to help consumers manage their salt intake. Indeed, previous community intervention studies using spoons to restrict salt intake have shown encouraging effects.[21]

As such, the main objective of this study is to verify the impact on participants' salt consumption, of an intervention, that is the use of the Salt Control H equipment during the preparation and cooking of meals (innovation to monitor and control salt - iMC SALT project).

METHODS AND ANALYSIS

Trial design

Participants were recruited from the staff of the University of Porto who were enrolled to occupational health appointments. Occupational health appointments are annual health appointments mandatory for all workers of the university (white-collar and blue-collar workers). Recruitment was carried out by the doctor responsible for the appointment, which started in June 2019 and will last until enough number of participants have been obtained for the study (n=260) or until March 2021.

The participants were randomised into two groups: control group (CG) or intervention group (IG). The intervention lasts 8 weeks, during which the participants use the Salt Control H equipment to dose salt when preparing and cooking food at home. At 6 months after the first intervention, the participants will be reassessed (follow-up) (figure 1).

The Salt Control H equipment has been patented (INPI, N° 20191000033265)[22] and consists of a dosing device that provides doses of salt according to the number and age (children or adult) of the person who will consume the meal. The prototype is available only for testing, and not for commercial distribution. It will be tested by researchers in controlled dietary studies. This prototype system relates to a dosing device that comprises a dosing mechanism that dispenses 0.8 g of salt (for adult) or 0.2 g of salt (for children) for meals, and 0.2 g of salt for every 250 mL of soup for adults or 0.1 g of salt for every 250 mL of soup for children. Between each group of participants, the prototype equipment will be sanitised, disinfected and packed in an airtight bag.

The trial is registered at ClinicalTrials.gov.[23]

Hypothesis

The main hypothesis of this study is that by using the Salt Control H equipment to prepare and cook meals, participants will reduce their overall daily intake of salt in order to achieve WHO's recommended intake. Nevertheless, this intervention could have an impact on other parameters, such as the sodium to potassium ratio of diet,[24] blood pressure,[25] hydration status[26] and iodine intake,[27] as shown by previous studies.

Results of a recent research suggest that the intestinal microbiome is affected by diet, with potential consequences for the host organism and the immune system.[28] Therefore, in our study we address the role of diet in shaping the microbiome and the influence of salt consumption on gut microbiota composition. Other parameters will be analysed in an exploratory way, such as knowledge on dietary salt requirements, quality of life, quality of diet and participants' culinary skills. Since the intervention can promote behavioural change among individuals, namely the need to adapt new culinary knowledge with regard to cooking with lower salt content, the search continues for more information on topics such as salt food sources and the potential to change some home cooking habits and family conviviality routines.

Participants

The following were the eligibility criteria used by the doctor responsible for the occupational health appointment: adult (>18 years), frequently eats home-cooked meals (more than 4 days a week and at least 3 Sundays per month), one annual occupational health appointment at the hospital and reports motivation to control dietary salt consumption. The following were the exclusion criteria: pregnant, with hypotension, kidney disease, active infection that impacts renal function, urinary incontinence,

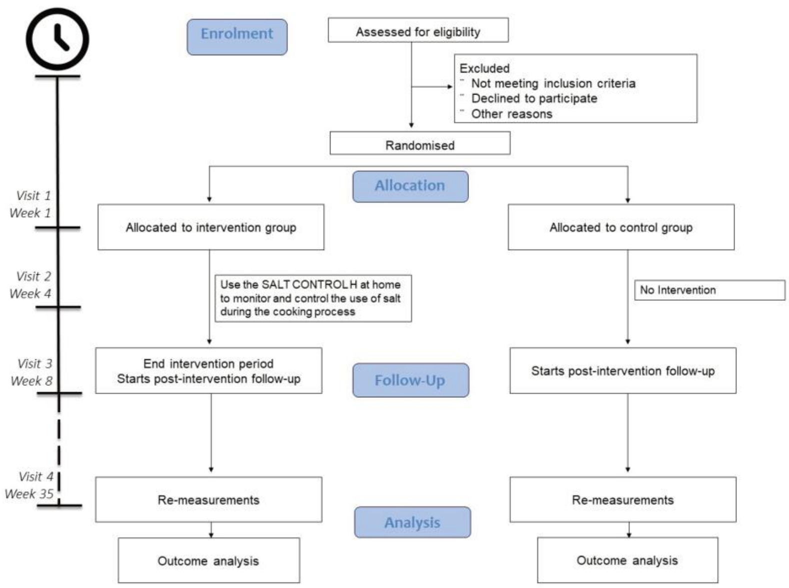

Figure 1 Study design.

acute coronary syndrome, severe liver disease or heart failure, not using salt for cooking, and staff member of the faculty that promotes the study.

Sample size

The sample size was calculated to provide more than 80% statistical power at a significance level of 0.05 bicaudal, assuming a difference in the mean 24-hour urinary sodium excretion equal to or greater than 27 mmol/day between IG and CG, with an SD of 70 mmol/day.[29] In addition, this calculation was adjusted considering a 20% participant dropout, resulting in a sample size of 260 participants. A subsample of participants (n=20) will be used for intestinal microbiota analysis.

Randomisation

Considering differences in salt intake between sex and the clinical condition of arterial hypertension,[6] stratified randomisation of participants was done taking into account the following steps:

- Stratification of participants by sex (1:1 ratio).
- Stratification of participants according to diagnosis of arterial hypertension (0.4:0.6 ratio)[6].
- Allocation of participants to the control or intervention group (1:1 ratio) using computerised random numbers.

A researcher independent of the recruitment and intervention process will perform the randomisation, and the allocation sequence was concealed until visit 1, during which the participants and the researchers discover the group to which the participant belongs by opening sequentially numbered, opaque and sealed envelopes.

Blinding

Participants and researchers were not blinded because the study compares interventions with one equipment that cannot be masked. Nevertheless, the laboratory analysis (sodium, potassium, iodine and so on) was performed by laboratory technicians who are unaware of the origins of the samples for analysis (control or intervention group and the identity of the participant). In addition, the researcher responsible for randomisation and statistical analysis was not involved in the recruitment, nor did the researcher has contact with the participants during data collection. The researcher was also unaware of the participants' origin (ie, control or intervention group and the identity of the participant).

Study intervention

The monitoring points (visits) of the study need to be carried out on days when the participant consumed meals prepared at home (preferably data collection was done on Sundays). Visits for data collection were as follows:

Screening visit (week 0)

During the first visit, participants' eligibility criteria are verified by the doctor. If eligible, the participant signs the informed consent form and is given the questionnaires. The participant then undergoes anthropometric and blood pressure measurements and is also given 24-hour urine collection containers. The participant will then be randomly allocated to CG or IG.

Visit 1 (week 1)

One week after the screening visit, the participant will be in contact with the researchers to deliver the 24-hour urine container and to fill out the questionnaires.

IG participants will receive one standardised presentation session that explains, through a tutorial video, how the Salt Control H equipment works to ensure adequate salt content during food preparation and cooking. A researcher will also explain some culinary strategies on how to prepare meals with adequate salt content. Participants are also given food education book, as well as a leaflet on Portuguese food guide.[30] CG participants will only receive a leaflet on Portuguese food guide.[30]

In one subsample of IG participants, a kit for collection of intestinal microbiota sample will be provided.

Visit 2 (week 5)

After the first month of intervention, the participants will be in contact with the researchers to deliver the 24-hour urine container. Anthropometric and blood pressure data will also be collected during this visit.

Visit 3 (week 9)

After the second month of intervention, the participants will be in contact with the researchers to deliver the 24-hour urine container and the intestinal microbiota sample and to fill out the questionnaires. Anthropometric and blood pressure data will also be collected during this visit. IG participants will stop the use of equipment after this visit.

Visit 4 (week 35)

Six months after the intervention, the participants will be in contact with the researchers to deliver the 24-hour urine container and to fill out the questionnaires. Anthropometric and blood pressure data will also be collected during this visit.

Outcomes

Primary outcome

The primary outcome is the difference in the 24-hour urinary sodium between the control and the intervention group from baseline over the 8-week follow-up. The 24-hour urine collection will be performed on any day of the week (preferably on Sunday, but not on Friday and Saturday due to laboratory availability), and a total of four urine collections will be obtained by each participant: before the intervention, on the fourth and eighth week of the intervention, and 6 months after intervention. Urine collection will be performed using sterile containers that were provided to the participants. The containers were coded to conceal their provenance.

The 24-hour urine collection procedure was explained to each participant and a pamphlet was given with indications about the procedure.

On receipt of the containers on the day immediately following the 24-hour urine collection, the researcher sends the containers to a certified laboratory. The following parameters were analysed: volume, sodium (by indirect potentiometry), potassium (by indirect potentiometry), iodine (by ammonium persulfate digestion with spectrophotometric detection of the Sandell-Kolthoff reaction), osmolality (by osmometry), creatinine (by photometry), density (by reflection refractometry) and pH (by dual wavelength reflectance). The validity of urine specimen collection will be assessed by volume, creatinine and complete collection reported by the participant.

Secondary outcomes

The assessment of each secondary outcome will be described separately. All secondary outcomes except one (intestinal microbiota) will be assessed at baseline, at fourth and eighth weeks, and at 6 months after intervention.

Intestinal microbiota

To collect intestinal microbiota samples, participants were provided with an EasySampler Collection Kit, which was used according to the instructions, and an explanatory leaflet. Participants collect their samples at home, and the researcher will forward the samples to a certified laboratory. The samples will be thoroughly analysed and the parameters will address the following: alpha and beta diversity indices (by new generation sequencing of ribosomal RNA (rRNA) subunit 16 gene in the intestinal microbial community, followed by bioinformatic analysis) and filo-level distribution of operational taxonomic unit (OTUs) (by bacterial categorisation based on similarities between 16S rRNA gene sequence variants). The samples will be collected before the intervention and at the eighth week of intervention. The analysis will be performed on the first 20 IG participants who agreed to collect a sample. This analysis will be an exploratory study performed in a subsample of participants determined by the number of collection kits available according to our budget (n=20).

Anthropometric variables

Height (SECA 213 portable stadiometer, Hamburg, Germany) and waist and hip perimeter (SECA 201 tape) were measured according to international standard procedures.[31] With participants wearing light clothing and without shoes, body composition (fat, fat free mass, bone mass, basal metabolic rate, total body water and body mass index (BMI)) was assessed using Tanita MC180MA body composition analyser (Tanita, Illinois, USA). Only weight was taken from participants with pacemaker using SECA 813.

Blood pressure

Blood pressure was measured using a portable sphygmomanometer (Edan M3A, Edan Instruments, China) with participants seated and was taken after a 5 min rest. Blood pressure measurements were done in both arms during the first assessment to determine possible arm-related measurement differences. Using the arm with the highest blood pressure value as a reference, the blood pressure was assessed twice. If the difference between the first two evaluations was higher than 10 mm Hg, one more evaluation is done.

Dietary intake

Dietary intake was assessed by a 24-hour dietary recall and a semiquantitative Food Frequency Questionnaire (FFQ). This semiquantitative FFQ has been validated among Portuguese adults[32] and adapted to include a variety of typical Portuguese food items. The FFQ administered at visit 1 covers the previous 12 months before inclusion in the study, while that at visit 4 covers the previous 8 months after inclusion in the study.

With regard to 24-hour dietary recall, participants were asked to recall all foods and drinks consumed the previous day (during the time of urine collection) and to estimate the portion size with the help of an illustrated book[33] and household measures. Energy and nutritional intake were estimated using an adapted Portuguese version of the nutritional analysis software Food Processor Plus (ESHA Research, Salem, Oregon, USA). The nutritional content of local food was taken from standard nutrient tables, whereas the content of commercial food (eg, pizza and ready-to-eat-food) was derived from labelled ingredients and nutrients. The intake of dietary supplements such as multivitamin/minerals/vitamin supplements will also be evaluated in an interview, covering dosage and frequency of intake.

Quality of life

The WHOQOL-Bref (World Health Organization Quality of Life Instruments - Bref) Questionnaire adapted to and validated in the Portuguese population will be used.[34]

Additional variables

Covariates as descriptive variables or potential confounders for the analyses will be collected and are described separately.

Physical activity

The level of physical activity will be characterised using the International Physical Activity Questionnaire-Short Form, validated and adapted to the Portugal population,[35] and will be assessed at baseline, at eighth week of intervention and at 6 months after intervention.

Sociodemographic and health characterisation

The sociodemographic questionnaire was based on the WHO STEPS questionnaire,[36] and some pertinent questions to characterise our study were also included, such as the district where the participant resides (iodine), medication consumption, and probiotic and nutritional supplement consumption. Skin phenotype was characterised according to Fitzpatrick's classification,[37] classified as redhead with freckles, blond, brunette, Latino, Arab, Asian or black. To characterise knowledge and habits with regard to salt consumption, a translation of the questionnaire proposed by WHO[36] and the Pan American Health Organization[38] will be used. The doctor responsible for the recruitment appointment will perform hypertension diagnostics on participants. These variables will be assessed at baseline, at eighth week of intervention and at 6 months after intervention.

Culinary skills characterisation

A questionnaire developed by the research team based on the questionnaire used by Santos[39] will be administered at baseline, at eighth week of intervention and at 6 months after intervention.

Salt consumption

Participants collected a 20 g (one tablespoon full) sample of salt used on the Salt Control H equipment while cooking and placed the sample in a coded plastic bag. The iodine content of the sample was then analysed by potentiometric determination. Only IG participants will perform this collection during the intervention period. This is to determine the iodine content of salt usually used at home by IG participants.

Non-participants and subjects lost to follow-up

A questionnaire about simple sociodemographic questions was administered to the participants who drop out or do not agree to participate in the study. Missing data will be imputed using multiple imputation.

Treatment fidelity

Instructions about the use of Salt Control H equipment to prepare and cook meals were presented to participants through a short video. After watching the video, participants were asked to verbally confirm their understanding of the use of the equipment. If participants had doubts, the researcher reinforces the instructions using practical examples.

Monitoring of the correct use of equipment was carried out by a researcher through telephone, email and at visit 2 in order to clarify doubts about its use and to verify compliance with its use. At visit 3 a questionnaire on the frequency of use of the Salt Control H equipment to prepare and cook meals was administered.

Patient and public involvement

Patients or the public were not involved in the design, conduct, reporting or dissemination of the research.

Statistical analysis plan

Statistical analysis will be performed using the latest version of Statistical Package for Social Sciences (SPSS Version 25) for Windows. All statistical analyses and CIs will be two-sided, with $p<0.05$ regarded as significant.

Differences in baseline characteristics between the control and the intervention group will be reported for primary and secondary outcomes. Descriptive statistics (mean, mode, median, SD and IQR, number and percentages) will be used taking into account the characteristics of the variables. Normality of variables will also be studied using the Kolmogorov-Smirnov statistical test. Differences between the control and the intervention group will be analysed using independent t-test or Mann-Whitney U test for continuous variables and χ^2 test for categorical variables.

The primary effect parameter will be the difference in the 24-hour urinary sodium between the control and the intervention group, and will be done using an intention-to-treat approach with participants analysed according to initial randomisation. Linear mixed model will be conducted to test the change in 24-hour urinary sodium from baseline over the 8-week follow-up. Additionally, a per-protocol analysis will be performed on all participants with valid urine collection both at baseline and at 8-week follow-up. Linear mixed model will be adjusted for potential confounders (age, BMI and other variables that differ between the trial arms). There are preplanned subgroup analyses for sex and hypertension.

The aim of the secondary analysis is to test the effect of intervention on intestinal microbiota, anthropometric measurements, blood pressure and dietary intake (macronutrients, micronutrients and percentage contribution of dietary sources to total intake of sodium). As described for the primary outcome, an intention-to-treat analysis will be performed for each of the secondary outcomes and linear mixed models will be applied. Adjustment for potential confounders will be done for age, BMI and other variables due to their differences between the control and the intervention group.

For primary outcome and each secondary outcome, we will estimate the mean differences during the 8-week intervention with 95% CI.

One possible limitation of our study is the contamination of CG participants by IG participants since all participants will be recruited from the same university, although the total number of blue-collar workers is 2436 while that of white-collar workers is 1593, distributed in 14 faculties that are geographically dispersed. In order to mitigate this situation, we will perform a contamination-adjusted intention-to-treat analysis.

DATA MANAGEMENT

Only the principal investigator (PI) will have access to the encoding file and will be responsible for keeping it separately from the data set, ensuring data confidentiality. To promote data quality, one researcher will introduce data to the databases, and a double data entry check and verification of strange values outside the possible range will be carried out. The PI has the responsibility to reserves the paper questionaires generated after data collection. Access to totally anonymised and complete data set by other researchers from the team requires prior agreement with the PI.

ETHICS AND DISSEMINATION

The project was approved by the Ethics Committee of the Centro Hospitalar Universitário São João. Good clinical practices regarding clinical trials with intervention[40] and the Clinical Investigation Law guidelines were followed.[41] All participants signed an informed consent statement and received a document containing information about the study. The results of the investigation will be published in peer-reviewed scientific papers and presented at international conferences.

TRIAL STATUS

Recruitment began in June 2019 and is estimated to be complete by March 2021. The results of the trial will be available in 2021.

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Contributors Study design: CG, SA, PP, PM and OP. Drafting of the manuscript: CG and TS-S. Critical revision of the manuscript: SA, PP, PG, LO, SE, PN and PM. Approval of the final version for publication: all coauthors.

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Competing interests The study will use one prototype system that has been submitted with a provisional patent number (INPI, Nº 20191000033265). CG, PG, LO, SE, PM and OP are inventors of the prototype system. The inventors have intellectual property rights.

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Chapter III - Results

Study 2 - Review of successful interventions to reduce adults salt intake

nutrients

Review

Interventions That Successfully Reduced Adults Salt Intake—A Systematic Review

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Abstract: Background: Adequate sodium intake is important for lowering blood pressure and thus reducing cardiovascular disease risk and other complications. The aim of this review is to identify recent interventions around the world that have been successful in reducing salt intake. Methods: A search in the PubMed, Web of Science and Scopus databases was performed. We include studies published in the last 10 years; randomized trials, pilot intervention without a control arm or experimental study; adult participants; and interventions that successfully reduced salt intake. Study quality was assessed. Results: We included 21 studies, 16 randomized intervention trials and five nonrandomized intervention studies. Eleven interventions described health and nutritional education, seven interventions described nutritional education plus other interventions, and three studies used salt meters to reduce sodium intake. Conclusion: Health and nutritional education, nutritional education plus other interventions and estimates of salt intake showed success in the reduction of salt consumption. There is no evidence that one type of intervention analyzed is more effective than other in reducing salt consumption, so we must analyze each in which individuals or subpopulations will have the intervention performed and use the most suitable approaches to lead to better results.

Keywords: salt reduction; sodium; behavior change; hypertension; dietary intervention

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1. Introduction

Noncommunicable diseases are the main factor for global morbidity and mortality. Approximately 17 million people die annually from cardiovascular diseases and about 9.4 million of these deaths are due to complications of hypertension [1,2].

