Nutrición Hospitalaria

Efecto de la sal baja en sodio y rica en potasio basada en la dieta china DASH modificada sobre la monitorización domiciliaria de la presión arterial en pacientes con hipertensión y diabetes tipo 2: un ensayo clínico

Effect of low-sodium, potassium-rich salt based on the Chinese modified DASH diet on home blood pressure monitoring in patients with hypertension and type 2 diabetes: a clinical trial

10.20960/nh.05681

06/04/2025

OR 5681

Effect of low-sodium, potassium-rich salt based on the Chinese modified DASH diet on home blood pressure monitoring in patients with hypertension and type 2 diabetes: a clinical trial

Efecto de la sal baja en sodio y rica en potasio basada en la dieta china DASH modificada sobre la monitorización domiciliaria de la presión arterial en pacientes con hipertensión y diabetes tipo 2: un ensayo clínico

Li Zhao[1], Jiaxian An[1], Wenjun Luo[1], Ying Mei[2], Xiaoqing Bu[1], Shili Xian[1], Pingping Yu[2], Huang Yao[1], Lihong Mu[1]

[1]Department of Epidemiology. School of Public Health. Research Center for Medicine and Social Development and [2]Health Management Center of the Second Affiliated Hospital. Chongqing Medical University. Chongqing, People's Republic of China

Received: 19/12/2024
Accepted: 06/04/2025
Correspondence: Lihong Mu. Department of Epidemiology. School of Public Health. Research Center for Medicine and Social Development. Chongqing Medical University. 131 Yubei Road, Shapingba District. 400030 Chongqing, People's Republic of China
e-mail: 100101@cqmu.edu.cn

Authors´ contribution: Jiaxian An and Wenjun Luo contributed equally to this work. Lihong Mu participated in the conceptualization and *design of this study. All authors participated in the survey and data management and have approved the final manuscript.*

Acknowledgments: We thank all study participants and their families,project staff, and the Science and Technology Bureau of Chongqing Municipality (STBC), China for funding [Project No. cstc2019jscx-msxm X0267].

Funding: this study was funded by the Science and Technology Bureau of Chongqing Municipality (STBC), China [Project No. cstc2019jscx-msxm X0267]. The Chongqing Science and Technology Bureau (STBC) was not involved in the design, implementation, data collection, analysis, and manuscript writing process of this study.

Ethics approval and consent to participate: The study protocol was approved by the Ethics Committee of Chongqing Medical University (approval date: 07/28/2020). Trial registration: Chinese clinical trial registry (ChiCTR2000029017), http://www.chictr.org.cn/. All participants and their families provided written informed consent prior to enrollment in the trial.

Data availability statement: All data obtained or analyzed in this study are not included in this article. Data on the results of this study are available from the corresponding author upon reasonable request.

Conflicts of interest: The authors declare no conflicts of interest.

Artificial intelligence: The authors declare not to have used artificial intelligence (AI) or any AI-assisted technologies in the elaboration of *the article.*

ABSTRACT

Objective: to investigate the impact and safety of Chinese Modified Dietary Approaches to Stop Hypertension (CM-DASH) combined with sodium-restricted formula salts on home blood pressure monitoring (HBPM) in patients with hypertension and type 2 diabetes.

Design: employing a semi-open randomized, controlled, single-blind trial, patients were allocated into four groups—Group A (control), Group B (52 % salt), Group C (23 % salt), and Group D (meal packs)—for an eight-week dietary intervention. Throughout the intervention, patients self-measured their blood pressure daily and were followed up weekly. Additionally, 24-hour urine was performed at baseline, week 4, and the end of the intervention.

Results: of the 132 initial participants, only two were lost to follow-up. Following an 8-week intervention, blood pressure exhibited a downward trend across all four subject groups ($p < 0.05$). Both HSBP and HDBP exhibited a more pronounced decrease in group B compared to group A. HSBP decreased the most in group D (-13.06, 95 % CI: -18.84 to 7.64, $p < 0.001$). The 24-hour urinary Na/K ratios significantly dropped in low-sodium salt participants ($p < 0.001$). Nevertheless, the differences between the groups were not statistically significant. No serious adverse events were reported throughout the trial.

Conclusions: this study's preliminary findings indicate that the CM-DASH dietary pattern combined with 23 % and 52 % sodium-limited formula salts has a beneficial effect on home blood pressure in hypertensive and type 2 diabetes patients. Additionally, it improves patients' urinary sodium and potassium levels and demonstrates safety. However, more studies are needed for validation.

Keywords: Hypertension. Type 2 diabetes. DASH. 23 % sodium-restricted formula salts. 52 % sodium-restricted formula salts. Home blood pressure.