Excessive sodium in the diet increases blood pressure and therefore increases the risk of cardiovascular diseases [3]. It is estimated that 3 million deaths worldwide are associated with high sodium intake [4].

Reducing sodium intake is important to lower blood pressure and thus reduce cardiovascular diseases and other complications associated with high sodium intake, such as chronic kidney disease, obesity, gastric cancer and liver diseases. The most common form of sodium consumption is sodium chloride, commonly known as table salt [5,6]. Reducing salt intake by 3 g per day is projected to reduce the annual number of new coronary heart disease cases by 60,000 to 120,000, stroke by 32,000 to 66,000, myocardial infarction by 54,000 to 99,000, and myocardial infarction by 44,000 to 92,000 the annual number of deaths from any cause. It would save 194,000 to 392,000 quality-adjusted life years and $10 billion to $24 billion in health care costs annually [7].

The World Health Organization (WHO) has flagged population salt reduction as one of the five priority interventions to prevent noncommunicable diseases. The WHO has adopted a global target of 30% reduction in the mean salt intake by the population until 2025 [8,9].

In 2014, 75 countries with national salt reduction strategies were identified, more than double the 32 reported in 2010. However, there are limited examples of effective strategies to reduce dietary salt intake around the world and uncertainty about the specific initiatives or elements of the strategy that are central to its success [10,11].

In 2016, WHO published the SHAKE package to assist in the development, implementation and monitoring of salt reduction by the population, based on five principles; namely surveillance, harness industry, adopt standards for labeling and marketing, knowledge and environment [12]. In countries where salt added to the table or during cooking is the main source of salt intake, education and communication strategies are important to influence the behavior of consumers, cooks and suppliers to reduce the use of salt. Educational interventions provide consumers with information, education or skills to reduce salt intake, altering people's salt behavior, strengthening knowledge of salt and its adverse effects and abilities to help reduce salt intake [11,12]. In countries where processed foods are the main source of salt, the food industry and government policy makers are the target audience. However, consumer engagement gained through education and communication can put pressure on the food industry to follow through on salt reduction commitments [12].

Previous reviews have evaluated interventions to reduce salt intake [13,14]. Our review summarizes recent interventions that have been successful in reducing salt as measured by urinary excretion measures. Therefore, the aim of this review is to identify interventions around the world over the past ten years that have been successful in reducing salt intake.

2. Materials and Methods

The systematic review followed the recommendations of the Cochrane collaboration method [15] and was written according to the Preferred Reporting Items for Systematic Reviews and Meta-Analyzes (PRISMA) [16]. The review protocol was registered with the International prospective register of systematic reviews (PROSPERO), the University of York Center for Reviews and Dissemination (CRD42020221165).

2.1. Eligibility Criteria

2.1.1. Types of Studies

We include studies published in the last 10 years and written in English, Portuguese, French or Spanish. Randomized studies, pilot interventions without a control arm and experimental studies were included in this review.

2.1.2. Types of Participants

Studies of all populations, adults (>18 years) and living in any region worldwide. We excluded studies that not exclusively targeted on sodium intake, but on various health behaviors (e.g., physical activity) and participants with kidney disease.

2.1.3. Types of Intervention

This review focused on interventions that successfully reduced salt intake. Success in reducing salt was defined as a statistically significant reduction ($p < 0.05$). Studies with an intervention period of less than four weeks were excluded.

2.1.4. Types of Outcome Measures

The primary outcome of this review was the reduction in salt intake estimated by urinary measurements (24-h urine collection and urine spot). The secondary outcome was changes in blood pressure values.

2.2. Information Sources

The studies were identified by searching electronic databases and scanning reference lists of the articles included in this article and in systematic reviews that emerged in the search for data. The databases searched were PubMed, Web of Science and Scopus. The research period in November 2020 was the last 10 years (between 2010 and October 2020); however, processing the review data took time and to ensure that the evidence was current and applicable to the current environment, additional research was carried out to include the period between October 2010 and August 2021, but no additional articles were found that met the inclusion criteria.

2.3. Search Strategy

The search was performed by one author (TS-S) and included two categories: "Interventions for reducing salt intake" terms and "Urinary measures" terms.

The search terms used in PubMed were as follows: (Intervention or "Food programmes" or "food policy" or "meal plan" or "food and nutrition education" or "health promotion" or activity or project or campaign or initiative or marketing or media) and (("dietary salt" or "dietary sodium") or ((salt OR sodium) and (consumption or intake ordiet orfood ornutrition ordietetics))) and (urin*). These terms have been adapted for research on the Web of Science and Scopus.

2.4. Selection Process

Two authors (TS-S, MR) independently selected the titles and abstracts first and then the full text of the studies. Discrepancies in the selections were discussed until consensus was reached. When no agreement was reached, a third author decided (CG).

2.5. Data Collection Process

Two authors (TS-S, MR) independently extracted all data and verified the extracted data. Disagreements were resolved by discussion between the two.

Data were extracted according to the Cochrane handbook for systematic intervention reviews [15] and included author, publication year, title, country, participants (e.g., number, age, sex), study eligibility criteria, study design, recruitment and sampling procedures, enrolment start and end dates; length of participant follow-up, random sequence generation, allocation sequence concealment, masking for randomized trials, and methods used to prevent and control for confounding, selection biases, and information biases for non-randomized studies, methods used to prevent and address missing data, statistical analysis, source(s) of funding or/and potential conflicts of interest, description of the intervention(s) and comparison intervention(s), type of urinary measurements, laboratory method used to analyze urine, method of aggregation (e.g., mean and standard deviation of sodium intake and blood pressure values before and after the intervention), number of urine collections, timing of outcome measurements, number of participants randomly assigned and included in the analysis; and number of participants who withdrew, were lost to follow-up or were excluded (with reasons for each).

2.6. Study Risk of Bias Assessment

The quality of the study was independently assessed by two reviewers (TS-S, MR). Discrepancies in the selections were discussed until consensus was reached. The risk of bias in randomized clinical trials was assessed using the Cochrane risk of bias tool (RoB 2) [17] and in non-randomized intervention studies using the ROBINS-I tool [18].

RoB tool considered the assessment of bias in five domains; namely, randomization process, deviations from intended interventions, missing results data, measurement of the outcome and selection of reported results. The judgments of risk of bias in each domain are assessed as low risk of bias, some concerns or high risk of bias. According to each domain assignment, an overall risk of bias judgment was made.

The ROBINS-I tool includes seven domains divided by pre-intervention and at-intervention (confounding, selection of participants into the study, classification of intervention) and post-intervention (derivations from intended intervention, missing data, measurement of outcomes, selection of the reported result). The results of the judgment for each domain and for the final overall bias were categorized as low, moderate, serious, or critical risk of bias, or no information.

3. Results

3.1. Study Selection

The search identified 2065 records and three additional records were added by scanning the reference lists of articles included in this article and in systematic reviews that emerged from the data search. After discarding duplicates, 1553 abstracts were selected to review titles and abstracts, leaving 83 complete articles to be evaluated for eligibility. Of these, 62 full articles were excluded; the reasons for the exclusion of these studies were: 14 studies in which the interventions did not successfully reduce salt intake, 15 were not an intervention to reduce salt, two did not meet the intervention time, one study was published over 10 years ago, nine studies with study design did not meet the inclusion criteria, one was a duplicate article, there were 10 studies in which the target population was not adult, and 10 studies did not distinguish the impact on salt consumption of a broader initiative. After screening, 21 articles were included for qualitative synthesis (Figure 1).

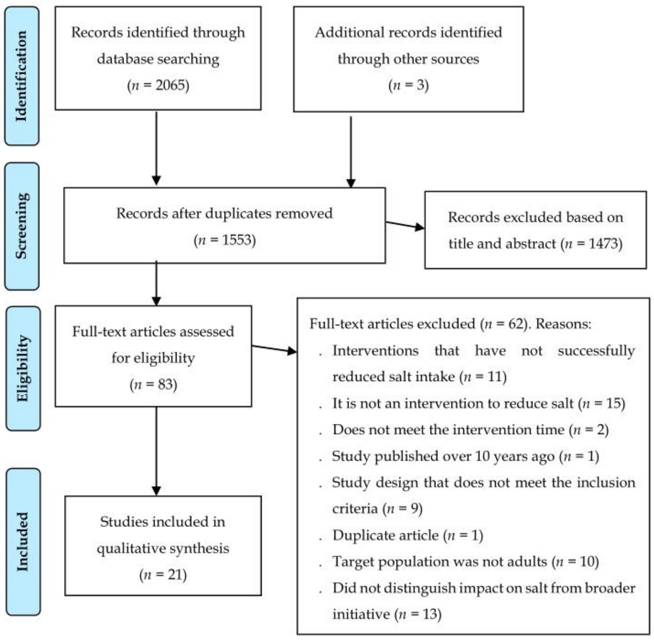

Figure 1. PRISMA flow chart of included studies.

3.2. *Study Characteristics*

Tables 1 and 2 describe an overview of all included studies.

3.2.1. Participants Characteristics

All studies were published between 2010 and 2020; the sample of each study ranged between 30 and 753 participants; the median of participants was 117. Eleven studies were conducted in Asia (Japan [19–23], Iran [24–26], China [27,28] and Thailand [29]), four studies were conducted in Europe (Republic of Ireland [30], Denmark [31], Bosnia-Herzegovina [32] and Italy [33]), four studies conducted in America (United States [34–36] and Brazil [37]) and two studies conducted in Australia [38,39].

Eleven studies were conducted in the general population [19,20,23,25–28,31,36,38,39], eight studies in participants with hypertension or pre-hypertension [21,22,24,30,32–34,37], one in people at high risk of cardiovascular disease [29], and one study in heart failure participants [35].

Participants in the studies included in this review were recruited from the community (n = 10) [19,23,25,26,28,30,31,34,38,39], clinics for the treatment of hypertension, health centers or hospitals (n = 5) [21,29,32,35,37], a railway company (n = 1) [22], from other previous study (n = 1) [24], in a school (n = 1) [27], in a university (n = 1) [36] and in several locations, including an agricultural cooperative, a hospital, and two cities (n = 1) [20]. One study included in this review did not contain information about the place of recruitment the participants [33].

Table 1. Overview of characteristics of the included randomized trials.

Study Author (Year), Country	Participants	Study Design	Enrolment Start and End Dates; Length of Participant Follow-Up	Intervention	Method of Assessment	Results		
						Reduction in Salt Intake (g/day) in the IG	Difference in Salt Intake (g/day) between IG and CG	Blood Pressure (mmHg)
Ireland [38] (2010), Australia	43 Healthy free-living adults (33 women). Tick group, $n = 22$. Food Standards Australia New Zealand group, $n = 21$.	8-week parallel design randomized	August 2008 and October 2008.	Participants received dietary education to choose foods identified by either Australia's National Heart Foundation Tick symbol or by the Food Standards Australia and New Zealand's low-salt guideline of 120 mg sodium/100 g food.	24 h urinary Na excretion, 1 urine collection at 3 different times (baseline, week 4, week 8).	0.9 in Tick group 2.0 in Food Standards group	NI	NA
Morikawa [22] (2011), Japan	41 Hypertensive male workers employees of a rail-road company. IG, $n = 22$, (48 mean years). CG ($n = 19$, 47 mean years).	Quasi-randomization intervention control	4-week follow-up.	Self-monitoring of daily salt excretion by an electronic salt sensor and sent personalized e-mail advice via cellular phone.	Overnight urine using the electronic salt sensor, only participants in IG (for 1 week at baseline and during the week 4). BP (baseline and week 4)	0.7	NA	SBP: −5.4 in IG DBP: −6.2 in IG
Barros [37] (2014), Brazil	38 Hypertensive individuals (56 mean years, 65.7% women). IG, $n = 19$. CG, $n = 16$.	Single-blind randomized controlled trial	May to October 2012, 4-week intervention.	All patients were instructed to consume only the provided salt throughout this study (light salt for the intervention group and regular salt for the control group). In addition, they were instructed to reduce sodium-rich food consumption during the study period, being particularly warned about industrialized foods.	24 h urinary Na excretion, 1 urine collection at 2 different times (baseline and at the end of the trial). BP (baseline and at the end of the trial).	4.5	−3.2	SBP −12.47 ($p = 0.034$) in IG×CG. DBP −7.58 ($p = 0.046$) in IG×CG
Anderson [34] (2015), USA	40 Individuals for whom the Dietary Guidelines for Americans recommends 1500 mg Na/day (61 mean years, 88% African American). IG, $n = 20$. CG, $n = 20$.	Randomized clinical trial	2012 to 2014, 20-week intervention.	2-phase study. In phase 1, all participants consumed a low-sodium diet for 4 weeks. Participants were provided all foods, snacks, and calorie-containing drinks. In phase 2, were randomly assigned to either a multifactorial behavioral intervention emphasizing spices and herbs to reduce sodium intake or a self-directed control group.	24 h urinary Na excretion, 7 urine samples as follows: 2 samples at screening, 2 samples at week 4 (baseline), one sample at week 14, and 2 samples at week 24.	2.3	−2.4	NA

Table 1. *Cont.*

Study Author (Year), Country	Participants	Study Design	Enrolment Start and End Dates; Length of Participant Follow-Up	Intervention	Method of Assessment	Results		
						Reduction in Salt Intake (g/day) in the IG	Difference in Salt Intake (g/day) between IG and CG	Blood Pressure (mmHg)
He [27] (2015), China	553 Adult family members of primary school children. CG, $n = 275$ (44 mean years). IG, $n = 278$; 44 mean years.	Cluster-randomized controlled trial	May to December 2013, 3.5-month intervention.	Children in the intervention group were educated on the harmful effects of salt and how to reduce salt intake within the schools' usual health education lessons. Children then delivered the salt reduction message to their families. Parents were provided with educational materials in the form of a newsletter.	24 h urinary Na excretion, 2 urine collections at 2 different times (at baseline and at the end of the trial). BP (at baseline and at the end of the trial).	2.1	−2.9	SBP −2.3 ($p < 0.05$) in IG×CG. DBP −0.9 ($p = 0.31$) in IG×CG
Markota [32] (2015), Bosnia-Herzegovina	150 Adults treated hypertensives. CG, $n = 74$ (59 mean years, 37 women). IG, $n = 76$ (59 mean years, 40 women).	Randomized clinical trial	September 2012 to July 2013	Intervention group: received individual information leaflets about the untoward effects of excessive salt consumption and received warning stickers to be mounted on all salt containers. Control group: only information leaflets.	24 h urinary Na excretion, 1 urine collection at 3 different times (baseline; 1 month and 2 months after the intervention). BP (baseline, 1 month and 2 months after the intervention).	2.0	NI	SBP: −5.3 in IG DBP: −2.9 in IG
Dunbar [35] (2016), USA	117 Heart Failure patients and one family member–dyads (56 mean years, 37% women). Usual Care (UC), $n = 37$. Family Education (PFE), $n = 41$. Family Partnership Intervention (FPI), $n = 37$.	3-Group randomized control trial	4-Month behavior change. 4 to 8-month maintenance phase of behavior change.	UC group: received usual care from their providers and was provided with educational pamphlets that were created by the Heart Failure Society of America (HFSA). PFE group: received usual care, the HFSA pamphlets, and educational sessions. FPI group: received the same education and counseling as described in the UC and PFE groups plus 2-additional group sessions that focused on teaching the dyads how to give support, communication, empathy, and autonomy support for one another's roles.	24 h urinary Na excretion, 1 urine collection at 3 different times (baseline, 4 and 8 months after the intervention).	3.1 in FPI	NI	NA

Table 1. *Cont.*

Study Author (Year), Country	Participants	Study Design	Enrolment Start and End Dates; Length of Participant Follow-Up	Intervention	Method of Assessment	Results		
						Reduction in Salt Intake (g/day) in the IG	Difference in Salt Intake (g/day) between IG and CG	Blood Pressure (mmHg)
Li [28] (2016), China	120 Townships from five provinces (*n* = 1903). Control villages, *n* = 60. Intervention villages, *n* = 60.	Two parallel cluster-randomized trial.	May 2011 to November 2012. 18-month intervention.	Intervention villages-Community-based health education and availability of reduced-sodium, added-potassium salt substitute at village shops. Control villages-Continued their usual practices	24 h urinary Na excretion, 1 urine collection in a single moment (end of intervention). BP (end of intervention).	NI	−0.8	SBP: −1.1 ($p = 0.33$) in IG×CG. DBP: −0.7 ($p = 0.35$) in IG×CG
Nakano [21] (2016), Japan	95 Hypertensives IG, *n* = 51 (35 women, 58 mean years). CG, *n* = 44 (24 women, 60 mean years).	Prospective, randomized, and open-label study	September 2012 to May 2014, 3-month follow-up.	Intervention: intensive nutritional education aimed at salt restriction to 6 g/d by nutritionists. Control: conventional salt-restriction education.	24 h urinary Na excretion, 1 urine collection at 2 different times (baseline and after intervention). Monitoring of clinic, home, and ambulatory BP values (baseline and after intervention).	1.8	NI	SBP: −4,5 in IG (Ambulatory 24 h SBP)
Takada [19] (2016), Japan	35 Housewife's and 31 family members. IG, *n* = 36 (63 mean years, 20 women). CG, *n* = 32 (65 mean years, 22 women).	Single-blinded, family-based Cluster randomized controlled trial	September 2015 to October 2015, 2-month intervention.	Intervention Group: 2x Cooking classes by registered dietitians, a general physician and a nephrologist, and it consisted of a practical course for evaluating the amount of salt in a meal and instruction on salt-reduced cooking. Control group: participants attended lectures about healthy living. The lecture contents did not include information related to salt reduction.	Spot urine, 1 urine collection at 2 different times (baseline and 2 months after intervention) BP measured only in the housewife's subgroup (baseline and 2 months after intervention	0.57	−1.16	SBP: −3.6 ($p = 0.371$) in IG×CG. DBP: −1.68 ($p = 0.606$) in IG×CG
Ipjian [36] (2017), USA	30 Healthy adults (34 mean years; *n* = 23 women). MyFitnessPal app group, *n* = 15. Journal group, *n* = 15.	Randomized parallel trial	August to December 2014, 4-week intervention.	Participants were instructed to reduce their sodium intake to ≤2300 mg/d by using the MyFitnessPal app to receive feedback on sodium content of foods or by paper tallying of estimated sodium intake.	2 first morning spot urine collection at 2 different times (baseline and after intervention). BP (baseline and after intervention)	2.1	NI	NI

Table 1. *Cont.*

Study Author (Year), Country	Participants	Study Design	Enrolment Start and End Dates; Length of Participant Follow-Up	Intervention	Method of Assessment	Results		
						Reduction in Salt Intake (g/day) in the IG	Difference in Salt Intake (g/day) between IG and CG	Blood Pressure (mmHg)
Takada [20] (2018), Japan	158 Participants from 105 families. IG, $n = 79$ (61 mean years, 68.4% women). CG, $n = 79$ (64 mean years, 64.6% women).	Single blinded, family-based, cluster randomized controlled trial	September 2016 to April 2017. 4-week intervention	Participants in both the intervention and control groups attended lectures about salt reduction by a general physician and a registered dietitian. In the intervention group, participants used the self-monitoring device to estimate their daily salt intake, and they recorded their results for 4 weeks.	Spot urine, 1 urine collection at 2 different times (baseline, week 4) BP (baseline, week 4).	0.77	−0.50	SBP: −4.4 in IG×CG
Cashman [30] (2019), Republic of Ireland	46 Adults with slightly to moderately elevated BP (47 mean years, 40 women)	Randomized crossover trial	January 2008 to July 2010. 5-week intervention.	Intervention: Combination of pragmatic dietary advice with the replacement of bread and a limited number of other foods with equivalent foods with a lower salt content. Control: normal diet, but were asked to consume an in-house bread, equivalent in composition to the low-salt version, but with its more typical salt content.	24 h urinary Na excretion, 1 urine collection at 3 different times (baseline, week 5, week 10) BP (baseline, week 5, week 10)	1.7	NI	SBP: −3.3 in IG
Rahimdel [24] (2019), Iran	140 Adults at risk of developing hypertension (43 mean years, 59.3% women). IG, $n = 70$. CG, $n = 70$.	Randomized clinical trial	February 2017 to December 2017	Intervention: Education program based on the theory of planned behavior (TPB) for salt intake in individuals at risk of hypertension. Based on the results of the pretest, the educational content was prepared in the form of a booklet. Control: No educational program was conducted for the control group.	24 h urinary Na excretion, 1 urine collection at 2 different times (baseline and 2 months after the intervention) BP (baseline and 2 months after the intervention).	4.7	NI	SBP: +1.1 ($p = 0.2$) in IG DBP: +1.26 ($p = 0.22$) in IG
Riis [31] (2020), Denmark	Family with at least one child. IG A, $n = 41$ (42 mean years). IG B, $n = 63$ (41 mean years). CG, $n = 49$ (41 mean years).	single-blinded, cluster randomized controlled trial with a parallel design	January 2018 to July 2018, 4-month intervention.	Intervention A: Families received sodium-reduced bread Intervention B: Families received sodium-reduced bread and dietary counseling Control: Families received regular sodium bread	24 h urinary Na excretion, 3 urine collections at 2 different times (baseline and 4 months after the intervention).	1 in IG A ($p = 0.085$) 1.8 in IG B ($p < 0.001$)	−0.5 (IG A x CG), $p = 0.523$ −1.0 (IG B x CG), $p = 0.079$	NA

Table 1. *Cont.*

Study Author (Year), Country	Participants	Study Design	Enrolment Start and End Dates; Length of Participant Follow-Up	Intervention	Method of Assessment	Results		
						Reduction in Salt Intake (g/day) in the IG	Difference in Salt Intake (g/day) between IG and CG	Blood Pressure (mmHg)
Yokokawa [29] (2020), Thailand	753 Patients at high risk of CVD stratified by the Framingham general CVD risk scoring system (367 women). 8 clusters: n = 4 CG, n = 4 IG.	cluster randomized controlled trial	February 2012 to January 2013	Intervention group: education program, visualization tools to inform the patients of their estimated 24-h salt intake and dietary salt content in daily food/ soup (analyzed by investigators) and special health education classes organized by the dietician. Control group: routine care services and a brief individual health education session, not focused on salt reduction.	Overnight urine collection, average of 3 successive days' measurements at 3 different times (baseline, 6 and 12 months). BP (baseline, 6 and 12 months)	0.86 at 6 months (p < 0.01) 0.22 at 12 months (p = 0.02)	−0.66 at 6 months (p = 0.03) −0.42 at 12 months (p = 0.16)	SBP At 6 months in IG: −12.34 IG×CG: −7.55 SBP

NI—No information; NA—Not applicable; BP—Blood pressure; SBP—Systolic blood pressure; DBP—Diastolic blood pressure; IG—Intervention Group; CG—Control group.

Table 2. Overview of characteristics of the included nonrandomized trials.

Study Author (Year), Country	Participants	Study Design	Enrolment Start and End Dates; Length of Participant Follow-Up	Intervention	Method of Assessment	Results		
						Reduction in Salt Intake (g/day) in the IG	Difference in Salt Intake (g/day) between IG and CG	Blood Pressure (mmHg)
Yasutake [23] (2011), Japan	30 Healthy adult volunteers (15 women, 43 mean years).	Quasi-experimental	March to April 2009, 4-week intervention.	Measurement of daily salt excretion at home for 4 weeks using the self-monitoring device for educating healthy adults regarding their levels of salt intake and the dangers of excessive salt use.	Overnight urine sample, 4 weeks using the self-monitoring device. BP (baseline and 8 weeks later).	0.4	NA	SBP: −3.4
Jafari [26] (2016), Iran	Two cities. Intervention, n = 346 (61% women, 49 mean years). Control, n = 310 (50.3% women, 48 mean years).	Community intervention trial	March to July 2014, 4-week intervention.	Installation of educational banners and door-to-door distribution of pamphlets in the intervention city and in the control city. In the intervention city, they reduced the bread salt by 40%	Urine sample collection from 8:00 to 9:00 am after discarding the first urine, 1 urine collection at 2 different times (baseline and after 12 weeks). BP (baseline and after 12 weeks).	0.9	NA	SBP: −7.4 in IG
Land [39] (2016), Australia	419 individuals at baseline and 572 at follow-up (56 mean years, 58% women).	Interventional (Clinical Trial)/Community-based intervention	March 2011 to May 2014, 18-month intervention.	A multi-faceted, community-based salt reduction program using the Communication for Behavioral Impact (COMBI) framework.	24 h urinary Na excretion, 1 urine collection at 2 different times (baseline and at the end of the intervention)	0.8	NI	NA
Musso [33] (2018), Italy	291 Patients on antihypertensive treatment (166 women, 63 mean years). Dietary protocol n = 240, control n = 51.	Intervention control Trial	2-month intervention.	Low-sodium diet prescribed by the dietitian.	24 h urinary Na excretion, 1 urine collection at 2 different times (baseline and after intervention). BP (baseline and after intervention).	1.14	NI	SBP: −7.66 in IG DBP: −4.69 in IG
Layeghiasl [25] (2020), Iran	166 participants (50% women, 36 mean years).	Quasi-experimental pretest-posttest with control group design	2-month intervention.	Intervention: Marketing mix components were determined for designing an intervention. An educational package focused on reducing salt intake and using alternatives was developed. Control: received routine interventions in healthcare centers.	Urine samples collected daily in the morning, 1 urine collection at 2 different times (baseline and at the end of the intervention).	3.01	NI	NA

NI—No information; NA—Not applicable; BP—Blood pressure; SBP—Systolic blood pressure; DBP—Diastolic blood pressure; IG—Intervention Group; CG—Control group.

3.2.2. Interventions Characteristics

The present work included 16 randomized intervention trials [19–22,24,27–32,34–38] and five nonrandomized intervention studies [23,25,26,33,39]. All used a pre- and post-test design, except for one study [28], which used only a post-test design.

Most studies (*n* = 15) compared a group of intervention participants with a control group of participants, two studies compared two different interventions [36,38], two studies compared a control group with two interventions groups [31,35], and two studies had no control group [23,39]. The intervention period ranged between four weeks and 18 months.

Must studies have described education interventions to reduce salt intake. Seven interventions were just health and nutritional education [21,24,25,27,33,35,38], eleven interventions were nutritional education plus other interventions [19,22,26,28–32,34,37,39] and three studies used only salt meters to reduce sodium intake, an app and a urine sodium meter [20,23,36].

3.2.3. Outcome Characteristics

Salt consumption was assessed by urinary sodium excretion, as defined in the methodology of this review. The included studies used different methods, and most used 24-h urinary excretion (*n* = 13) [21,24,27,28,30–35,37–39], followed by spot urine collection (*n* = 5) [19,20,25,26,36] and overnight urine sample (*n* = 3) [22,23,29]. The number of urine collections in the studies that used 24-h urinary excretion to assess salt intake varied: one collection twice (*n* = 5) [21,24,33,37,39], one collection at three times (*n* = 4) [30,32,35,38], three consecutive collections in twice (*n* = 1) [31], two collections consecutive at two times (*n* = 1) [27], only one collection at the end of the study (*n* = 1) [28] and four times of urine collections, in which three times they asked to collect two days followed and at one time only one urine collection (*n* = 1) [34]. In the studies that used the urinary spot to assess salt consumption, four studies requested a collection in two moments [19,20,25,26] and one study requested two collections also in two moments [36]. The studies that measured salt through overnight urinary excretion used the following methodology: urine collection for three consecutive nights at three different times (*n* = 1) [29], urine collection during the first week of intervention and in the last week (*n* = 1) [22], urine collection for four weeks (*n* = 1) [23].

Fifteen studies assessed participants' blood pressure [19–24,26–29,33,36,37]. Most studies assessed blood pressure twice (*n* = 12) and only three assessed blood pressure three times [29,30,32].

3.3. Types of Interventions

The interventions were summarized and categorized into: (1) Health and nutritional education; (2) Nutritional education plus other interventions; and (3) Estimates of salt intake.

All studies included in the review showed statistically significant differences in salt reduction between the intervention group and the control group. With the exception of the two studies [23,39] that did not have a control group, success in reducing salt was verified between the baseline period and after the intervention.

3.3.1. Health and Nutritional Education

Interventions in health and nutrition education were carried out mainly by health professionals (nutritionists, doctors, psychologists and nurses) [21,24,25,33,35,38] with the exception of one intervention, carried out by health educators trained by researchers [27].

Ireland et al. [38] described that dietary education was provided in groups of four to five in 15-min sessions, in which the participants were informed that the purpose of the study was to reduce salt intake and were instructed to continue their usual dietary patterns using either the Tick symbol or the Food Standards Australia New Zealand guideline to identify reduced salt foods. In addition, participants in both groups were provided with a list of low-sodium foods and a second 10-min one-on-one session in week 4 [38].

Nakano et al. [21] described that they provided participants with intensive nutritional education held five times during the intervention period, lasting 20 min. At the time of the first and fifth sessions of nutrition education, each patient answered the Food Frequency Questionnaire and performed a survey to determine the amount of salt intake. Nutrition education sessions were customized based on individual questionnaire and survey results [21]. Also, Rahimde et al. [24] based on the results of the pre-test, developed educational content in the form of a booklet containing information about salt and its consumption rate in Iran, the definition of blood pressure, the effects of high salt intake, sources of salt intake and diseases associated, salty foods, ways to reduce salt intake and the amount of salt in different foods. The educational intervention included 10 educational sessions using slides and a blackboard, and during the sessions, booklets were distributed among the participants. The authors defined the intervention as an education program based on the theory of planned behavior for salt intake [24].

In the study by Layeghias et al. [25] described that the intervention group received an educational package with the aim of reducing salt consumption and using alternatives, through posters for installation in the kitchen, leaflets, free telephone service, four educational classes and brief interventions by doctors and other health professionals [25].

Dunbar et al. [35] described a three-group intervention (usual care, patient family education, and family partnership intervention). In the usual care group, they only provided usual care and educational pamphlets created by the Heart Failure Society of America. In the patient's family education group, they provided the usual care, pamphlets and added educational content written and on DVD, a second group session with their family member, received feedback on their usual sodium intake and after 4 months they received a telephone education reinforcement session. In the family partnership intervention group, participants received the same education as the other two groups, plus 2 group sessions that focused on teaching family members how to support, communicate, empathize and empower each other's roles. They also received written information about family partnership and support for autonomy [35].

The intervention described by Musso et al. [33] was a low-sodium diet prescribed by the nutritionist. The diet was based on simple recommendations printed on a single sheet of A4 paper.

He et al. [27] developed an educational program in which program materials were developed around cartoon characters and consisted of lesson plans, activity worksheets, and homework assignments. In the intervention group, the usual health education classes were replaced by classes on salt reduction. Classes included lectures with the participation of the family and posters were also placed in the classroom about the harmful effects of salt and how to reduce salt consumption. The children were instructed to emphasize the 50% salt reduction goal at home and to remind the whole family of this goal after each lesson, to deliver salt reduction messages, salt reduction methods and skillful tips for the whole family and to develop a salt reduction action plan for their own family and oversee actions at home. Parents received educational materials in the form of a newsletter that covered topics such as salt and its effects on blood pressure and cardiovascular disease, the main sources of dietary salt, and cooking with less salt. The researchers monitored the child's family's use of salt, verified how much the family's salt use differed from the established goal, and communicated the results to them. Each family also received a control spoon of salt (2 g of salt) [27].

3.3.2. Effects of Interventions

In the study by Ireland et al. [38] mean salt intake decreased by around 0.9 g/day (from 7.3 ± 3.0 g/day, $p < 0.05$) in the tick group and in the Food group Australia New Zealand standards mean salt intake decreased by around 2.0 g/day (from 7.9 ± 2.6 g/day, $p < 0.05$).

Nakano et al. [21] reported a decrease by around 1.8 g/salt per day (from 8.6 ± 3.2, $p = 0.002$) in the intervention group. Ambulatory 24-h systolic blood pressure was significantly lowered in the intervention group (−4.5 ± 1.3 mmHg) compared with the control group (2.8 ± 1.4 mm Hg), $p < 0.001$).

Rahimdel et al. [24] showed that the mean salt intake decreased by 4.7 g/day (from 12.9 ± 4.4 g/day, $p < 0.001$) in the intervention group. There were no differences in blood pressure.

In the study by Dunbar et al. [35] mean salt intake decreased by around 3.1 g/day (from 9.0 ± 4.4 g/day, $p < 0.05$) in the family partnership intervention.

He et al. [27] described that in adults, mean salt intake decreased by around 2.1 g/day (from 12.6 ± 0.4 g/day, $p < 0.001$) in the intervention group and the difference mean between groups was −2.9 ($p < 0.001$). The difference mean between groups on systolic blood pressure was −2.3 mm Hg, $p < 0.05$. The effect on diastolic blood pressure was not significant.

In the study by Musso et al. [33] mean salt intake decreased by around 1.1 g/day (from 8.8 ± 2.6 g/day, $p < 0.05$). Systolic and diastolic blood pressure in the intervention group also decreased (134.16 to 126.5 mmHg, $p = 0.014$ and 80.59 to 75.9 mmHg, $p = 0.026$, respectively).

Layeghiasl et al. [25] showed that mean salt intake decreased by 3.01 g/day in the intervention group (from 14.34 g/day, $p < 0.001$).

3.3.3. Nutritional Education plus Other Interventions

Multicomponent educational interventions that, in addition to health and nutrition education, used salt substitutes (n = 2) [28,37], low-salt bread (n = 3) [26,30,31], urine-excreted salt meter (n = 1) [22], health campaigns large-scale awareness (n = 1) [39], cooking classes (n = 1) [19], warning stickers (n = 1) [32], digital handheld pocket salt meter (n = 1) [29] and a sodium-specific tracking tool (n = 1) [34]. Interventions were delivered by health professionals (n = 5) [19,22,29,30,32], health educators (n = 1) [28], study counselors (n = 1) [34] and bakers (n = 1) [26]. Three studies did not discriminate who delivered the interventions [31,37,39].

Cashman et al. [30] described that during the intervention period they provided participants with pragmatic dietary advice, replacing bread and a limited number of other foods with equivalent foods with lower salt content. At the beginning of the salt restriction period, participants were given a list of foods that contained common salt (salty and naturally salty) and asked to limit their consumption of these foods. Subjects received brown or white sliced bread with low salt content (0.3 g/100 g), unsalted margarine and received lunch meats without added salt (turkey and cooked meat), if desired (optional) [30]. In the study by Riis et al. [31] they also provided bread with a lower sodium content, which was distributed free of charge twice a week. During the first 2 weeks of intervention, the sodium content in bread was similar to the average content in supermarket and bakery bread. In both intervention groups, the sodium content was gradually reduced by 0.08 g per 100 g (0.2 g salt/100 g) each week until the sodium content reached 0.24 g per 100 g (0.6 g salt/100 g) on rye bread and 0.16 g per 100 g (0.4 g salt/100 g) on wheat bread, which remained for the remainder of the intervention. In Intervention A, they reduced only the sodium content of the bread, but in Intervention B they combined it with a dietary counseling program. Diet counseling consisted of a 2-h group introduction, a 1-h family counseling session, followed by two telephone counseling sessions with a parent, and weekly emails [31]. In the study by Jafari et al. [26] reduced the salt content by 40% over 4 weeks. They gave lectures on the harmful effects of salt, posted banners in squares and crossroads, and posters on the harmful effects of salt in all bakeries and supermarkets. In selected homes, they distributed a leaflet about salt damage. The main intervention in the intervention municipality was the gradual reduction in the consumption of salt in people's diets through bread [26].

Li et al. [28] described a salt reduction program that comprised community-based health education and availability to purchase added-potassium salt substitute from village stores. The health education component consisted of public lectures, exhibition and distribution of promotional materials, and special interactive education sessions aimed at individuals at high risk for vascular disease [28]. In the study by Barros et al. [37] all participants were instructed to consume only the salt provided throughout the study and to reduce their consumption of foods rich in sodium. They provided 28 plastic bags containing the daily amount of salt for each participant. The light salt consisted of 130 mg of sodium, 346 mg of potassium and 44 mcg of iodine per gram [37].

Morikawa et al. [22] described that in the first and last week of the study, participants in the intervention group measured daily urinary salt excretion using the electronic salt sensor. In addition, participants received an email 10 times during the study period with information about the salt content of foods, salt reduction methods and a message encouraging a salt-reduced diet [22].

The salt reduction intervention described by Land et al. [39] targeted the whole community and was based upon the Communication for Behavioral Impact (COMBI) framework. This framework utilizes an integrated communication model to enact community advocacy and impact, so there were several meetings held with local government, local doctors, health professionals, five of the largest employers, with the local business association, business owners (mostly owners of cafes, bars and restaurants) and community groups. The local communication channels were all directed with information and stories about the program. Information booths were installed in the two main commercial areas and around 500 individual houses were visited by two employees who worked in this activity. They used salt substitutes and the "FoodSwitch" smartphone app to encourage a reduction in salt intake. The salt substitute consisted of 136 mg of sodium and 176 mg of potassium per 0.8 g serving and was made available free of charge for use by consumers. The smartphone app, "FoodSwitch", allowed consumers to identify foods packaged with less salt and was available for free download [39].

Takada et al. [19] described an intervention with cooking classes. The 90-min classes were held twice and consisted of a practical course for evaluating the amount of salt in a meal and instruction on salt-reduced cooking.

Markota et al. [32] provided warning stickers about the harmful effects of excessive salt to be affixed to all salt containers, as well as providing individual information leaflets received on the undesirable effects of excessive salt consumption [32].

Yokokawa et al. [29] described an education program with visualization tools to inform participants about their estimated salt intake and health education classes. Participants provided a sample of their soup three times over the course of the study, and researchers reported the amount of salt the soup contained, measured using a digital handheld device. In addition, participants were informed of their sodium excretion. The education classes involved participants in reducing their daily dietary salt intake, suggesting ways to prepare tasty, low-salt meals [29].