RESUMEN

Objetivo: investigar el impacto y la seguridad de los Enfoques Dietéticos Modificados Chinos para Detener la Hipertensión (CM-DASH) combinados con sales de fórmula con restricción de sodio en la monitorización domiciliaria de la presión arterial (MAPA) en pacientes con hipertensión y diabetes de tipo 2.

Diseño: empleando un ensayo semiabierto aleatorizado, controlado y a ciegas simple, los pacientes fueron asignados a cuatro grupos -Grupo A (control), Grupo B (52 % de sal), Grupo C (23 % de sal) y Grupo D (paquetes de comida)- para una intervención dietética de ocho semanas. A lo largo de la intervención, los pacientes se midieron diariamente la tensión arterial y se les hizo un seguimiento semanal. Además, se realizaron análisis de orina de 24 horas al inicio, en la semana 4 y al final de la intervención.

Resultados: de los 132 participantes iniciales, solo dos se perdieron durante el seguimiento. Tras una intervención de 8 semanas, la presión arterial mostró una tendencia descendente en los cuatro grupos de sujetos (*p* < 0,05). Tanto la HSBP como la HDBP mostraron una disminución más pronunciada en el grupo B en comparación con el grupo A. La HSBP disminuyó más en el grupo D (-13,06; IC 95 %: -18,84 to 7,64; *p* < 0,001). Los cocientes Na/K urinarios de 24 horas disminuyeron significativamente en los participantes con bajo contenido en sal sódica ($p < 0{,}001$). No obstante, las diferencias entre los grupos no fueron estadísticamente significativas. No se notificaron acontecimientos adversos graves a lo largo del ensayo.

Conclusiones: los hallazgos preliminares de este estudio indican que el patrón dietético CM-DASH combinado con sales de fórmula limitadas en sodio al 23 % y al 52 % tiene un efecto beneficioso sobre la presión arterial domiciliaria en pacientes hipertensos y con diabetes tipo 2. Además, mejora los niveles urinarios de sodio y potasio de los pacientes y demuestra seguridad. Sin embargo, se necesitan más estudios para su validación.

Palabras clave: Hipertensión. Diabetes de tipo 2. DASH. Sales de fórmula con un 23 % de restricción de sodio. Sales de fórmula con un 52 % de restricción de sodio. Tensión arterial domiciliaria.

INTRODUCTION

Hypertension and diabetes are prevalent chronic non-communicable diseases and often coexist owing to shared etiologic factors and risk factors (1). The frequency of their co-occurrence escalates with age (2). A cross-sectional survey conducted in China revealed that up to 72 % of Chinese patients with type 2 diabetes also have hypertension (3). The coexistence of hypertension with type 2 diabetes not only increases the risk of cardiovascular disease and chronic kidney disease (2) but also quadruples the risk of mortality (4). Furthermore, hypertensive patients with type 2 diabetes are frequently classified as having refractory hypertension (5). Remarkably, both diseases are strongly associated with lifestyle. Diets high in sodium (mainly sodium chloride) and low in potassium are essential contributors to elevated blood pressure (6), making the reduction of sodium intake particularly important for blood pressure control (7).

The Dietary Approaches to Stop Hypertension (DASH) is widely recognized for its effectiveness in reducing blood pressure and emphasizes the consumption of foods rich in magnesium, potassium, calcium, and dietary fiber, and stipulates that daily NaCl intake should be controlled below 2.4 g (8). However, the average daily salt intake for most adults globally exceeds 6 g, and it often surpasses 12 g in regions like East Asia and Europe. The low-sodium salts currently available on the market typically contain approximately 70 % NaCl, presenting challenges in reducing salt intake without altering dietary habits (9,10). In addition, the direct replication of DASH recipes is impractical due to the differing dietary structures and habits between Eastern and Western populations. To better align with the dietary preferences of the Chinese population, we modified the original DASH diet, thereby developing the Chinese modified dietary approaches to stop hypertension (CM-DASH) diet. We combined this modified diet with sodium-restricted salt formulations containing 23 % and 52 % sodium chloride, respectively, and applied them to clinical trials.

Home blood pressure monitoring (HBPM) plays a significant role in the diagnosis, treatment adjustment, and long-term follow-up of hypertension (11). It is also can identify white-coat and occult hypertensive patients (12). It can also identify patients with white-coat and occult hypertension. HBPM is more closely associated with target organ damage and cardiovascular prognosis than office blood pressure (OBP). It predicts the risk of cardiovascular disease with greater accuracy and serves as a reliable indicator of cardiovascular disease risk factors (13,14). Additionally, there is a substantial predictive value for morbidity and mortality in patients with diabetes (15), which enhances hypertension control and boosts patient adherence to treatment (16).