In the study by Anderson et al. [34] before starting the intervention, all participants consumed a controlled low-sodium diet for 4 weeks. Participants received all foods, snacks and beverages that contain calories. After the controlled diet, participants in the intervention group were asked to continue eating a low-sodium diet. Participants had one-on-one counseling sessions, by phone or email, and group counseling sessions that included cooking demonstrations and received spices and a cookbook. Participants monitored their sodium intake through a sodium-specific tracking tool that allowed them to record the foods, brand name and description, and the amount of sodium consumed [34].

3.3.4. Effects of Interventions

In the study by Cashman [30] et al. the intervention showed a decrease in salt intake of 1.7 g/day, $p < 0.0001$ on average during the low-salt diet period. Systolic blood pressure was significantly lower (3.3 mmHg on average, $p < 0.0001$) and there was no statistically significant difference in diastolic blood pressure.

Morikawa et al. [22] showed that the mean daily salt excretion decreased 0.7 g/day (from 11.5 $\pm$ 1.8, $p = 0.008$) in intervention group. Mean diastolic blood pressure decreased by 6.2 mmHg ($p < 0.001$) in the intervention group and between groups the difference was 4.5 mmHg ($p = 0.012$). Systolic blood pressure decreased by 5.4 mm Hg in the intervention group ($p = 0.012$), with no significant difference between groups.

Land et al. [39]. reported that estimated mean salt intake decreased by around 0.8 g/day (from 8.8 ± 3.6 g/day, $p < 0.001$.

In the study by Riis et al. [31] mean salt intake decreased by 1.8 g/day (from 9.25 ± 2.5, $p < 0.001$) in adults in intervention group A and in intervention B it decreased by 1 g/day (from 9.5 ± 3.0, $p = 0.085$). The mean difference between groups in intervention A was −0.5 g/day ($p = 0.523$) in intervention B it was −1 g/day/day ($p = 0.079$).

In the study by Barros et al. [37] mean salt intake decreased by around 4.5 g/day (from 11.8 ± 7.6 mg/day in the intervention group and the mean difference between groups was −3.2 g/day ($p = 0.023$). Systolic blood pressure and diastolic blood pressure differed significantly between the intervention group and the control group, 12.47 mmHg, $p = 0.034$ and 7.58 mmHg, $p = 0.046$, respectively.

In the study by Li et al. [28] the mean difference in salt intake between groups was 0.8 g/day. In villages with price subsidy the mean salt intake was 13.34 ± 5.5 g/day and without price subsidy was 14.0 ± 5.6 g/day. There was no significant difference in blood pressure.

Jafari et al. [26] described that mean salt intake decreased by around 0.9 (from 8.8 ± 0.2 g/day, $p = 0.001$) in the intervention group. Systolic blood pressure decreased by around 7.4 mmHg in the intervention group. There were no significant differences in diastolic blood pressure.

The intervention described by Yokokawa et al. [29] described that mean salt intake decreased by around 0.86 g/day (from 10.0 ± 2.2 g/day, $p < 0.01$) in the intervention group and the adjusted difference between the intervention group and the control group was −0.66 g/day ($p = 0.03$) at 6 months. At 12 months, salt intake decreased by 0.22 g/day ($p = 0.02$) and the mean difference between groups was −0.42 g/day, but it was not significant ($p = 0.16$). Systolic blood pressure decreased by around −7.55 mmHg ($p < 0.01$) between groups after adjusting for covariates at 6 months. These differences were not observed at 12 months. There were no differences in diastolic blood pressure.

Takada et al. [19] reported that mean daily salt intake decreased by 0.57 g/day (from 9.57 ± 2.45 g/day) in the intervention group and the mean difference between groups was −1.16 g/day ($p = 0.033$). There was no effect on blood pressure.

In the study by Anderson et al. [34] during controlled consumption (phase 1), salt intake decreased by 4.6 g/day. At the end of the intervention (phase 2), the mean difference between groups was −2.4 g/d ($p = 0.002$) after controlling for sodium intake at screening.

Markota et al. [32] reported that the mean salt intake decreased by around 2.0 g/day (from 12.1 ± 4.9 g/day, $p < 0.0001$) in the intervention group. Systolic blood pressure decreased around by −5.3 mmHg ($p < 0.0001$) and diastolic blood pressure decreased around by −2.9 mmHg ($p < 0.0001$) in the intervention group.

3.3.5. Estimates of Salt Intake

The intervention to reduce salt intake in three interventions was to provide tools for participants to estimate salt intake: an app ($n = 1$) [36] and a self-monitoring device for urinary sodium excretion ($n = 2$) [20,23].

Ipjian et al. [36] used a "MyFitnessPal" application to reduce participants' salt intake. The profile of participants in the app was programmed by the investigator to a sodium level of 2300 mg/d. Verbal and written instructions were given about using the app, and participants were instructed to use the app daily for food and beverage input to monitor dietary sodium levels [36].

Both authors, Takada et al. [20] and Yasutake et al. [23] described asking participants to measure daily salt excretion at home for 4 weeks using the self-monitoring device.

3.3.6. Effects of Interventions

In the study by [36] Ipjian et al. [36] mean salt intake decreased by around 2.1 g/day (from 10.46 ± 5.27 g/day) in the app group.

In the study by Takada et al. [20] mean salt intake decreased by around 0.77 g/day (from 9.37 ± 2.13 g/day) in the intervention group. The mean difference between the two groups was −0.50 g/day (p = 0.030). The mean difference between the two groups was −4.4 mm Hg in systolic blood pressure.

In the study by Yasutake et al. [23] salt excretion decreased at weeks 3 and 4 by around 0.07 g/day (from 8.31, $p < 0.059$ and 0.2 g/day (from 8.24, $p < 0.01$), respectively. In total, from baseline to the end of the study decreased by 0.2 g/day. Diastolic blood pressure decreased by around 3.4 mmHg ($p < 0.05$). There were no differences in diastolic blood pressure.

3.4. Risk Ob Bias in Studies

In randomized controlled trials, three studies had a low overall risk of bias [27,28,31], five studies showed some concerns about the overall risk of bias [21,30,32,34,38] and eight studies had a high overall risk of bias [19,20,22,24,29,35–37]. Most studies had a low risk of bias in bias arising from the randomization process, with the exception of three [22,37,38]. The bias in selection of the reported result was the one with the most concerns about the risk of bias (n = 11) [19–22,24,30,32,34,35,37,38] and one had a high risk of bias [36] (Figure 2).

All nonrandomized intervention studies had a serious risk of global bias [23,25,26,33,39]. The five non-randomized studies had low risk of bias in classification of interventions, bias due to deviations from the intended interventions, and bias in selection of the reported outcome. All studies had severe risk bias due to confounding (Figure 3).

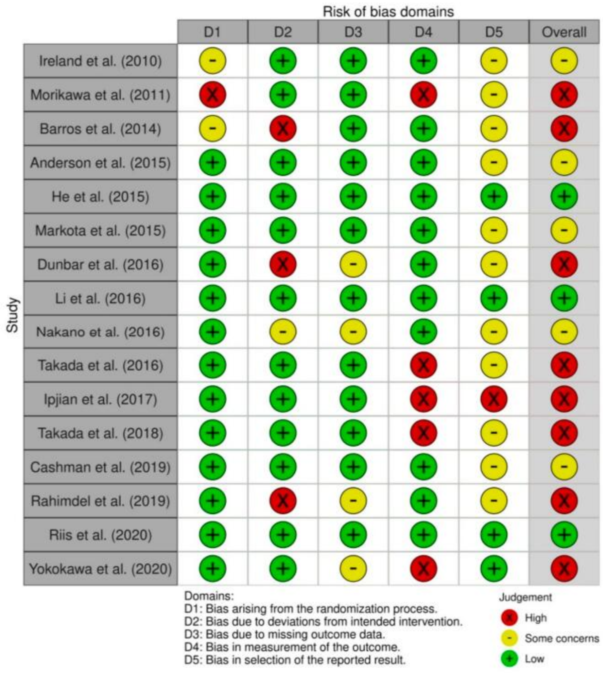

Figure 2. Risk of bias summary for randomized controlled trials (Cochrane risk of bias tool (RoB 2)).

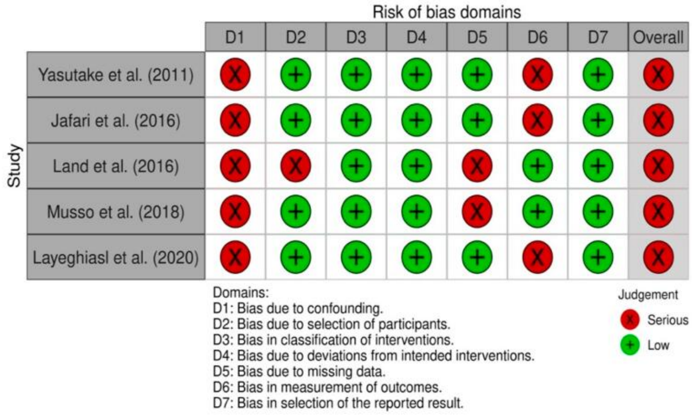

Figure 3. Risk of bias summary for nonrandomized studies (ROBINS-I tool).

4. Discussion

This review identified 21 recent interventions that successfully reduced salt intake. It provides evidence that interventions based on individual education, with or without other associated interventions and tools to estimate salt intake, have positive results in reducing salt intake. However, the analyzed studies must be interpreted with care due to the mixed quality of the study designs, the different interventions and the lack of some intervention details, in addition to the difficulty in identifying specific characteristics of the interventions that led to success in reducing salt consumption.

Health and nutrition education interventions appeared to be the ones that achieved the greatest salt reduction, with salt reduction ranging from about 0.9 g/day to 4.7 g/day. Salt reduction in nutritional education, plus other interventions, ranged from about 0.57 g/day to 4.5 g/day. Estimates of salt intake interventions reduced salt intake between about 0.4 and 2.1 g/day. However, it is important to keep in mind that the mean baseline sodium value varied widely across all interventions. Reductions in higher basal values seems to can reach greater magnitudes; however, these data must be interpreted with caution.

The understanding of the underlying mechanisms and causes of chronic diseases is transforming medicine from a reactive discipline to a proactive and preventive one. Therefore, a Predictive, Preventive, Personalized and Participatory Medicine (medicine P4) [40] which also applies to nutrition, with the objectives of quantifying well-being, will predict and prevent disease. Consumers are different in each country and the form of salt consumption is also different.

Tailoring treatment to each person's characteristics means classifying others into subpopulations that differ in their susceptibility to a specific intervention or in their response to a specific treatment. Preventive interventions can then be focused on those who will benefit, saving resources for those who will not [41]. This approach reflects the importance of interventions that are based on the individual and not the general population.

We identified three randomized studies with low-risk of bias that successfully reduced adults salt intake: dietary education and availability of a salt substitute with added potassium at village shops [28]; salt reduction in bread and nutritional advice [31]; and through the nutritional education of children who delivered the message to their families [27]. A reduction in salt intake is possible by integrating salt reduction education modules into school curricula and empowering children to deliver the message of salt reduction to their families. This intervention showed a new, viable and effective approach to reducing salt intake, and the authors showed an approximately 25% reduction in salt intake by the participants and a decrease in systolic blood pressure. Passing a salt reduction message to children has the potential to establish habits and attitudes that will persist throughout adult life, in addition to being able to reduce the consumption of salt by the family as well. It is an intervention that can be customized according to the children of each school. The authors report that to achieve a greater reduction in the population's salt intake, this approach must be combined with other strategies such as working with the food industry to gradually reduce the amount of salt added to all processed foods [27].

The family also plays an important role in reducing salt intake in patients with heart failure [35], as family members can provide motivation and positive communication to change family habits [42].

Providing low-salt bread is an effective salt reduction strategy combined with nutritional counseling [26,30,31]. By reducing salt added to bread or other foods, the specific salt taste receptors in the mouth become much more sensitive to lower salt concentrations, meaning that less salty foods will stimulate a sensorial response similar to very salty foods before the adjustment [43]. This intervention can be one of the solutions for reducing salt in places where processed foods are one of the main sources of salt intake.

The use of salt substitutes with lower sodium content was a strategy used in interventions by three studies in this review [28,37,39]. Salt substitute is effective in reducing salt intake and has potassium in its constitution, increasing potassium intake by consumers. In the studies included in this review, potassium intake was higher in the intervention groups, but participants did not reach the WHO recommended daily intake (3510 mg/day). Also, a recent study showed that the use of salt substitute (with potassium in the constitution) decreased urinary sodium excretion and the rates of stroke, cardiovascular events, and deaths from any cause in people over 60 years of age [44].

The use of substitute salt costs about twice as much as regular salt [28], and it can be a social barrier in countries with less economic power. In addition, it has been reported that the taste of the salt substitute is bitter, not being accepted by all consumers [37]. It is important to consider whether dietary education focused on reducing salt intake can be a better and cheaper strategy that is more integrative from a social point of view. This review included seven interventions focused only on educating the individual to reduce salt intake and customized according to the target audience or their consumption habits. These interventions were successful and do not depend on the economic power of the consumer to buy a substitute that will make them ingest less salt.

In the study by Land et al. [39] the salt substitutes were part of a multifaceted community-based salt reduction program. As the intervention consisted of several components that were implemented simultaneously, it is not possible to quantify the relative contributions of each one to the success of the program. The same was found in the interventions by Anderson et al. [34] and Layeghiasl et al. [25], and it is not possible to identify a factor as being more important than another in the success of the intervention. Changing eating behavior is a complex process and dealing with multiple and interrelated factors appears to be effective in reducing salt intake [34]. The World Health Organization defends that different approaches can be applied in health education and communication campaigns; namely social mobilization, social marketing, behavior change communication and communication for development [12].

This review includes interventions where self-monitoring appears to be effective in behavior change and an effective complementary strategy in salt reduction [20,22,23,36]. There is a growing trend towards self-monitoring of health, especially through apps such as calorie counters, exercise or dietary advice, and there is evidence that self-monitoring benefits users. Monitoring has the advantage that users can share dietary monitoring with healthcare professionals and receive immediate feedback or long-term follow-up [45]. It is a patient-centered and personalized service, making it possible to verify the individual's salt intake and to be able to define strategies to reduce salt intake [36,46].

Maintaining the effects of salt-reducing interventions is difficult over time [47]. Sustainable changes in consumer behavior seem to be achievable through knowledge and awareness. Much of the population is not aware of the risks of salt consumption and its relationship with hypertension and its comorbidities. In addition to not being aware of the maximum recommended daily dose of salt intake, the amount of salt they eat and the main sources of salt in their diet [12].

The intervention based on the theory of planned behavior included in this review reduced salt intake by about 35% in the intervention group [24]. This approach is interesting in reducing salt consumption, as it customizes the intervention for each individual and there are different attitudes, stimulants and inhibitors about salt consumption in the population, in addition to several variables that affect the person's control over behavior. However, a central factor in the theory of planned behavior is the individual's intention to perform a certain behavior [48]. In the study by Rahimdel et al. [24] participants were at risk of developing hypertension, which can lead to being more motivated to change behavior than healthy individuals, which shows us that it is important to customize interventions according to the group target.

We have also seen success in reducing salt intake in interventions based on nutrition education with a nutritionist [21,33], educating the consumer to read labels to select healthier foods that contain less salt [32] and cooking classes given by health professionals, including a nutritionist [19]. Having a health professional who can teach and raise awareness about the impact of salt consumption on health and the main sources of salt in the diet seems to help influence consumer behavior [12].

This review only included interventions that reduced salt intake with statistical significance ($p < 0.05$). When searching for interventions that were successful in reducing salt intake, we found 11 interventions that either had no statistically significant salt reduction or did not reduce salt intake. Summary tables on these interventions can be found in Supplementary Materials (Supplementary Tables S1 and S2). These interventions included self-monitoring of salt excretion (n = 2) [49,50] and Na:K ratio (n = 1) [51] in urine. Self-monitoring of Na:K ratio excretion reduced salt excretion without statistical significance, probably because the sample size was insufficient and baseline potassium excretion was greater than the authors had expected. Also, in interventions with self-monitoring of salt excretion there was a non-statistically significant decrease in salt, the authors reported that this was probably due to a short intervention period (4 weeks) and insufficient sample size. Although these interventions were not included as successful interventions, it is likely that if they did not have problems with the methodology, they could have been successful. Participants being able to estimate salt intake appear to be effective salt reduction strategies as mentioned in other interventions [20,23] included in this review. A nutrition education intervention was unsuccessful in reducing salt, the intervention was to teach diabetic participants to use the nutrition information panel on food labels to choose products that comply with the Food Standards Australia New Zealand (FSANZ) guideline of <120 mg sodium/100 g food [52]. This intervention was used by Ireland et al. [38] in free-living adults and have successfully reduced salt. Therefore, this type of intervention is not effective in diabetics, which reinforces the importance of customizing interventions according to the population. We found three interventions that, in addition to nutrition education, used apps to reduce salt intake. Two interventions reduced salt without statistical significance and one intervention failed to reduce salt. Dorsch et al. [53] described an application-based intervention that sends just-in-time contextual adaptive messages. The reduction in urinary sodium excretion was 637 mg/day, but without statistical significance. Although the authors report that there were clinically significant improvements in the intervention group compared to the control, all participants were required to have an iPhone, so the effectiveness of this intervention may be related to the socioeconomic status of the participants. Lofthouse et al. [54] described an intervention that, in addition to using the app, used salt substitutes with lower sodium content, participants reduced salt excretion by 433 mg/day without statistical significance. This was a pilot study with only 11 volunteers, and these had a low baseline sodium (2342 mg) and so we probably could not see the potential of this intervention to reduce salt intake. In the study by Thatthong et al. [55] they described an intervention using a program that sends interactive messages about salt reduction. The study was carried out in hypertensive patients, at the end of the study, sodium excretion in the intervention group was higher than the baseline value. Although the sample size was small (n = 50), this result indicates that this intervention is probably not effective in reducing salt intake in hypertensive patients. Nakadate et al. [56] described an intervention in which they provided a salt monitoring instrument to measure the salt concentration of soup at home and low-sodium seasoning. They achieved a sodium reduction of 777 mg/day with monitoring and 413 mg/day with the low-sodium seasoning. Although the results were not statistically significant, probably due to the exploratory pilot design of the study, with sample size calculated based on provisional statistics, the results are interesting, especially the monitoring of salt in soup, in regions that have a high consumption of soup. Another study described an environmental and behavioral intervention in the workplace. They achieved an average reduction in salt intake of −0.6 g, from 8.7 g but without statistical significance. The authors reported that the cause of not achieving greater salt reduction was poor adherence to the study and programs in catering operations. The authors concluded that acceptance, effectiveness, and maintenance of workplace nutrition interventions require strong employer support [57]. Therefore, it is important to only consider intervening in the workplace when the employer is motivated to reduce the salt intake of workers. We found two studies that used Salt-Restriction-Spoon in the intervention. Chen et al. [58] in addition to the spoon, they provided nutritional education and informed the participants of the value of sodium excretion. At the end of the intervention, both the control group and the intervention group had decreased sodium excretion without statistical significance. Participants in both groups lived in the same place, probably causing contamination of the information for the study, the participants in the control group were informed about their sodium excretion, which may have contributed to the reduction in sodium excretion in this group. Cornélio et al. [59] described an intervention in hypertensive women that, in addition to the use of the Salt-Restriction-Spoon, provided an education based on behavior modification techniques to reduce salt intake. Also, in this intervention, both the control group and the intervention group decreased sodium excretion without statistical significance. Although the authors did not mention it is possible that there was an influence to reduce salt consumption in the control group because the women were asked to assess their usual monthly salt intake, and this may have led to awareness of the amount of salt they used and led them to reduce the amount they used when cooking. Salt-Restriction-Spoon are very interesting in populations where the biggest source of salt is the addition to cooking, helping people to limit the addition of salt.

In these 11 interventions that were not included in the review, we were able to perceive that they had no effect either for methodological reasons or because they had no effect on a particular population, reinforcing the importance of adapting interventions to reduce salt.

The inclusion of studies that only analyzed salt intake by urinary excretion could be pointed to as a strength of this review. The gold standard method is 24-h urinary excretion, as approximately 90 to 95% of ingested sodium is excreted in the urine [60]. However, we have included all studies that estimated salt intake through urinary measures such as spot urine collection and overnight urine sample, as they were previously described as measures to estimate acceptable salt intake [61–65].

5. Conclusions

Consumer education-based interventions alone reduce salt intake, but also when combined with other strategies. Tools for estimating salt consumption and self-monitoring of its consumption are also successful in reducing it.

In this review there is no evidence that the type of intervention analyzed is more effective in reducing salt consumption, but according to the medicine P4 approach, we must analyze each revised intervention and verify in which individuals or subpopulations it is most beneficial and will lead to better results. However, the results must be interpreted with caution as the quality of the studies is mixed. In the future, it is important to develop more high-quality clinical trials, with a longer intervention time and more participants, in order to understand which interventions work best for the reduction of salt consumption according to the target population.

Supplementary Materials: The following are available online at https://www.mdpi.com/article/10.3390/nu14010006/s1, Table S1: General characteristics of randomized trials without statistically significant salt reduction ($p < 0.05$), Table S2: General characteristics of non-randomized studies without statistically significant salt reduction ($p < 0.05$).

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Study 3 - Impact of an Innovative Equipment to Monitor and Control Salt Usage during Cooking at Home on Salt Intake and Blood Pressure-Randomized Controlled Trial iMC SALT

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Impact of an Innovative Equipment to Monitor and Control Salt Usage during Cooking at Home on Salt Intake and Blood Pressure—Randomized Controlled Trial iMC SALT

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Abstract: (1) Background: Excessive salt consumption is associated with an increased risk of hypertension and cardiovascular disease, and it is essential to reduce it to the level recommended by the World Health Organization (<5 g/day). The main objective of this study is to verify the impact of an intervention, which used the Salt Control H equipment to reducing salt consumption; (2) Methods: The study was an 8-week randomized control trial with 114 workers from a public university. The intervention group (n = 57) used the equipment to monitor and control the use of salt during cooking (Salt Control H) at home for 8 weeks. The primary outcome was 24 h urinary sodium excretion as a proxy of salt intake. Secondary outcomes included changes in 24 h urinary potassium excretion, sodium to potassium ratio (Na:K), and blood pressure. (3) Results: There was a decrease in sodium intake after the intervention but with no statistical significance. When analyzing the results by sex and hypertension status, there was a reduction in sodium (−1009 (−1876 to −142), p = 0.025) and in Na:K ratio (−0.9 (−1.5 to −0.3), p = 0.007) in hypertensive men in the intervention group. (4) Conclusions: Interventions with dosage equipment can be valid approaches in individual salt reduction strategies, especially in hypertensive men.

Keywords: dietary sodium; sodium restricted; hypertension; RCT; cardiovascular disease

1. Introduction

Excessive salt intake is associated with an increased risk of hypertension and cardiovascular disease [1]. It is estimated that 3 million of deaths worldwide are associated with high salt intake [2], making it essential to reduce salt intake.

There is evidence that reducing salt intake reduces blood pressure [1,3], in addition to bringing other health benefits in terms of cardiovascular disease and other chronic conditions [4].

In Portugal, in 2014, the main risk factors that contributed to the total disability-adjusted life years were inadequate eating habits, with low fruit intake and salty food intake being the main responsible factors [5].

The average intake of salt in Portuguese adults (10.7 g/day) is higher than recommended by the World Health Organization (5 g/day) [6,7] and similar to the global average for salt (10.06 g/day) [8]. The main source in Portugal is the salt added in the preparation and cooking, corresponding to 25 to 50% of the consumed salt [9,10]. Therefore, innovative interventions to reduce salt intake at the household level should be a priority in the country.

The reduction of population salt consumption was identified by the World Health Organization as one of the five major priority interventions to prevent non-communicable diseases based on criteria such as health effects, cost-effectiveness, low implementation costs, and political and financial viability. The goal is to reduce world salt consumption to less than 5 g per person per day by 2025 [11]. However, despite efforts to combat high dietary salt intake [9,12], progress remains slow.

Where the main source of salt intake is through salt added at the table or during cooking, education and communication strategies are important to influence consumer behavior to reduce salt intake [7]. A quick and easy-to-use instrument to monitor and control the salt added to foods during cooking may be the solution as consumers are not aware of the amount of salt consumed [7].

Thus, the main objective of this study is to verify the impact of an intervention, which is the use of the Salt Control H equipment in reducing salt consumption.

2. Materials and Methods

The trial design was registered at clinicaltrials.gov (accessed on 20 November 2021) (NCT03974477), and a detailed description of the methods of the iMCSalt study has been published previously [13].

2.1. Study Design and Participants

The study was an 8-week randomized controlled trial. In total, 139 participants were recruited from routine occupational health appointments of the University of Porto (white-collar and blue-collar workers). Recruitment was carried out by the doctor responsible for the appointment and started in June 2019 and ended in January 2021. The last participant evaluations ended in September 2021. The participants were evaluated four times: first at baseline, then two times during the intervention (week 4 and week 8, at end of intervention) and 6 months after the end of the intervention.

The following inclusion criteria were used by the doctor responsible for the recruitment: adult (>18 years), frequent home-cooked meals (more than 4 days a week and at least 3 Sundays per month), and reports motivation to control dietary salt consumption. The exclusion criteria were pregnancy, with hypotension, active infection that impacts renal function, kidney disease, urinary incontinence, acute coronary syndrome, severe liver disease or heart failure, member of the faculty that promotes the study (i.e., Faculty of Nutrition and Food Sciences), and not using salt for cooking.

The sample size calculated a priori was 260 participants [13], which was calculated to provide a significance level of 0.05 two-tailed and more than 80% statistical power, to assume a difference in 24 h mean urinary sodium excretion equal to or greater than 27 mmol/day between the intervention group and the control group, with a SD of 70 mmol/day [14].

2.2. Randomization

Included participants were randomly allocated to the control or intervention group (ratio 1:1), using computerized random numbers. Randomization of participants was stratified according to sex (ratio 1:1) and diagnosis of arterial hypertension (ratio 0.4:0.6) [6].

Randomization was performed after recruitment by a researcher independent of the recruitment and intervention process. The allocation sequence was concealed until the baseline assessment; participants and researchers discovered which group the participant belonged to at the same time by opening opaque envelopes identified with the participant's identifier number.

2.3. Intervention

The intervention consisted of using the Salt Control H equipment by the participants at home to control salt quantity for cooking all meals during the intervention period [13].

Salt Control H is a dispenser that offers doses of salt according to the number of persons and their age (child or adult) of the consumers. The equipment dispenses 0.8 g or 0.2 g of salt for adult and child meals, respectively. It dispenses 0.2 g or 0.1 g of salt for every 250 mL of adult soup or children's soup, respectively (Figure 1). Participants in the intervention group received a standardized presentation session that explained, through a video tutorial, how the salt control equipment works to ensure adequate salt content during food preparation and cooking. The researcher also provided some cooking strategies to prepare meals with adequate salt content. The prototype is only available for testing and not for commercial distribution. The Salt Control H equipment has been patented (INPI, No. 20191000033265) [15].

Figure 1. Salt Control H prototype.

2.4. Control Group

We made the Portuguese food guide [16] available to all participants, whether in the intervention group or the control group. This guide consists of seven food groups with serving recommendations for each group.

2.5. Outcomes

2.5.1. Primary and Secondary Outcomes

The primary outcome of this study was the difference in 24 h urinary sodium between the intervention group and the control group from the baseline to the end of the intervention (week 8). The secondary outcomes were the differences in urinary potassium excretion, Na:K ratio, and systolic and diastolic blood pressure between the two groups from the baseline to the end of the intervention (week 8).

These outcomes were evaluated four times: at baseline, during the intervention (week 4), at the end of the intervention (week 8), and six months after the end of the intervention (follow up).

The 24 h urine collection as a proxy of salt intake was performed any day of the week (preferably Sunday, but not Friday and Saturday due to laboratory availability). All participants for each evaluation were given one standard sterilized and coded container for urine collection and an illustrative leaflet with the collection procedure.

The following parameters were analyzed: volume, sodium (by indirect potentiometry), potassium (by indirect potentiometry), and creatinine (by photometry). The validity of 24 h urine collection was assessed by the relationship between urinary creatinine (mg/day) and body weight (kg). Samples were excluded when creatinine (mg/day/kg) was <10.8 and >25.2 in women and <14.4 and >33.6 in men [17]. Six urines were excluded in the intervention group and 10 urines were excluded in the control group.

The conversion of mmol to mg was performed by multiplying sodium (mmol) and potassium (mmol) respectively by 23 or 39 (mmol = mg/atomic weight). The Na:K ratio was obtained by dividing sodium (mmol) by potassium (mmol).

Blood pressure was measured using a portable sphygmomanometer (Edan M3A, Edan Instruments, Shenzhen, China) and was performed with the participants seated and after a 5 min rest. Blood pressure measurements were taken on both arms to determine possible arm-related measurement differences. A new measurement was taken on the arm that gave the highest value, and an average of the values of the two measurements was taken. If the difference between the first two assessments in the same arm was greater than 10 mm Hg, another third assessment was performed, and the mean was taken from the values of the last two assessments.

2.5.2. Sample Characterization and Adjustment Variables

The sociodemographic questionnaire was based on the WHO STEPS questionnaire [18], and the skin phenotype was characterized according to the Fitzpatrick classification, which was classified as redhead with freckles, blonde, brunette, Latino, Arab, Asian, or black [19].

The level of physical activity was assessed using the International Physical Activity Questionnaire-Short Form, which was validated and adapted for the Portuguese population [20].

Height was measured by a stadiometer (SEA 213 portable stadiometer, Hamburg, Germany) measured according to international standard procedures [21]. The weight was measured with the Tanita MC180MA body composition analyzer (Tanita, IL, USA), after introducing the height calculated the body mass index (BMI). Measurements were taken with participants wearing light clothing and no shoes.

Food intake was assessed using a 24 h dietary recall. Participants were asked to recall all foods and beverages consumed the day before (time of urine collection) and estimated the portion size with the aid of a picture book. Energy and nutritional intake were estimated using the Food Processor Plus nutritional analysis software (version 11.9, ESHA Research, Salem, OR, USA).

The participants' diagnosis of hypertension was made by the doctor responsible for the recruitment visit.

Participants who dropped out or did not agree to participate in the study filled out a questionnaire on simple sociodemographic questions.

2.6. Blinding

Participants and researchers were not blinded because the Salt Control H equipment cannot be masked. The 24 h urine analysis was performed by laboratory technicians who were unaware of the origin of the samples for analysis, and the researcher responsible for the randomization was not involved in the recruitment nor had any contact with the participants during data collection.

2.7. Statistical Methods

Statistical analysis was performed using the Statistical Package for the Social Sciences (SPSS Version 27). All statistical analyses and confidence intervals were two-sided, with $p < 0.05$ regarded as significant.

The normality of the variables was assessed using the Kolmogorov–Smirnov statistical test. Descriptive statistics were performed according to the characteristics of the variables, and the baseline differences between the intervention group and the control group were analyzed by the independent t-test (variables with normal distribution) or the Mann–Whitney U-test (variables with non-normal distribution) for continuous variables and $\chi 2$ test for categorical variables. Variables were presented as mean $\pm$ standard deviation (variables with normal distribution) or mean [P25; P75] (variables with non-normal distribution).

The difference in 24 h urinary sodium and potassium excretion and blood pressure was made using linear mixed models with an intention-to-treat approach with analyzed participants according to initial randomization [22]. Multiple imputations were performed to obtain a data set with no missing values. Models with health assessments (baseline, week 4, week 8 and follow up) and treatment group (intervention vs. control group) as fixed effect and person as random effect were performed to test the change from baseline to the 8-week follow-up in 24 h urinary sodium and potassium excretion and blood pressure. Autoregressive structure with heterogenous variances was chosen as the variance structure. These variables were also analyzed by subgroups for sex and hypertension. A per-protocol analysis was also performed on all participants at baseline and at the 8-week follow-up. The fixed effect models were adjusted for energy intake in sodium and potassium excretion models, and skin phenotype in blood pressure models. Mean differences were estimated with 95% CI.

3. Results

3.1. Participants

From 345 screened people, 231 were excluded for not meeting the inclusion criteria (n = 49) or refusing to participate in the study (n = 182). There were no significant differences in age, sex, education level, marital status, and whether they are hypertensive between people who refused and those who agreed to participate in the study. A total of 114 participants were included to be randomized, of which 57 were allocated to the intervention group and 57 were allocated to the control group. During the intervention, 11% of participants dropped out: seven participants in the intervention group and five in the control group. There was no significant difference between participants who were lost during the intervention or follow-up and those who completed the study regarding age, sex, marital status, education level, and whether they are hypertensive ($p > 0.05$ for all variables). The participants' reasons for dropping out are shown in Figure 2. For the final analysis, six participants from the intervention group and 10 participants from the control group were excluded for incomplete urine at baseline and/or at the end of the intervention (Figure 2).

Data collection for the study took place during the global SARS-CoV-2 pandemic. The intervention period and the follow up period were not fulfilled during this period due to the confinements. The mean weeks in the intervention period was 14 (95 days) and the mean months in the follow-up period was 7 (206 days), with no difference between the intervention time and the follow-up time between groups.

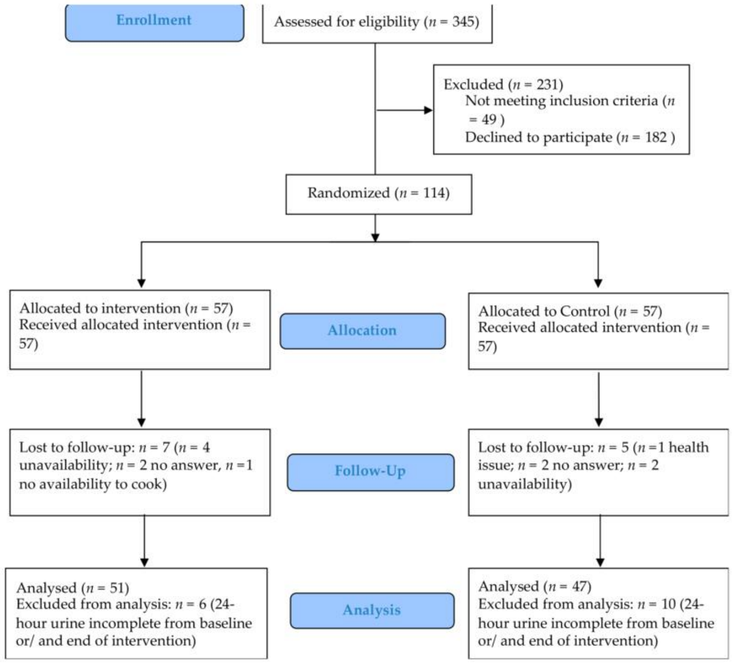

Figure 2. Flow diagram of participants in an intervention to reduce salt intake.

3.2. Baseline Data

Table 1 shows the baseline characteristics of the participants. The mean age was 48, and 54.4% were women. Most participants were married, had higher education, were non-smokers, and on average consumed less than one alcoholic beverage per week. On average, participants had a BMI of 26 kg/m^2, an energy intake of 2033 kcal/day, practiced 60 min per week of moderate to vigorous physical activity, and 39% were hypertensive. There were no significant differences between the intervention group and the control group (Table 1).

3.3. Outcomes

At baseline, only 21.1% of the participants complied with the World Health Organization sodium intake recommendations (<2000 mg/day), at the end of the intervention, 23.3% complied with the recommendations.

Figure 3 demonstrates the mean excretion of sodium, potassium, Na:K ratio, and blood pressure from baseline to follow-up. Urinary sodium excretion decreased in the four assessments in the intervention group, while in the control group, it increased from baseline to the end of the intervention and then decreased in the follow-up assessment. However, there was no statistically significant mean difference at any time of the assessments between the groups (Figure 3a). Urinary potassium excretion showed a non-significant decrease (Figure 3b).

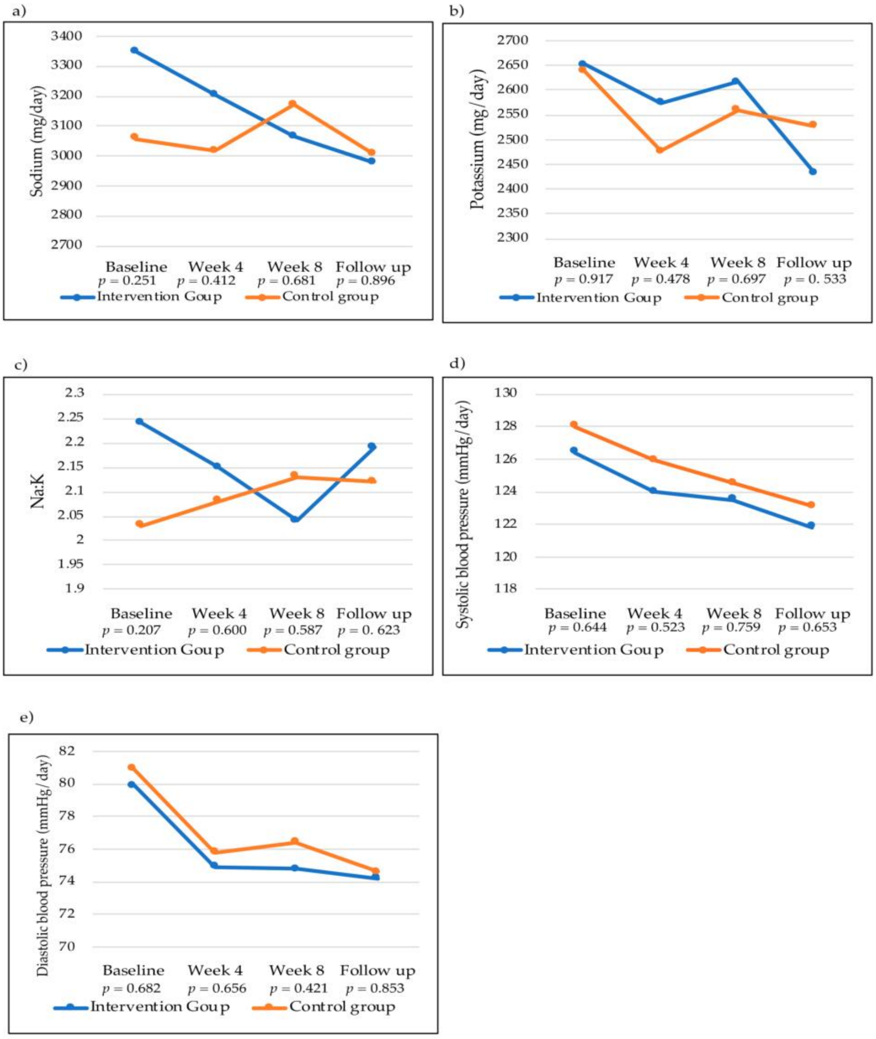

Figure 3. Two-dimensional (2D) line graphs with markers of the means of the four assessments of sodium and potassium excretion, Na:K ratio, and blood pressure in the intervention and control groups performed throughout the study. (**a**) Urinary sodium excretion (mg/day) of the intervention and control groups; (**b**) Urinary potassium excretion (mg/day) of the intervention and control groups; (**c**) Na:K ratio of the intervention and control groups; (**d**) Systolic blood pressure (mmHg/day) of the intervention and control groups; (**e**) Diastolic blood pressure (mmHg/day) of the intervention and control groups. *p*-Adjusted mean difference between intervention group and control group (sodium and potassium excretion and Na:K ratio were adjusted for energy intake and blood pressure was adjusted for skin phenotype).