This study employed the CM-DASH dietary pattern in combination with sodium-restricted formula salts containing 23 % and 52 % sodium chloride. The objective was to investigate the efficacy and safety of this dietary intervention in reducing Home blood pressure with hypertension combined with type 2 diabetes.

MATERIALS AND METHODS

Sample size

Based on pre-trial data, it was estimated that 30–40 cases were needed in each group (17,18), totaling approximately 120-150 cases.

Participants

The trial was conducted in Chongqing, China, from July to December 2021. Eligible participants were selected from the Resident Chronic Disease Management Systems of two community health centers. Inclusion exclusion criteria were consistent with the previously published article (19).

The study protocol was approved by the Ethics Committee of of Chongqing Medical University (approval date: 07/28/2020). All participants and their families provided written informed consent before enrollment in the trial.

Study design

This study used a randomized, controlled, single-blind trial with a semi-open design.

There were 132 participants, and two cases were lost to follow-up.

The participants were allocated into four groups: Group A (CM-DASH diet + common salt, *n* = 34); Group B (CM-DASH diet + 52% sodium-restricted formula salt, *n* = 30); Group C (CM-DASH diet + 23 % sodium-restricted formula salt, *n* = 33); and Group D (CM-DASH Nutrition Dietary Pack + 23 % sodium-restricted formula salt, *n* = 33). Salt consumption was maintained at 5 g/day per capita in all groups, aligning with WHO-recommended salt standards.

After completion of the baseline questionnaire and physical examination, the eight-week dietary intervention was initiated. There was a DASH diet adaptation phase (salt + CM-DASH diet recipes) in weeks 1 and 2, a centralized feeding phase (meals served in the hospital cafeteria) in weeks 3 and 4, and a home health care phase (salt + CM-DASH diet recipes) in weeks 5 through 8. Throughout the intervention, participants monitored and recorded blood pressure daily at home; weekly follow-up visits were conducted to collect home blood pressure and adverse events, and trial salt was distributed. Participants' adherence to salt intake and dietary guidelines was also reinforced. Questionnaires and physical examinations were repeated at week 4 and the end of the intervention. Previously published article has exhaustively addressed the specifics of different sodium-restricted formula salts with CM-DASH recipes (19).

Meal packs

Dietary packs (CM-DASH Nutritional Dietary Pack, produced by Chongqing Shanshun Biotechnology Co., Ltd. and implementing product standard GB/T29603, Food Production License No.: SC12450023228393) dietary treatment of type 2 diabetes and hypertension. According to the dietary structure and eating habits of Chinese people, combined with hypertension, diabetes dietary therapy principles, Chinese medicine treatment methods, and modern hypertension, diabetes nutritional medicine is formulated. Mixed grains and homogenised diets are used as the core of nutritional intervention. It includes CM-DASH Homogenized Meal Solid Drink, CM-DASH Solid Drink (Normal Companion), and CM-DASH Eight Treasures Rice. Details of the ingredients are shown in table I.

Breakfast in the meal pack group consisted of a CM-DASH homogenised dietary solid drink, drink mate and an egg. The CM-DASH Eight Treasures Rice replaced the main meal of the CM-DASH diet at lunch and dinner. The meal pack group was richer in dietary fibre compared to the other three groups. Specifically, 7.486 g of dietary fibre was found in each 100 g of CM-DASH Eight Treasures Rice. In comparison, the traditional staple food combination consisting of 45 g of rice, 10 g of corn grits and 10 g of red beans contained only 1.5 g of dietary fibre.

Home blood pressure measurement

Following health education on HBPM, patients self-monitored their blood pressure at home using a standardized sphygmomanometer. The measurement protocol was as follows: 1) Measurements were taken twice daily: in the morning after urination and before taking antihypertensive medication, between 6:00-10:00, and between 6:00-10:00 *p*.m.; 2) Participants were advised to avoid smoking, coffee, and exercise for half an hour before measurement and to sit still for 5 minutes after the measurement; 3) When measuring blood pressure, participants were asked to restrict talking, not move the limbs, keep quiet, and repeat the measurement 3 times at intervals of 1-2 min in a state of rest to record the results of each blood pressure measurement, and to take the average value of the last 2 times as the blood pressure measurement value; and 4) The weekly blood pressure average excluded the first day's measurement, with the average of the remaining six days calculated as the average blood pressure for the week.