Table 1. Sociodemographic, lifestyle, clinical, anthropometric, and nutritional characteristics of 114 adults participating in a randomized control trial.

Participants' Characteristics	Total (*n* = 114)	Intervention Group (*n* = 57)	Control Group (*n* = 57)	*p*-Value
Age (mean ± SD)	48 ± 11	47 ± 10	49 ± 11	0.178
Women (%)	54.4	52.6	56.1	0.707
Education (%)				
No higher education	13.2	8.8	17.5	0.166
Higher education	86.8	91.2	82.5	
Marital Status (%)				
Single	16.7	17.5	15.8	
Married	68.4	64.9	71.9	0.813
Divorced	11.4	14	8.8	
Widow/er	3.5	3.5	3.5	
Hypertensive (%)	38.6	42.1	35.1	0.442
Body mass index, kg/m^2 (mean ± SD)	26.0 ± 3.9	25.8 ± 4.0	26.2 ± 3.9	0.587
Energy intake (kcal) (median [P25; P75])	2033 [1632; 2596]	2042 [1697; 2629]	2007 [1559; 2461]	0.375
Moderate and/or vigorous physical activity/week (minutes per week) (median [P25; P75])	60 [0; 240]	70 [0; 255]	60 [0; 210]	0.804
Skin phenotypes [1] (%)				
Type 1	1.8	1.8	1.8	
Type 2	10.5	10.5	10.5	
Type 3	51.8	50.9	52.6	NA
Type 4	34.2	35.1	33.3	
Type 5	0.0	0.0	0.0	
Type 6	1.8	1.8	1.8	
Smoking habits (%)				
Non smoking	63.2	63.2	63.2	
Smoker	12.3	15.8	8.8	0.424
Former smoker	24.6	21.1	28.1	
Alcohol intake, drinks/week (median [P25; P75])	0.29 [0.15; 0.75]	0.29 [0.1; 0.7]	0.29 [0.14; 0.86]	0.590

[1] Type 1—redhead with freckles; Type 2—blonde; Type 3—brunette; Type 4—Latino; Type 5—Arab; Type 6—Asian or black. SD—Standard deviation; NA—Not applicable.

The Na:K ratio in the intervention group decreased from baseline to the end of the intervention and increased in the follow-up assessment. In the control group, the Na:K ratio increased during the intervention period and decreased slightly at follow-up. There were no statistically significant mean differences at any time between groups (Figure 3c). Systolic and diastolic blood pressure decreased in both groups over the four assessments, with no statistically significant mean difference at any time of the assessment between groups (Figure 3d,e).

Table 2 presents the results on 24 h urine measurements for sodium, potassium, Na:K ratio, and blood pressure within groups between baseline and the end of intervention.

Table 2. Adjusted mean difference in urinary excretion of sodium and potassium, Na:K ratio, blood pressure based on intention-to-treat analysis in an intervention to reduce salt intake.

Outcomes	Intervention Group				Control Group			
	Baseline (Mean [95%CI])	End of Intervention, Week 8 (Mean [95%CI])	Change from Baseline [95%CI]	*p*-Value	Baseline (Mean [95%CI])	End of Intervention, Week 8 (Mean [95%CI])	Change from Baseline [95%CI]	*p*-Value
Sodium (mg) *	3369 [3021 to 3717]	3033 [2653, 3413]	−336 [−723 to 51]	0.088	3135 [2782 to 3488]	3185 [2812 to 3558]	50 [−327 to 428]	0.792
Potassium (mg) *	2658 [2454 to 2862]	2615 [2403, 2828]	−43 [−270 to 184]	0.710	2665 [2457 to 2871]	2565 [2357 to 2773]	−99 [−321 to 123]	0.377
Na:K *	2.2 [2.0 to 2.5]	2.0 [1.8 to 2.2]	−0.2 [−0.5 to 0.0]	0.104	2.1 [1.8 to 2.3]	2.1 [1.9 to 2.4]	0.1 [−0.2 to 0.4]	0.583
SBP (mmHg) **	126.2 [121.4 to 131.0]	123.0 [118.8 to 127.2]	−3.2 [−7.0 to 0.6]	0.094	127.7 [122.9 to 132.6]	124.1 [119.9 to 128.2]	−3.7 [−7.4 to −0.0]	0.048
DBP (mmHg) **	79.7 [76.5 to 82.8]	74.9 [72.0 to 77.7]	−4.8 [−6.7 to −2.9]	<0.001	81.2 [78.0 to 84.4]	76.4 [73.6 to 79.2]	−4.8 [−6.7 to −2.9]	<0.001

* Adjusted for energy intake. ** Adjusted for skin phenotype. SBP—systolic blood pressure; DBP—diastolic blood pressure; CI—confidence interval. *p*-value calculated using linear mixed models.

Mean urinary sodium excretion decreased in the intervention group by around 336 mg/day (p = 0.088), corresponding to a 10% reduction in sodium excretion. The Na:K ratio also decreased by 0.2, but it was not statistically significant (p = 0.104). In the control group, mean sodium excretion increased by 50 mg/day (p = 0.792), and the Na:K ratio also increased by 0.1 (p = 0.583). Potassium excretion decreased in both groups at the end of the intervention, but the mean difference was not statistically significant (intervention group p = 0.710, control group p = 0.377). The mean difference for systolic blood pressure was significant in the control group (−3.7 (−7.4 to −0.0), p = 0.048) and for diastolic blood pressure, the mean difference was significant in both groups (intervention group −4.8 (−6.7 to −2.9), p < 0.001, control group −4.8 (−6.7 to −2.9), p < 0.001) (Table 2).

Table 3 shows the adjusted mean difference between the control group and the intervention group analyzed by intention to treat and per protocol. Data were similar in both analyses; there were no statistical differences in any of the outcomes analyzed.

Table 3. Mean intervention effect (adjusted mean difference (intervention vs. control)) in intention-to-treat and per-protocol analysis.

Outcomes	Intention to Treat		Per Protocol	
	Adjusted Difference [95%CI] (Intervention vs. Control)	***p*-Value**	**Adjusted Difference [95%CI] (Intervention vs. Control)**	***p*-Value**
Sodium (mg) *	−152 [−684 to 380]	0.350	−163 [−753 to 428]	0.585
Potassium (mg) *	50 [−247 to 347]	0.738	−58 [−223 to 107]	0.487
Na:K *	−0.1 [−0.4 to 0.2]	0.426	−0.2 [−0.5 to 0.2]	0.267
SBP (mmHg) **	−1.0 [−6.9 to 4.8]	0.729	−1.2 [−7.7 to 5.3]	0.715
DBP (mmHg) **	−1.6 [−5.6 to 2,4]	0.441	−1.7 [−6.1 to 2.7]	0.445

* Adjusted for energy intake. ** Adjusted for skin phenotype, Fitzgerald scale. SBP—systolic blood pressure; DBP—diastolic blood pressure; CI—confidence interval. p-value calculated using linear mixed models.

Table 4 presents the adjusted mean difference in sodium and potassium excretion, Na:K ratio, and blood pressure from baseline to end of intervention and mean intervention effect in intention to treat by sex and by hypertension status.

In male hypertensive participants, there was a statistically significant mean difference of −1009 (−1876 to −142, p = 0.025) mg of sodium/day in the intervention group; in relation to the Na:K ratio, there was also a statistically significant mean difference of −0.9 (−1.5 to −0.3) in the intervention group. In systolic blood pressure, there was a mean difference in hypertensive men in the control group of −11.3 (−20.4 to −2.2), p = 0.018. Regarding diastolic blood pressure, there was a statistically significant mean difference in hypertensive men, hypertensive women, and non-hypertensive women in the intervention group and in the control group, corresponding to decreases in diastolic blood pressure. There was no statistically significant difference from baseline to the end of intervention between groups in any outcome (urinary excretion of sodium, potassium, Na:K ratio, and blood pressure), in intention to treat by sex and by hypertension status (Table 4).

Table 4. Adjusted mean difference in sodium and potassium excretion, Na:K ratio, and blood pressure from baseline to end of intervention and mean intervention effect (adjusted mean difference (intervention vs. control)) in intention to treat by sex and by hypertension status.

			Intervention Group		Control Group			
Outcomes	**Sex**	**Hypertension**	**Adjusted Difference [95%CI] (Change from Baseline)**	***p*-Value**	**Adjusted Difference [95%CI] (Change from Baseline)**	***p*-Value**	**Adjusted Difference [95%CI] (Intervention vs. Control)**	***p*-Value**
Sodium (mg) *	Women	Yes	105 [−795 to 1013]	0.810	109 [−795 to 1013]	0.798	−536 [−1916 to 845]	0.420
		No	−253 [−761 to 256]	0.320	211 [−263 to 685]	0.320	42 [−638 to 721]	0.902
	Men	Yes	−1009 [−1876 to −142]	0.025	26 [−977 to 1030]	0.957	−649 [−1778 to 481]	0.245
		No	127 [−808 to 1062]	0.781	−126 [−977 to 726]	0.764	175 [−1036 to 1385]	0.768
Potassium (mg) *	Women	Yes	−31 [−543 to 482]	0.899	−157 [−674 to 359]	0.518	−194 [−820 to 433]	0.518
		No	126 [−255 to 507]	0.506	113 [−247 to 473]	0.528	135 [−285 to 555]	0.518
	Men	Yes	199 [−348 to 745]	0.453	−316 [−933 to 301]	0.296	−24 [−894 to 847]	0.955
		No	−474 [−958 to 11]	0.055	−154 [−594 to 285]	0.473	136 [−566 to 839]	0.692
Na:K *	Women	Yes	0.2 [−0.4 to 0.9]	0.473	0.3 [−0.4 to 0.9]	0.369	−0.3 [−1.3 to 0.7]	0.543
		No	−0.3 [−0.7 to 0.017]	0.062	0.0 [−0.3 to 0.4]	0.811	−0.1 [−0.5 to 0.3]	0.562
	Men	Yes	−0.9 [−1.5 to −0.3]	0.007	0.3 [−0.4 to 1.1]	0.376	−0.4 [−1.2 to 0.4]	0.292
		No	0.4 [−0.3 to 1.1]	0.442	−0.2 [−0.3 to 1.1]	0.203	0.2 [−0.4 to 0.8]	0.512
SBP (mmHg) **	Women	Yes	−10.5 [−23.7 to 2.6]	0.109	−7.3 [−20.3 to 5.6]	0.109	−9.3 [−27.4 to 8.7]	0.287
		No	−3.4 [−8.6 to 1.9]	0.203	1.6 [−3.2 to 6.6]	0.501	−3.7 [−10.5 to 3.2]	0.284
	Men	Yes	−6.7 [−14.8 to 1.4]	0.100	−11.3 [−20.4 to −2.2]	0.018	0.8 [−11.9 to 13.5]	0.901
		No	5.2 [−1.1 to 11.4]	0.101	−2.9 [−8.7 to 2.9]	0.306	2.5 [−8.4 to 13.4]	0.642
DBP (mmHg) **	Women	Yes	−8.4 [−15.1 to −1.6]	0.018	−8.4 [−15.1 to −1.6]	0.018	−0.6 [−8.9 to 7.6]	0.872
		No	−2.6 [−5.0 to −0.1]	0.040	−2.6 [−5.0 to −0.1]	0.040	−0.7 [−5.2 to 3.8]	0.758
	Men	Yes	−8.1 [−12.6 to −3.6]	0.001	−8.1 [−12.6 to −3.6]	0.001	−5.9 [−12.9 to 1.0]	0.089
		No	−2.6 [−5.6 to 0.5]	0.097	−2.6 [−5.6 to 0.5]	0.097	−0.7 [−9.4 to 7.9]	0.866

* Adjusted for energy intake. ** Adjusted for skin phenotype, Fitzgerald scale. SBP—systolic blood pressure; DBP—diastolic blood pressure; CI—confidence interval. *p*-value calculated using linear mixed models with an intention-to-treat approach.

4. Discussion

This intervention to reduce salt intake with an innovative dispenser (Salt Control H) that offers doses of salt according to age characteristics and the number of meals prepared appears to decrease sodium intake and improve the Na:K ratio in hypertensive men from the intervention group, although no significant differences were found for these urinary markers in relation to the control group. Nevertheless, this intervention can be considered as part of the solution to effectively reduce the consumption of salt, which remains one of the main priorities, including in clinical populations such as people with hypertension. There was no effect on potassium excretion in both groups. Diastolic blood pressure decreased in both groups.

The mean urinary sodium excretion of our sample at baseline was 3221 mg/day, which corresponds to more than 60% of the recommended intake by the World Health Organization. This high sodium intake is similar to sodium consumption reported by other authors in other countries [23–25].

During the intervention, particularly in some periods, a gradual reduction in sodium excretion in the intervention group and an increase in the control group, also in the Na:K ratio, was verified, however without statistical significance when comparing the groups. The results of per-protocol analysis were comparable with intention-to-treat, indicating the completeness of most urine collections. We believe that intervention with the Salt Control H equipment to reduce salt consumption was limited due to lockdown during the pandemic. The lockdown implemented during the pandemic changed people's food preferences, and there is evidence that there has been an increase in the consumption of salt and sodium-rich foods in different countries [26]. People ingested more processed foods such as snack foods, canned goods, and instant foods, most of which were high in sodium [27]. The change in consumer behavior was driven by fears of being infected during trips to the supermarket, inflated prices for fresh produce, limited supplies, preference for foods with a long shelf life, and emotional eating [26]. Furthermore, it was reported that sodium intake not only increased during lockdown but also increased after the lockdown [28]. Together, these dietary and nutritional changes during the COVID-19 pandemic may have impacted the magnitude of urinary sodium and Na:K ratio reduction in the intervention group. For the same reason, potassium excretion decreased in both groups during the intervention period and in the follow-up assessment, and this could be due to the change in eating behavior of people in the lockdown when they decreased the intake of fresh foods such as vegetables [28], which are rich in potassium. The Na:K ratio also decreased although it was statistically significant only in hypertensive men in the intervention group. The Na:K ratio is considered a relevant measure when assessing the risk of developing high blood pressure and cardiovascular disease [29].

Systolic and diastolic blood pressure decreased in both groups over time, which may also be a consequence of lockdown as described in other studies [30,31]. In addition, a meta-analysis of randomized trials of salt reduction showed that reducing 1 g of salt per day decreased systolic blood pressure by about 1 mmHg [3].

This study can be defined as a food education intervention that combines one innovative equipment with cooking instructions and tips to reduce the salt content in food preparation that was used in clinical usual care. Previous studies have reported the effectiveness of cooking instruction in decreasing salt intake. A study of 35 housewives and 31 family members decreased 1.19 g/day of salt in the intervention group compared to the control group ($p = 0.034$) by giving cooking classes focusing on the amount of salt in a meal and instructions on how to cook with less salt [32]. Another study of 753 participants at high risk for cardiovascular disease reduced 0.66 g/day of salt between groups ($p = 0.03$) with an education program that included cooking instructions using a pocket-sized digital salt meter to display the content of their food daily. In addition, systolic blood pressure also decreased by 7.55 mm Hg, $p < 0.01$ [33]. In another study of 403 participants, the intervention group received an improvement salt-restriction-spoon and health education and reduced daily salt intake by 1.42 g [34].

Meeting the World Health Organization's recommendations for salt intake (<5 g/day) remains a problem, and the main sources of salt intake continue to be varied, including bread products, cereals and grains, meat products, and dairy products, but the discretionary use of salt has marked variation across the world and is a major source of dietary salt in many countries, including Portugal [9]. The use of equipment that offers doses of salt according to the number of persons and their age group could be considered as a promising strategy to be part of the solution for reducing salt population intake, considering that it responds to people's difficulty in measuring and knowing the maximum amount of salt that is recommended for cooking their meals, being especially useful to tackle added salt.

Our results have important implications for public health. Salt Control H, in addition to providing salt doses according to the daily salt recommendations, is an educational tool that can be used by health professionals to teach people about the maximum dose of salt they can use to prepare their meals. It is important to emphasize that in order to achieve the greatest reduction in salt consumption by the population, it is important to combine with other strategies, namely working with the food industry to reduce the amount of salt added to processed foods.

A strength of the study was that sodium consumption was assessed through 24 h urinary excretion, and multiple measurements were performed during intervention period. It is the gold standard method as approximately 90 to 95% of ingested sodium is excreted in the urine [35]. Although it may have inaccuracies and collection errors [36], it is the most reliable method [37]. Another strength is that the study design followed the recommendations and best practices of clinical trials.

Our study has limitations. First, as already mentioned, data collection was carried out during the period of the COVID-19 pandemic, changing the duration of intervention and follow-up, and we were not able to reach the calculated sample size. Second, participation in the study was limited to employees of a university, most had a high level of education, and the results are not generalizable to the general population. Third, although our effort was that the participants in the control group did not change their behavior, we must admit that changing the intake is always possible just by being a participant in a trial.

5. Conclusions

Our study showed that the tested equipment that provides salt doses according to the number of persons and their age, accompanied by general written cooking instructions, decreased sodium and improve the Na:K urinary excretion in hypertensive men from the intervention group, although no significant differences were found for these urinary markers in relation to the control group. It will be important in the future to test this intervention with a larger sample size and in a period after the pandemic.