Quality control

The following measures were undertaken to ensure quality control: 1) scientifically rigorous research program design; 2) professional training for investigators to standardize methods and standards; 3) before the start of the trial, the patients' sphygmomanometers were checked to comply with national standards, the cuffs were checked to be of the right size, and the patients were trained in 1-to-1 blood pressure measurement; 4) during follow-up visits, standardization of blood pressure measurement by patients was checked; weekly health education on salt consumption and standardized blood pressure measurement was performed; 5) patients were required to record the consumption of food during the trial other than that provided by the investigator; 6) the investigator repeatedly reminded and requested the patients to eat out < 3 times/week (or < 1 day/week) during the follow-up visit and to record the instances of eating out; 7) the ingredients and use of salt in the cafeteria were recorded in detail; a record sheet for the distribution of salt and recipes and a record sheet for the use of daily ingredients and condiments was filled out; and 8) uniform and standardized containers for condiments were provided to reduce weighing errors.

Statistical analysis

The Shapiro-Wilk test was used to test the normality of the data, and

Levene's test was used to test the data's homogeneity of variance. Normally distributed continuous variables are expressed as the mean ± standard deviation; skewed continuous variables are expressed as the median and interquartile range. Categorical variables are expressed as counts and percentages using the Chi-square test or Fisher's precision probability test.

Intra-and inter-group comparisons were performed using the paired t-test and one-way analysis of variance. Changes in trends in home blood pressure were analyzed using a generalized estimating equation and adjusted for the variables. All statistical analyses were performed using SPSS 27.0 (IBM, Armonk, NY, USA) statistical software, and the tests were two-sided, with differences considered statistically significant at $p < 0.05$.

RESULTS

Demographic characteristics

In this study, 132 patients with hypertension combined with type 2 diabetes were enrolled; two cases with a lapse rate of 1.5 % were withdrawn from the trial owing to work schedules away from home and personal medical reasons (back pain and inability to walk), respectively. There were no statistically significant differences in general demographic characteristics except for age (Table II).

Home blood pressure changes

Compared to baseline values, participants in all four groups exhibited a trend towards reduced HSBP and HDBP at the end of the intervention. Specifically, HSBP decreased by 8.46 mmHg ($p = 0.004$) in Group A, 11.09 mmHg ($p = 0.004$) in Group B, and by 5.36 mmHg ($p = 0.043$) and 13.06 mmHg ($p = 0.001$) in Groups C and D, respectively; notably, Group D demonstrated the most significant reduction in HSBP. However, no statistically significant differences were observed in the rate of decrease among the groups (Table III; Fig. 1).

Regarding HDBP, Group A experienced a decrease of 4.88 mmHg (p = 0.009), Group B showed a reduction of 5.13 mmHg (p = 0.038), while Groups C and D recorded decreases of 3.42 mmHg (p = 0.016) and 3.56 mmHg (p = 0.013), respectively; with Group B exhibiting the greatest decline in HDBP as well. Consistent with findings for HSBP, there were no statistically significant differences noted in the decline for HDBP between the groups (Table IV; Fig. 2).

Changes in urinary sodium and potassium intake over 24 h

At the end of the intervention, there was a trend of increasing 24-hour urinary potassium and decreasing 24-hour urinary sodium in groups B, C, and D. The 24-hour urine sodium/potassium ratio decreased from baseline in all groups except Group A ($p < 0.05$). There was no difference between the groups (Table V). No serious adverse events occurred during the trial.

DISCUSSION

Studies have shown that patients following the DASH diet experienced an average decrease in systolic and diastolic blood pressure of 5.5 mmHg and 3.0 mmHg, respectively, compared to the regular diet (21). In addition, combining reduced sodium intake with the DASH diet was more effective in lowering blood pressure than the DASH diet alone (22). The CM-DASH diet differed from the original in containing lower total energy (DASH: 2,100 kcal; CM-DASH: 1,600 kcal), less fat and cholesterol, and more protein and dietary fibre. HBPM has more excellent reliability and improves patient compliance compared to office blood pressure (23). Based on these insights, we conducted a study aimed at exploring the effects of combining low-sodium salt containing 23 % and 52 % NaCl with the CM-DASH diet on the effectiveness of home blood pressure control in patients with hypertension combined with type 2 diabetes.

The findings of this study indicated that, after the intervention, both HSBP and HDBP exhibited a decreasing trend across all four participant groups. Specifically, in group A, HSBP and HDBP decreased by 8.46 mmHg and 4.88 mmHg, respectively, whereas in group B, these values decreased by 11.09 mmHg and 5.13 mmHg. These results suggest that the use of 52 % low-sodium salt had a significant positive impact on reducing blood pressure compared to regular table salt. Group C exhibited a slightly less effective reduction in blood pressure after the intervention compared to the first two groups. This may be attributed to the lower sodium content of the low-sodium salt utilized in Group C, which has a poorer taste relative to 52 % low-sodium salt or regular table salt that contains higher sodium levels. This palatability may hinder patients' long-term adherence to this dietary modification. Group D, on the other hand, showed the most prominent reduction in SBP. This may be because the meal packs substitute some of the foods in the DASH dietary pattern, which can achieve stricter intake standards and intervention effects. Nonetheless, there was no statistically significant difference in the short-term blood pressure-lowering effect among the four groups of patients. This may be due to the limited sample size and the short follow-up period of patients in each group. Consequently, more extensive studies are warranted to draw more definitive conclusions.

In our study, OBP was also used as a monitoring method. The results likewise showed a decrease in the corresponding SBP and DBP in all four groups of patients compared to baseline blood pressure, and the reduction was more significant than that of Home blood pressure (19). The possible reasons for this are as follows: (1) OBP is measured using a uniform sphygmomanometer, whereas HBPM uses sphygmomanometers purchased by the patients themselves, which come in different models; (2) although the patients were trained in blood pressure measurement, there may have been irregularities in actual practice; (3) considering that the study population consisted of mainly elderly patients, who may have needed assistance from family members to carry out their blood pressure measurements, whereas OBP was carried out by professional personnel performed, and therefore its results may be more accurate. Despite the existence of two different methods of blood pressure monitoring, their results both suggest that dietary interventions have a positive impact on lowering blood pressure.

Another significant finding of this study is that reducing sodium intake resulted in significantly higher reductions in systolic blood pressure than diastolic blood pressure in all groups. Studies have shown that, compared to DBP, SBP is more strongly associated with cardiovascular disease in the elderly. Aging is associated with structural and functional changes in the vascular wall, leading to increased arterial stiffness and increased SBP (24). A prospective study in the United Kingdom noted a monotonic relationship between SBP and the risk of cardiovascular disease in diabetic patients between the ages of 60 and 90 years, i.e., the higher the level of SBP, the higher the risk of cardiovascular disease (25). In patients with type 2 diabetes, a clinical SBP of ≥ 130 mmHg was associated with a higher risk of cardiovascular disease mortality (26). Moreover, studies have further demonstrated that in hypertensive patients aged 60 to 80 years, keeping SBP strictly below 130 mmHg may provide additional cardiovascular benefits (27). Reducing sodium intake leads to a more pronounced change in SBP than in DBP, which helps to reduce the risk of developing cardiovascular disease in patients with hypertension and type 2 diabetes. However, further research is needed to determine which formulated salt has the most significant effect.

Global sodium consumption considerably exceeds recommended levels (28), and lowering sodium intake diminishes the risk of elevated blood pressure and the subsequent development of related non-communicable diseases (29). Recent meta-analyses have shown that reducing sodium intake has a negligible effect on blood pressure in normotensive people (-1.14/+0.01 mmHg in systolic/diastolic blood pressure) but a significant reduction in hypertensive people (-5.71/-2.87 mmHg in systolic/diastolic blood pressure) (30). Patients with essential hypertension had substantial decreases in blood pressure (9/5 mmHg lower systolic/diastolic blood pressure) following a reduced sodium diet (31). In addition, a study in America showed that reducing dietary sodium intake lowered blood pressure in most middle-aged and older adults, independent of hypertension status and antihypertensive medication use (32). Meanwhile, potassium can increase vasoactivity and decrease blood pressure by reducing vascular smooth muscle contraction (33). The 24-hour urine collection is the gold standard for testing sodium and potassium intake. The results of this study showed improvement in 24-hour urinary sodium and potassium in four groups. At the end of the intervention, the 24-hour urinary sodium was lower than the baseline in four groups. In contrast, the 24-hour urinary potassium was higher than the baseline value in the 52 % salt group, the 23 % salt group, and the dietary package group, indicating that short-term dietary interventions can also achieve favourable health benefits. However, more studies are needed to validate these preliminary findings further. The trial had no serious adverse events during the intervention period.

Cardiovascular disease is one of the leading causes of death worldwide, and reducing sodium intake is one of the key measures for prevention (34). Low-sodium salt is effective in lowering blood pressure and cardiovascular events, economical, safe, easy to implement, and has significant cost-effectiveness (35,36). In European and American countries, where the prevalence of hypertension is high and salt intake is excessive, the promotion of low-sodium salt and modified DASH diets may reduce the incidence of blood pressure and cardiovascular disease and provide a basis for policy development (37). In addition, in resource-limited countries, simple dietary interventions, such as the promotion of low-sodium salt and healthy diets, can be effective in improving public health.