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Institutional Review Board Statement: The study was conducted according to the guidelines of the Declaration of Helsinki and approved by the Ethics Committee of Centro Hospitalar de São João (Approval Code: 11/2019, Approval Date: 15 February 2019).

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Data Availability Statement: The data presented in this study are available on request from the corresponding author. The data are not publicly available due to ethical.

Conflicts of Interest: The study used a prototype system that was presented with a patent number (INPI, No. 20191000033265). C.G., L.O., S.E., P.M. and O.P. are inventors of the prototype system. The inventors have intellectual property rights.

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Study 4 – Salt-related knowledge, attitudes and behavior in an intervention to reduce added salt

foods

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Article

Salt-Related Knowledge, Attitudes and Behavior in an Intervention to Reduce Added Salt When Cooking in a Sample of Adults in Portugal

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Abstract: (1) Background: Excessive salt intake is associated with an increased risk of hypertension and cardiovascular disease, so reducing it is critical. The main objective of this study was to verify whether one intervention to reduce added salt during cooking changed knowledge, attitudes and behavior (KAB) towards salt, and to analyze changes in the main sources of salt. (2) Methods: The intervention study was an 8-week randomized controlled trial with 97 workers from a public university. KAB in relation to salt were obtained through the WHO STEPwise questionnaire, and the main sources of salt were obtained by 24-h food recall and 24 h urinary sodium excretion over two days. (3) Results: After the intervention, participants in the intervention group reported a decrease in the addition of salt when cooking (p = 0.037), an increase in the percentage of subjects who avoided the consumption of processed foods (from 54.2% to 83.3%, p = 0.001), who looked for salt on food labels (from 18.8% to 39.6%, p = 0.013), and who bought low-salt food alternatives (from 43.8% to 60.4%, p = 0.039). However, there were no significant differences between the intervention group and the control group at baseline and post-intervention assessments. In the intervention group, after the intervention, the added salt decreased by 5%; food sources of salt such as the snacks and pizza group decreased by 7%, and the meat, fish and eggs group increased by 4%, but without statistical significance. (4) Conclusions: With innovative equipment for dosing salt when cooking, it is possible to change some dimensions of consumer behavior in relation to salt.

Keywords: dietary salt; dietary sodium; cardiovascular disease; salt-related knowledge; KAB

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1. Introduction

About 17 million people die every year from cardiovascular disease and approximately 9.4 million are from complications of hypertension [1,2].

Strong evidence has shown a causal relationship between sodium intake and blood pressure [3–8]. A modest reduction in sodium causes a reduction in blood pressure in hypertensive and normotensive individuals with clinical and public health significance [9,10]. Sodium is an essential nutrient, and the most common form of sodium consumption is sodium chloride, consisting of 40% sodium, and commonly known as table salt [11].

Hypertension is one of the main causes of cardiovascular diseases, and reducing salt intake lowers blood pressure, therefore also decreasing the risk of cardiovascular disease [12]. Furthermore, salt reduction has an additive effect, direct and independent of the effect on blood pressure in cardiovascular diseases, for example, in reducing the risk of stroke [3,12]. In studies with long-term follow-up, results showed that a 2.5 g/day reduction in salt is associated with a 20% reduction in cardiovascular events [12].

The World Health Organization (WHO) recommends reducing salt intake to <5 g/day, although the average global adult intake is twice the recommended limit, about 10.06 g/day of salt [13]. The exact minimum daily requirement for salt is unknown but is estimated to be around 1.25–2.5 g. A salt intake of 5 g per day is sufficient to meet sodium and chloride needs in adults, as well as to reduce the risk of high blood pressure and heart disease [14].

A recent review identified bread, cereal and grain products and meat and dairy products as major contributors to dietary salt intake in most populations. It found that there is a wide variation in the consumption of discretionary salt across the world, depending on the economic development of the country. The contribution of discretionary salt to the diet ranged from less than 25% to more than 50% [15]. In the national food and physical activity survey carried out in Portugal, the main sources of salt were added salt (29.2%), the group of cereals, derivatives and tubers (20.6%) and the group of meat, fish and eggs (18.2%) [16].

The WHO has adopted the global target of a 30% reduction in average salt intake by 2025. About 75 countries have a national salt reduction strategy; most programs are multifaceted and include consumer education, target setting for salt content in foods, product reformulation, front-of-pack labeling schemes, interventions in public institutions and taxation of high-salt foods [17]. Interventions to reduce salt consumption must be tailored to individuals and subpopulations, as consumers are different in each country and the way in which salt is consumed is also different [18].

Better knowledge, attitudes and behaviors related to diet were associated with higher health status [19]. Therefore, its comprehension in relation to salt enhances the effect of interventions in changing behavior towards healthier choices [20].

The iMCSalt randomized controlled trial evaluated the impact of an intervention to reduce salt intake, which used a device to measure salt for cooking [21,22]. There was a decrease in sodium intake after the intervention, but without statistical significance, and a reduction in sodium and an improvement in the sodium/potassium ratio in hypertensive men in the intervention group, with statistical significance [22]. The aim of this study is to verify whether this intervention changed knowledge, attitudes and behavior towards salt and the main sources of salt.

2. Materials and Methods

2.1. Study Design and Participants

A detailed description of the study methods was previously published [21,22]. The study was registered at clinictrials.gov (NCT03974477).

The study was an 8-week randomized controlled trial with adults recruited from routine occupational health consultations at the University of Porto, which is located in the north of Portugal. Recruitment started in June 2019 and ended in January 2021 and was carried out by the doctor responsible for recruitment. Participants were assessed at baseline (week 0) and twice during the intervention (week 4 and week 8).

The following inclusion criteria were adult (>18 years old), report of motivation to control food consumption of salt and frequent home-cooked meals (more than 4 days a week and at least 3 Sundays a month). Exclusion criteria were hypotension, pregnancy, urinary incontinence, kidney disease, active infection that impacts kidney function, acute coronary syndrome, severe liver disease or heart failure, does not use salt to cook, and worker at the faculty promoting the study.

Randomization was performed after recruitment by a researcher independent of the recruitment process and intervention, and the allocation sequence was concealed until the initial assessment. Included participants were randomly allocated to the control or intervention group (ratio 1:1), using computerized random numbers and were stratified according to sex (ratio 1:1) and diagnosis of hypertension (ratio 0.4:0.6).

The intervention was the use of the Salt Control H equipment (Salt Control H—INPI, N° 20191000033265, prototype printed by fast printing) by participants at home to control and dose the amount of salt used in cooking all meals during the intervention period, and the researcher also provided some cooking strategies to prepare meals with adequate salt content. All participants, whether in the control group or in the intervention group, received the Portuguese food guide [23]. This guide consists of seven food groups with serving recommendations for each group.

All participants at the end of the study received information only about their nutritional status and anthropometric assessment.

2.2. Salt-Related Knowledge, Attitudes and Behavior

Participants were assessed according to the WHO STEPwise approach to surveillance of chronic disease risk factors [24].

The questionnaire consists of 13 questions. Three questions assess the behavior related to added salt: use of salt in meal preparation, discretionary use of table salt, and consumption of processed foods with high salt content, using a 5-point Likert scale ("always", "often", "often", "sometimes", "rarely", "never"). Seven questions evaluated which behaviors were adopted to control salt intake with binary responses ("yes", "no"), namely, avoid the consumption of processed foods, observe salt labels on food, eat meals without salt at the table, buy low-salt alternatives, cook meals without adding salt, use spices in addition to salt when cooking, and avoid eating out. Three questions related to knowledge and attitudes, including knowledge of the relationship between salt and health problems ("yes", "no"), about the perception of salt consumption ("far too much", "too much", "just the right amount", "too little", "far too little") and the importance of reducing salt intake ("very important", "somewhat important", "not at all important").

2.3. 24-h Urinary Sodium Excretion

The 24-h urinary excretion collection was used as a proxy for salt intake.

Participants collected one urine sample at baseline and two urine samples during the intervention period (week 4 and week 8). Urine collection was performed on any day of the week, but preferably on Sunday. Participants received written instructions on the urine collection procedure and a coded sterilized container. On the day of collection, they rejected the first void and included all urine for that day and the first void for the following day, at the same time as that for the urine rejected the day before.

In urine, the following parameters were evaluated: sodium (by indirect potentiometry), creatinine (by photometry) and volume. The validity of the 24-h urine collection was analyzed through the relationship between urinary creatinine (mg/day) and body weight (kg). When creatinine (mg/day/kg) was <10.8 and >25.2 in women and <14.4 and >33.6 in men, samples were excluded [25].

The conversion of sodium from mmol to mg was performed by multiplying sodium (mmol) by 23 (mmol = mg/atomic weight). The conversion of sodium (Na) to salt (NaCl) was done by multiplying the sodium value by 2.542 (NaCl (g) = Na (g) $\times$ 2.542).

2.4. 24-h Dietary Recall

For the analysis of food groups, only those who ate cooked meals at lunch and dinner were considered, since the intervention focused on the reduction of added salt.

A 24-h dietary recall was used to estimate energy intake, sodium intake and major sources of sodium, including added salt. The analyzed day corresponded to the day of the 24-h urine collection. The questionnaire was administered by trained investigators and all food and beverage, commercial brands and cooking methods were questioned in detail and portion size estimated with the aid of a picture book. The conversion of food intake into nutrients was performed using the Food Processor Plus software (ESHA Research, Inc., Salem, OR, USA) adapted for the Portuguese population.

The foods were distributed into 12 food groups, adapted from the methodology of the national food and physical activity survey [16]: (1) cereals, cereal products and starchy tubers (paste, rice and other grains, potatoes and other starchy tubers, bread and rusks, flour, bread dough and pastry dough, infant cereals, breakfast cereals and cereal bars); (2) meat, fish and eggs (white meat, red meat, offal, processed meat, fish, crustaceans, mollusks and derivatives, processed fish and seafood); (3) dairy (milk, milk cream, yoghurt and other fermented milk, cheese); (4) soups (vegetable, meat, fish and chicken soups); (5) sweets, cakes and biscuits (table sugar, honey, molasses, syrup, jellies, jams, candied fruits, candy, gums, chewing gum, chocolates, chocolate snacks, ice cream, sweet desserts, cakes, cookies and biscuits); (6) salty snacks and pizzas (bread snacks, potato chips, salted popcorn, packaged fried snacks, patties, croquettes, codfish cakes, pies, puffed pastries and pizzas); (7) fruit, vegetables and vegetables (vegetables, nuts and oilseeds, fresh fruit and processed fruit); (8) non-alcoholic beverages (water, tea and infusions, coffee, natural and 100% fruit juices nectars, soft drinks, other non-alcoholic beverages); (9) other foods (yeasts, gelatins, flavors, herbs, spices, condiments, sauces, mayonnaise, powdered soups); (10) fats and oils (vegetable oils, olive oil, butter, margarines and minarines, other fats); (11) alcoholic beverages (wine, liquors, beer, spirits, other alcoholic beverages); (12) added salt.

Sodium in the foods of each food recall was divided by the corresponding food groups and its contribution was calculated in % terms, in relation to the sodium assessed by the 24-h urinary excretion. Cooked meals were introduced raw, according to the food yield by the cooking method. Added sodium was calculated by the difference between the sum of sodium values of foods in each group and the urinary sodium excretion value. After the calculations the sodium was converted to salt. Added salt is the salt added in the preparation and cooking, excluding the intrinsic sodium of raw foods.

2.5. Other Measures

Sociodemographic data were collected using a sociodemographic questionnaire based on the WHO STEPS questionnaire [24], physical activity level was assessed using the International Physical Activity Questionnaire-Short Form, validated and adapted for the Portuguese population [26], hypertension was diagnosed by the doctor responsible for the recruitment, and body mass index was calculated by Tanita MC180MA (Tanita, IL, USA), after entering the height of the participants measured by a stadiometer (portable stadiometer SEA 213, Hamburg, Germany) according to international standard procedures [27]. Physical activity was divided into moderate, vigorous and walking according to type, required energy expenditure (MET) and time spent (min). Physical activity level was considered high if total MET $\times$ min $\times$ week $\geq$3000, moderate $\geq$600 and low <600 [28].

2.6. Statistical Methods

The Kolmogorov-Smirnov test was used to test for normality. The statistics were performed according to the characteristics of the variables, the differences between the continuous independent variables were analyzed by the independent *t*-test (variables with normal distribution) or by the Mann-Whitney U test (variables with non-normal distribution) and for variables categorical the χ^2 test. Differences between continuous dependent variables were analyzed using the Wilcoxon test and categorical variables were analyzed using the McNemar test. A Spearman's correlation (non-normal distribution) was performed between urinary sodium excretion and sodium estimated by the food survey and between the sodium sources variables and the variables of the questionnaire on knowledge, attitudes and behavior in relation to salt.

Statistical analysis was performed using the Statistical Package for the Social Sciences (SPSS Version 27).

3. Results

3.1. Baseline Data

The study included 114 participants, of which 17 were excluded because they did not have valid urine at baseline and/or in the intervention period. A detailed description of the flow diagram of participants in the intervention to reduce salt intake has been published previously [22].

Table 1 shows the baseline characteristics of the participants. The mean age was 48, 52.6% were women and 40.2% were hypertensive. Most participants had higher education (86.6%), were married (68%) and has a moderate practice of physical activity (47.4%). On average, participants had a BMI of 25.9 kg/m^2 and an energy intake of 2072 kcal/day. There were no significant differences between the intervention group and the control group.

Table 1. Sociodemographic, lifestyle, clinical, anthropometric, and nutritional characteristics of 97 adults participating in an intervention to reduce added salt.

Participants' Characteristics	Total (*n* = 97)	Intervention Group (*n* = 48)	Control Group (*n* = 49)	*p*-Value [1]
Age (mean ± SD)	48 ± 10	46 ± 10	50 ± 10	0.065
Women *n* (%)	51 (52.6)	26 (54.2)	25 (51.0)	0.457
Education *n* (%)				
No higher education	13 (13.4)	5 (10.4)	8 (16.3)	0.393
Higher education	84 (86.6)	43 (89.6)	41 (83.7)	
Marital Status *n* (%)				
Single	17 (17.5)	10 (20.8)	7 (14.3)	
Married	66 (68.0)	29 (60.4)	37 (75.5)	0.281
Divorced	12 (12.4)	7 (14.6)	5 (10.2)	
Widow/er	2 (2.1)	2 (4.2)	0 (0.0)	
Hypertensive *n* (%)	39 (40.2)	20 (41.7)	19 (38.8)	0.772
Body mass index, kg/m^2 (mean ± SD)	25.9 ± 3.9	25.5 ± 3.9	26.2 ± 3.9	0.384
Energy intake (kcal) (median [P25; P75])	2072 [1642; 2588]	2041 [1664; 2597]	2105 [1631; 2538]	0.931
Physical activity *n* (%)				
Low	35 (36.1)	16 (33.3)	19 (38.8)	
Moderate	46 (47.4)	24 (50.0)	22 (44.9)	0.846
High	16 (16.5)	8 (16.7)	8 (16.3)	

[1] *p*-value calculated using the χ^2 test on nominal variables, independent *t*-test on ordinal variables with normal distribution and Mann–Whitney U-test on ordinal variables with non-normal distribution. SD—Standard deviation; P25—25th percentile; P75—75th percentile.

3.2. 24-h Urinary Excretion and 24-h Dietary Recall

There were no significant differences between sodium calculated by 24 h urinary excretion at baseline (Me = 3025 mg) and sodium estimated by 24 h dietary recall (Me = 2670 mg), $p = 0.204$. At baseline, 45 participants were found to report sodium intake lower than that assessed by 24-h urinary excretion. The correlation between sodium estimated by 24 h urinary excretion and sodium estimated by 24 h dietary recall at baseline was statistically significant (r = 0.330, $p = 0.003$), Table 2.

In the assessments carried out during the intervention, no significant differences were found between the sodium calculated through the 24 h urinary excretion (Me = 3007 mg) and the sodium estimated by 24 h dietary recall (Me = 3318 mg), $p = 0.514$. In the assessments carried out during the intervention, it was found that 38 participants reported sodium intake lower than that assessed by 24-h urinary excretion. The correlation between the sodium estimated by 24-h urinary excretion and the sodium estimated by 24 h dietary recall in the assessments carried out during the intervention was not statistically significant (r = 0.190, $p = 0.092$), Table 2.

Table 2. Descriptive data for sodium from 24-h urinary excretion and 24-h dietary recall.

Descriptive Data	Baseline		Intervention	
	Urinary Excretion (mg/day) $n = 80$	24 h Food Recall (mg/day) $n = 80$	Urinary Excretion (mg/day) $n = 80$	24 h Food Recall (mg/day) $n = 80$
Mean ± SD	3186 ± 1231	3124 ± 1688	3131 ± 1221	3318 ± 1724
Median	3025	2670	3007	3185
Minimum	1219	569	667	600
Maximum	5957	8938	6946	10,753
p-Value [1]	0.204		0.514	

[1] p-value calculated using the Wilcoxon test. SD—Standard deviation.

3.3. Sources of Salt Intake

In the analysis of the main sources of salt intake, 17 participants were excluded for not consuming cooked meals at lunch and dinner.

At baseline, the main sources of salt in the control group were added salt (24%, $\bar{x}$ 3.3 g/salt), cereals, cereal products and starchy tubers group (22%, $\bar{x}$ 1.5 g/salt) and salty snacks and pizzas group (18%, $\bar{x}$ 0.9 g/salt), Figure 1, while in the intervention group, the main sources of salt were the meat, fish and eggs group (24%, $\bar{x}$ 2.1 g/salt), the cereals, cereal products and starchy tubers group (23%, $\bar{x}$ 1.6 g/salt) and added salt (21%, $\bar{x}$ 2.7 g/salt), Figure 1. There were significant differences between the control and intervention groups at baseline in the meat, fish and eggs group ($p = 0.009$).

At intervention period, the main sources of salt in the control group were added salt (26%, $\bar{x}$ 2.8 g/salt), the cereals, cereal products and starchy tubers group (24%, $\bar{x}$ 1.7 g/salt) and the salty snacks and pizzas group (13%, $\bar{x}$ 0.6 g/salt), Figure 1. In the intervention group, the main sources of salt were the meat, fish and eggs group (28%, $\bar{x}$ 2.1 g/salt), the cereals, cereal products and starchy tubers group (22%, $\bar{x}$ 1.4 g/salt) and added salt (16%, $\bar{x}$ 1.9 g/salt), Figure 1. There were significant differences between the control and intervention groups at intervention period in the salty snacks and pizzas group ($p = 0.016$). There were no significant differences before and after the intervention in any of the groups.

3.4. Salt-Related Knowledge, Attitudes and Behavior

After the intervention, participants in the intervention group reported a decrease in the addition of salt when cooking ($p = 0.037$). There was an increase in subjects in the intervention group who avoided the consumption of processed foods (from 54.2% to 83.3%, $p = 0.001$), who looked for salt on food labels (from 18.8% to 39.6%, $p = 0.013$), and who bought low-salt food alternatives (from 43.8% to 60.4%, $p = 0.039$). In the control group, the percentage of participants looking for salt on food labels increased (from 24.5% to 42.9%, $p = 0.035$), who purchased low-salt food alternatives (from 44.9% to 63.3%, $p = 0.031$), and who avoided eating out (from 49.0% to 65.3%, $p = 0.039$), Table 3. There were no significant differences between the intervention group and the control group at baseline and post-intervention assessments.