There are several limitations to this study. First, the small sample size of this study may have affected statistical efficacy, especially in between-group comparisons where it was difficult to detect potential differences adequately. In addition, the study was limited to a specific population in Chongqing, China, which limits the generalisability of the results. Future studies should expand the sample size and include a more diverse group of subjects to enhance the extrapolation of the results. Second, the short duration of the intervention allowed only short-term antihypertensive effects and improvements in sodium and potassium intake to be observed, making it difficult to determine long-term persistence and stability. Future studies may extend the duration of the intervention to assess long-term health benefits.

Thirdly, the home blood pressure data relied on self-recording by the subjects. Despite health education and regular follow-up, there may still be measurement errors or irregularities in recording. Fourth, as this study was a semi-open trial, the home diet phase did not allow for strict control of patients' salt and sodium-containing condiment intake. Finally, patients' blood pressure is affected by a variety of factors, such as climate and mood. Future studies should incorporate these variables to provide a more comprehensive and accurate assessment.

CONCLUSIONS

This trial preliminarily demonstrated that the dietary intervention involving the CM-DASH diet, combined with 23 % and 52 % sodium-restricted formula salts, had a potentially positive effect on reducing home blood pressure in patients with hypertension and type 2 diabetes. Furthermore, the intervention was effective in improving urinary sodium and potassium levels among patients, indicating a degree of safety. However, larger studies are necessary to validate these preliminary findings further. Future research should aim to increase sample sizes, extend follow-up periods, and explore the specific effects of various sodium-restricted formula salts on home blood pressure control to develop more effective dietary intervention strategies for individuals suffering from hypertension and type 2 diabetes.

REFERENCES

1. Fox CS. Cardiovascular Disease Risk Factors, Type 2 Diabetes Mellitus, and the Framingham Heart Study. Trends Cardiovasc Med 2010;20(3):90-5. DOI: 10.1016/j.tcm.2010.08.001

2. Jindal A, Whaley-Connell A, Sowers JR. Type 2 diabetes in older people; the importance of blood pressure control. Curr Cardiovasc Risk Rep 2013;7(3):233-7. DOI: 10.1007/s12170-013-0301-5
3. Weiping J. A national assessment study of cardiovascular disease risk factors-blood glucose, blood pressure, and lipids-in Chinese patients with type 2 diabetes mellitus. Chinese Journal of Internal Medicine 2013;52:1064.
4. Yashkin AP, Kravchenko J, Yashin AI, Sloan F. Mortality and Macrovascular Risk in Elderly With Hypertension and Diabetes: Effect of Intensive Drug Therapy. Am J Hypertens 2018;31(2):220-7. DOI: 10.1093/ajh/hpx151
5. Jia G, Sowers JR. Hypertension in Diabetes: An Update of Basic Mechanisms and Clinical Disease. Hypertens Dallas Tex 1979 2021;78(5):1197-205. DOI: 10.1161/HYPERTENSIONAHA.121.17981
6. Brand A, Visser ME, Schoonees A, Naude CE. Replacing salt with low-sodium salt substitutes (LSSS) for cardiovascular health in adults, children and pregnant women. Cochrane Database Syst Rev 2022;8(8):CD015207. DOI: 10.1002/14651858.CD015207
7. Harvey JN. Trends in the prevalence of diabetic nephropathy in type 1 and type 2 diabetes. Curr Opin Nephrol Hypertens 2003;12(3):317-22. DOI: 10.1097/00041552-200305000-00015
8. He FJ, Li J, Macgregor GA. Effect of longer term modest salt reduction on blood pressure: Cochrane systematic review and meta-analysis of randomised trials. BMJ 2013;346:f1325. DOI: 10.1136/bmj.f1325
9. Strazzullo P, D’Elia L, Kandala N-B, Cappuccio FP. Salt intake, stroke, and cardiovascular disease: meta-analysis of

prospective studies. BMJ 2009;339:b4567. DOI: 10.1136/bmj.b4567

10. Moore TJ, Conlin PR, Ard J, Svetkey LP. DASH (Dietary Approaches to Stop Hypertension) diet is effective treatment for stage 1 isolated systolic hypertension. Hypertens Dallas Tex 1979 2001;38(2):155-8. DOI: 10.1161/01.hyp.38.2.155
11. Mancia G, Fagard R, Narkiewicz K, Redon J, Zanchetti A, Böhm M, et al. 2013 ESH/ESC guidelines for the management of arterial hypertension: the Task Force for the Management of Arterial Hypertension of the European Society of Hypertension (ESH) and of the European Society of Cardiology (ESC). Eur Heart J 2013;34(28):2159-219. DOI: 10.1093/eurheartj/eht151
12. Stergiou GS, Kollias A, Zeniodi M, Karpettas N, Ntineri A. Home blood pressure monitoring: primary role in hypertension management. Curr Hypertens Rep 2014;16(8):462. DOI: 10.1007/s11906-014-0462-8
13. Parati G, Stergiou GS, Asmar R, Bilo G, de Leeuw P, Imai Y, et al. European Society of Hypertension guidelines for blood pressure monitoring at home: a summary report of the Second International Consensus Conference on Home Blood Pressure Monitoring. J Hypertens 2008;26(8):1505-26. DOI: 10.1097/HJH.0b013e328308da66
14. Hoshide S, Yano Y, Haimoto H, Yamagiwa K, Uchiba K, Nagasaka S, et al. Morning and Evening Home Blood Pressure and Risks of Incident Stroke and Coronary Artery Disease in the Japanese General Practice Population: The Japan Morning Surge-Home Blood Pressure Study. Hypertens Dallas Tex 1979 2016;68(1):54-61. DOI: 10.1161/HYPERTENSIONAHA.116.07201

15. Hoshide S, Kario K, Yano Y, Haimoto H, Yamagiwa K, Uchiba K, et al. Association of morning and evening blood pressure at home with asymptomatic organ damage in the J-HOP Study. Am J Hypertens 2014;27(7):939-47. DOI: 10.1093/ajh/hpt290
16. Kamoi K, Ito T, Miyakoshi M, Minagawa S. Usefulness of home blood pressure measurement in the morning in patients with type 2 diabetes: long-term results of a prospective longitudinal study. Clin Exp Hypertens N Y N 1993 2010;32(3):184-92. DOI: 10.3109/10641960903254513
17. Li J, Mu L, Rao H, Wu Y, Wang H, Tao H, et al. Preliminary Experiment on the Effect of 18% Substitute Salt on Home Blood Pressure Variability in Hypertensives. Int J Hypertens 2021;2021:9993328. DOI: 10.1155/2021/9993328
18. Liu T, Rao H, Wang M, Xu H, Wang W, Li G, et al. Comparative analysis of visit and home blood pressure in a pilot trial on the effect of 18% sodium substitute salt on blood pressure. Sci Rep 2021;11(1):907. DOI: 10.1038/s41598-020-79282-2
19. Zhang Z, Zhou X, Mei Y, Bu X, Tang J, Gong T, et al. Novel low-sodium salt formulations combined with Chinese modified DASH diet for reducing blood pressure in patients with hypertension and type 2 diabetes: a clinical trial. Front Nutr 2023;10:1219381. DOI: 10.3389/fnut.2023.1219381
20. Strilchuk L, Cincione RI, Fogacci F, Cicero AFG. Dietary interventions in blood pressure lowering: current evidence in 2020. Kardiol Pol 2020;78(7-8):659-66. DOI: 10.33963/KP.15468
21. Appel LJ, Moore TJ, Obarzanek E, Vollmer WM, Svetkey LP, Sacks FM, et al. A clinical trial of the effects of dietary patterns on blood pressure. DASH Collaborative Research Group. N Engl J Med 1997;336(16):1117-24. DOI:

0.1056/NEJM199704173361601
22. Sacks FM, Svetkey LP, Vollmer WM, Appel LJ, Bray GA, Harsha D, et al. Effects on blood pressure of reduced dietary sodium and the Dietary Approaches to Stop Hypertension (DASH) diet. DASH-Sodium Collaborative Research Group. N Engl J Med 2001;344(1):3-10. DOI: 10.1056/NEJM200101043440101
23. Bardak S, Turgutalp K, Özcan T, Eser ZE, Gözükara Y, Demir S, et al. How do we measure blood pressure at home? Blood Press 2015;24(3):174-7. DOI: 10.3109/08037051.2014.997082
24. Izzo JL, Levy D, Black HR. Clinical Advisory Statement. Importance of systolic blood pressure in older Americans. Hypertens Dallas Tex 1979 2000;35(5):1021-4. DOI: 10.1161/01.hyp.35.5.1021
25. Rao S, Li Y, Nazarzadeh M, Canoy D, Mamouei M, Hassaine A, et al. Systolic Blood Pressure and Cardiovascular Risk in Patients With Diabetes: A Prospective Cohort Study. Hypertens Dallas Tex 1979 2023;80(3):598-607. DOI: 10.1161/HYPERTENSIONAHA.122.20489
26. Seng LL, Hai Kiat TP, Bee YM, Jafar TH. Real-World Systolic and Diastolic Blood Pressure Levels and Cardiovascular Mortality in Patients With Type 2 Diabetes-Results From a Large Registry Cohort in Asia. J Am Heart Assoc 2023;12(23):e030772. DOI: 10.1161/JAHA.123.030772
27. Deng Y, Bai J, Yang X, Liu W, Guo Z, Zhang J, et al. Achieved systolic blood pressure and cardiovascular outcomes in 60-80-year-old patients: the Strategy of Blood Pressure Intervention in the Elderly Hypertensive Patients (STEP) trial. Eur J Prev Cardiol 2023;30(10):1017-27. DOI: 10.1093/eurjpc/zwad142
28. Elliott P. Sodium intakes around the world. Background