There were no significant differences between KAB in relation to salt and salt sources.

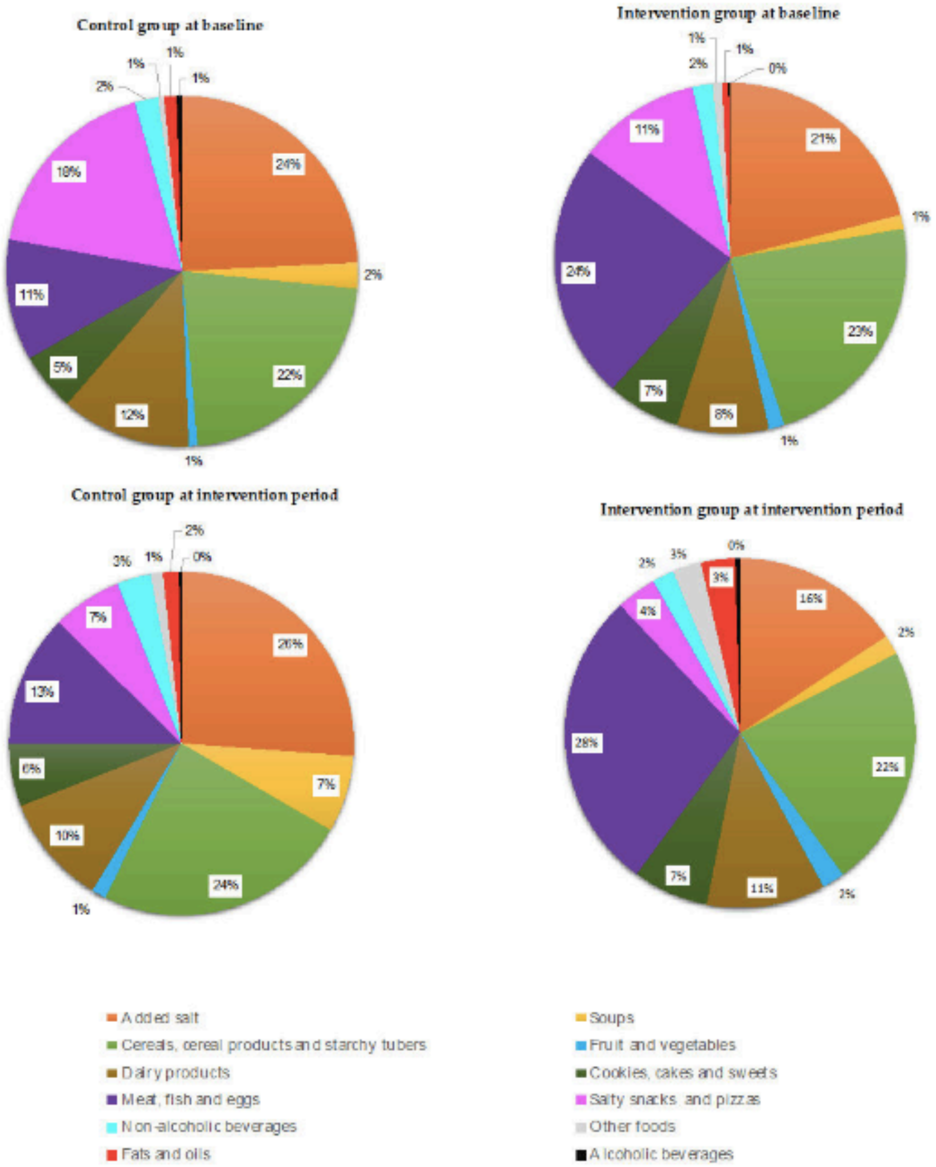

Figure 1. Food groups sources of salt in in the control and intervention group at baseline and in the intervention period.

Table 3. KAB towards dietary salt in the intervention group and in the control group before and after an intervention to reduce salt intake.

Knowledge, Attitudes and Behaviors Regarding Salt Intake	Intervention Group			Control Group		
	Baseline	After Intervention	p-Value [1]	Baseline	After Intervention	p-Value [1]
Behavior related to added salt						
Add salt to food (often or always) (%)	2.1	0.0	0.589	2.0	0.0	0.558
Add salt while cooking (often or always) (%)	93.7	81.2	0.037	91.8	85.7	0.078
Consume processed foods high in salt (often or always) (%)	37.5	31.3	0.221	38.7	24.5	0.119
Knowledge and attitudes						
Perceived salt consumption (too much or far too much) (%)	14.6	27.1	0.142	16.3	12.2	0.432
Importance of lowering salt in the diet (Not at all important) (%)	10.4	4.2	0.617	6.1	4.1	0.405
Agreed that too much salt could cause health problems (no) (%)	2.1	10.4	0.250	2.0	6.1	0.625
Behaviors to reduce salt						
Avoid consuming processed foods (yes) (%)	54.2	83.3	0.001	67.3	77.6	0.070
Look at the salt labels on food (yes) (%)	18.8	39.6	0.013	24.5	42.9	0.035
Eat meals without adding salt at the table (yes) (%)	87.5	91.7	0.687	95.9	89.8	0.687
Buy low-salt alternatives (yes) (%)	43.8	60.4	0.039	44.9	63.3	0.031
Cook meals without adding salt (yes) (%)	29.2	29.2	1.000	20.4	26.5	0.508
Use spices other than salt when cooking (yes) (%)	62.5	75.0	0.180	65.3	63.3	1.000
Avoid eating out (yes) (%)	35.4	54.2	0.064	49.0	65.3	0.039

[1] p-value calculated using McNemar test on nominal variables and the Wilcoxon test on ordinal variables. All answer options in Supplementary Materials, in Tables S1 and S2.

4. Discussion

As far as we know, this is the first study that assesses KAB towards salt during an intervention to reduce added salt during the cooking process.

The behavior related to salt after an intervention with a piece of equipment that measures the amount of salt for cooking improved in the intervention group, where there was an increase in the percentage of people who avoid eating processed foods, look for salt on food labels and buy food alternatives with less salt content. It was also found that participants in the intervention group reported adding less salt when cooking. There was no difference in knowledge about the health effects of salt and the importance of lowering salt intake, perhaps because participants already had a high level of knowledge.

The intervention did not include informative sessions that could increase the participants' KAB about salt and the researchers never reported to the participants their level of salt consumption throughout the study, but only at the end, with the aim of not biasing the results. Therefore, every change in KAB related to salt resulting from this intervention must be carefully analyzed.

Participants in the intervention group who reported they added less salt when cooking is in agreement with the aim of the present intervention study, which was to measure the amount of salt for cooking. This result is also in agreement with the analysis of the main sources of salt, where the salt added for cooking decreased in the intervention group.

In the control group, there was also an improvement in the behavior of controlling salt, there was an increase in the percentage of participants who look for salt on food labels, buy food alternatives with lower salt content and avoid eating out. The KAB questionnaire applied at baseline may have influenced the participants' salt behavior, and that they knew they were involved in a salt study may have contributed to positive behavior change.

In other studies, after an intervention to reduce salt consumption, improvements were also observed. A multifaceted community-based salt reduction program using a Behavioral Impact Communication framework, lasting one year, in addition to an increase in the percentage of participants who limited their consumption of processed foods and looked at salt on food labels, also improved other behaviors such as limiting eating out, and using herbs and spices instead of salt [29]. In another 22-month consumer awareness campaign study they also significantly increased the percentage of participants who started looking at food labels, used herbs instead of salt and avoided eating out, but increased salt added during cooking [30]. In a year-long mass media campaign that focused on reducing discretionary salt consumption, there was an increase in the percentage of participants who reported that they reduced the addition of salt when cooking. Also, more participants reported that they stopped using salt, used more herbs, reduced their use of table salt, and more participants reported that reducing salt consumption is important [31].

These interventions were more intensive and focused on transmitting information and knowledge with different strategies and of longer duration (12 to 22 months) than the intervention in the present study. Yet the latter had positive results in changing the behavior of the participants in relation to salt, in addition to having increased the number of participants with the perception that they consumed too much or far too much salt. Previous studies [32,33] indicate that there is a tendency to have a positive perception about the quality of one's diet, but with this intervention the participants increased their awareness of their salt consumption, which allows them to make more conscious choices. It is important to highlight that, although without statistical significance, the reported consumption of salt added to table food and industrialized foods rich in salt decreased after the intervention. There was also an increase in participants at the end of the intervention who stopped eating processed foods, ate foods without added table salt, used spices in addition to salt, avoided eating out, and recognized the importance of reducing salt in the diet.

A limitation of KAB questionnaires in relation to salt is the potential difference between reality and what is self-reported [34]. For example, some studies showed that when comparing self-reported behavior and what was observed, they concluded that people overestimated the use of nutrition labels [34,35]. Thus, in addition to the questionnaire, it is important to use biomarkers, such as urinary excretion. Biomarkers can be used to assess the difference between self-reported food intake and what is real, due to the bias in self-reported measures [36].

Added salt at baseline ranged from 21% to 24% in the intervention and control groups, respectively, a value below that mentioned in other articles in Portugal [16]. This reason may be related to the study sample having a high level of education. In a study of the change in salt intake of young adults over a mean follow-up time of 4.56 years, the reduction in salt intake was more pronounced in black adults of low and middle socioeconomic status, compared with a high socioeconomic status [37]. Added salt decreased in the intervention group after the intervention, but this was not significant. However, it is important to take into account that the average salt added at baseline was 2.7 g/day, the equipment provided 0.8 g per adult per meal, so in total the equipment dispensed 1.6 g/day for each adult. During the intervention period, the average intake of added salt decreased to 1.9 g/day, a value very close to the objective provided by the equipment, while the added salt in the control group increased. The snacks and pizzas group also showed a drop (7%), which coincides with the decrease in processed foods that participants reported. The meat, fish and eggs group increased by 4%, perhaps because more participants ate out less often. None of these changes were significant. In addition to added salt, the cereals and tubers group and the meat, fish and eggs group were the biggest contributors to salt intake, which is corroborated by other studies [15]. We found no relationship between salt sources and salt knowledge and behavior. Land et al. [38] also found no association between salt knowledge and behavior and measured salt intake.

A strength of the study was that sodium intake was assessed through 24-h urinary excretion, and two urine samples were taken and measured during the intervention period. Assessing sodium through urinary excretion is the gold standard method, because approximately 90–95% of ingested sodium is excreted in the urine [39]. Another strong point is that the recommendations and best practices of clinical trials were followed.

Our study has some limitations. First, data collection was carried out during the period of the COVID-19 pandemic, so we were unable to reach the sample size previously calculated and, due to confinements, the intervention time was longer in some participants. Second, most participants were highly educated, and the results are not extrapolated to the general population. Third, the questionnaire applied at baseline and knowing that they were involved in a study had influenced the participants' behavior towards salt.

5. Conclusions

An eight-week intervention with a piece of dosage equipment to measure the amount of salt added when cooking improved salt behavior, but not knowledge and attitudes. After the intervention, in the intervention group more people reported not consuming processed foods, looking for salt on food labels, buying food alternatives with less salt and adding less salt when cooking.

The main sources of salt were added salt, cereals, cereal-based products and starchy tubers, the meat, fish and eggs group and the snack foods and pizzas group. After the intervention, it was found that the added salt decreased, but without statistical significance.

Evaluation of the level of knowledge, attitudes and behaviors at baseline and after an intervention is important to customize interventions and to understand what dimensions need to be improved.

Supplementary Materials: The following supporting information can be downloaded at: https://www.mdpi.com/article/10.3390/foods11070981/s1, Tables S1 and S2: Knowledge, attitudes and behavior dietary salt in the intervention group and in the control group before and after an intervention to reduce salt intake.

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Institutional Review Board Statement: The study was conducted according to the guidelines of the Declaration of Helsinki and approved by the Ethics Committee of Centro Hospitalar de São João (Approval Code: 11/2019, Approval Date: 15 February 2019).

Informed Consent Statement: Informed consent was obtained from all subjects involved in the study.

Data Availability Statement: The data presented in this study are available on request from the corresponding author.

Conflicts of Interest: The study used a prototype system that was presented with a patent number (INPI, No. 20191000033265). C.G., P.M. and O.P. are inventors of the prototype system. The inventors have intellectual property rights.

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Chapter IV - General Discussion and Conclusions

Discussion

The results of this thesis can contribute to being one more step closer to achieving salt intake values in accordance with the WHO recommendations, especially in populations where added salt is the main contribution to the consumption of salt.

Reducing the population's salt consumption is a priority intervention for the prevention of non-communicable diseases and despite efforts around the world, progress remains slow and success is difficult. In this context, we tested an intervention with Salt Control H that measures the amount of salt for cooking. The intervention was successful in reducing salt intake and improving the Na:K ratio in the hypertensive men in the intervention group, and it lowered diastolic blood pressure and improved some salt behaviors in the intervention group. Intervention with Salt Control H had this positive impact even during a pandemic that had a profound impact on diet [62-66], with salt intake being reported to increase during and after lockdown [67], in addition to the difficulty of success in reducing salt consumption.

This intervention is especially important because it reduces salt consumption and provides the consumer with knowledge of the proper amount of salt to add when cooking, gains awareness about their consumption of added salt and changes their behavior towards salt. Furthermore, it appears to be of particular importance in clinical populations such as hypertensives. Indeed, we found that post-intervention salt behavior improved. More participants started looking at salt on food labels, bought food alternatives with less salt and avoided the consumption of processed foods. Interestingly, although participants after the intervention reduced their salt intake, more participants perceived that they consumed too much or far too much salt, which suggests that the participants became aware of the salt they added when cooking after using the equipment. Post-intervention participants also reported that they started to add less salt when cooking, which is in line with the analysis of salt sources which found that the intervention group, after the intervention, decreased added salt by 5%. The addition of salt at baseline in the intervention group, averaging 1.35 g of salt per meal, was low relative to previous existing data in Portugal [5,50]. After the intervention it decreased to 0.95 g per meal (the equipment dosed 0.8 g per meal for adults). Still, participants lowered their salt addition with the equipment and lowered their total salt intake. After the intervention, there was also a decrease in the contribution of the salty snacks and pizzas group, which corroborates what they reported in the questionnaire, that more subjects avoided consuming processed foods.

These data on behavior towards salt are very interesting especially because the intervention did not have information sessions, just some indications for cooking with less salt. This gives greater importance to the intervention with the equipment to reduce salt consumption because its use is capable of making subjects aware of the reduction of salt consumption. Consumer knowledge and awareness of their behavior towards salt is important for achieving sustainable change [68].

In the review study we identified 21 interventions that successfully reduced salt. The study provides evidence that interventions based on individual education alone, or together with other interventions or tools to estimate salt intake, have positive results in reducing salt intake. We analyzed the reason why other studies did not achieve success according to the defined criteria ($p<0.05$) or failed to reduce salt and we found that one of the reasons is related to the intervention not being adequate for the population that was intervened. For example, one intervention taught a group of diabetics to read and identify labels and was not successful in reducing salt consumption. However, with the same intervention in a group of free-living adults, there was a salt reduction of 0.9 g/day and 2.0 g/day, therefore, the same intervention is not suitable for all consumers. It is interesting to realize that it is very important to adapt interventions to the population we are going to intervene, which is in line with 4p medicine – predictive, preventive, personalized and participatory [69]. Consumers are different in each country and the way salt is consumed is also different.

This review study showed us the importance of personalizing and adapting interventions to the populations, where to intervene and also some methodological designs that contribute to success. It was relevant later in the analysis of the results of the intervention study with the Salt Control H.

The WHO developed the SHAKE package to assist Member States in the development and implementation of a salt reduction strategy to help reduce population salt consumption. One of the strategies identified by the WHO is the surveillance, measurement and monitoring of salt use, which includes knowing salt consumption, knowledge, attitudes and behaviors related to salt and sources of salt in the diet [68]. In this thesis, a contribution is made to this information from a sample characterized by a high level of education. In addition to providing information on knowledge, attitudes and behavior in relation to salt, we also check what happened after an intervention, which is very important for the future to optimize this type of intervention based on our results, that is, to understand what we can change with this intervention and what in the future we can improve in a next intervention.

Another strategy defined in the WHO SHAKE package is knowledge, education and communication to empower individuals to eat less salt. The intervention carried out in this thesis fits this strategy perfectly, since the Salt Control H can be used as an educational tool to empower consumers to use adequate doses of salt to cook, increasing their awareness of salt consumption. Indeed, this device educates individuals on the right amount of salt to cook for a given number of individuals and specific ages (adult or children). Consumers often hear that they should reduce their salt intake, but they don't know how much to reduce, and this equipment answers exactly that question. Consumer knowledge and awareness is essential to achieving sustainable changes in consumer behavior.

This thesis also contributes to achieving the ODS 3 – good health and wellbeing of the United Nations Agenda. By 2030, it aims to reduce premature mortality from non-communicable diseases by one third through prevention and treatment [70]. This intervention with salt control H showed that with only the behavioral change in reducing the added salt it is possible to have an impact on blood pressure. Evidence shows that lowering blood pressure decreases the risk of cardiovascular disease and therefore mortality from non-communicable diseases.

The Salt control H instrument has national and international application, and its potential use may modify food behaviors, making cooking healthier at home and thus helping food policies to reduce salt consumption, improving the capacity of citizens and governments to reduce a major risk factor for chronic no communicable diseases. In the future, it would be interesting to test the equipment in other populations, such as in hypertensive patients or individuals with a lower level of education, to understand its potential in altering salt consumption in other populations.

Conclusions

Interventions to successfully reduce salt intake should remain a priority until recommended levels of salt intake are reached and mortality rates by cardiovascular diseases decreases. This thesis contributes with a review article with successful interventions, including the target audiences in which these interventions were successful. It also contributes with an intervention with the innovative equipment Salt Control H to dose the amount of salt for cooking and its impact on the reduction of salt, blood pressure and knowledge and behavior in relation to salt.

To conclude, it should be noted:

I. Interventions based on consumer education alone or when combined with other strategies and tools for estimating salt intake are successful in reducing salt intake.

II. It is critical to customize each intervention to individuals or subpopulations as it will lead to better outcomes.

III. A device that delivers salt doses according to the number of subjects and their age, accompanied by written general cooking instructions, decreased sodium and improved urinary Na:K excretion in hypertensive men in the intervention group.

IV. The intervention improved behaviors in relation to salt, namely, more subjects reported not consuming processed foods, looking for salt on food labels, buying food alternatives with less salt and adding less salt when cooking. Assessing the level of knowledge and behaviors during an intervention is important to personalize interventions and understand which dimensions need improvement.

V. The main sources of salt were added salt, cereals group, cereal products and starchy tubers, the meat, fish and eggs group and the snack and pizza group. After the intervention, there was a decrease in added salt and in the salty snacks and pizzas group in the intervention group, although without statistical significance.

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