document prepared for the Forum and Technical meeting on Reducing Salt Intake in Populations (Paris 5-7 October 2006). Geneva, World Health Organization; 2007.
29. Bibbins-Domingo K, Chertow GM, Coxson PG, Moran A, Lightwood JM, Pletcher MJ, et al. Projected Effect of Dietary Salt Reductions on Future Cardiovascular Disease. N Engl J Med 2010;362(7):590-9. DOI: 10.1056/NEJMoa0907355
30. Kim BS, Yu M-Y, Shin J. Effect of low sodium and high potassium diet on lowering blood pressure and cardiovascular events. Clin Hypertens 2024;30:2. DOI: 10.1186/s40885-023-00259-0
31. Chang AY, Rahman M, Talukder A, Shah H, Mridha MK, Hasan M, et al. Effectiveness of a community health worker-led low-sodium salt intervention to reduce blood pressure in rural Bangladesh: protocol for a cluster randomized controlled trial. Trials 2023;24:480. DOI: 10.1186/s13063-023-07518-3
32. Gupta DK, Lewis CE, Varady KA, Su YR, Madhur MS, Lackland DT, et al. Effect of Dietary Sodium on Blood Pressure. JAMA 2023;330(23):2258-66. DOI: 10.1001/jama.2023.23651
33. Theodoridis X, Chourdakis M, Chrysoula L, Chroni V, Tirodimos I, Dipla K, et al. Adherence to the DASH Diet and Risk of Hypertension: A Systematic Review and Meta-Analysis. Nutrients 2023;15(14):3261. DOI: 10.3390/nu15143261
34. Abdel-Gawad N, Campbell NRC, Ide N, Cobb L, Garg R. The resolve to save lives sodium reduction framework; aligning global efforts to reduce the global burden of cardiovascular disease. J Hum Hypertens 2022;36(10):880-1. DOI: 10.1038/s41371-022-00745-2
35. Kim BS, Yu M-Y, Shin J. Effect of low sodium and high

potassium diet on lowering blood pressure and cardiovascular events. Clin Hypertens 2024;30(1):2. DOI: 10.1186/s40885-023-00259-0

36. Aminde LN, Nugraheni WP, Mubasyiroh R, Rachmawati T, Dwirahmadi F, Martini S, et al. Cost-effectiveness analysis of low-sodium potassium-rich salt substitutes in Indonesia: an equity modelling study. Lancet Reg Health Southeast Asia 2024;26:100432. DOI: 10.1016/j.lansea.2024.100432
37. Kario K, Okura A, Hoshide S, Mogi M. The WHO Global report 2023 on hypertension warning the emerging hypertension burden in globe and its treatment strategy. Hypertens Res 2024;47(5):1099-102. DOI: 10.1038/s41440-024-01622-w

Table I. CM-DASH Nutrition Dietary Pack

Nutrient content	CM-DASH homogenized meal solid drink (homogenized meal for breakfast)	CM-DASH solid drink (normal companion)	CM-DASH eight treasures rice (rice for mid-dinner)
Weight (g)	39	60	200
Energy (kcal)	119.74	171.36	722.26
Protein (g)	8.4	8.8	38.4
Fat (g)	1.5	2.7	14.4
Carbohydrates (g)	17.7	27.5	118.8
Fiber (g)	—	—	14.97
Sodium (mg)	90	26	10
Potassium (mg)	—	—	—
Magnesium (mg)	60	—	—
Calcium (mg)	120	—	—

Table II. Demographic characteristics

Variables	**Group A (control group, *n* = 34)**	**Group B (52 % salt group, *n* = 30)**	**Group C (23 % salt group, *n* = 33)**	**Group D (meal pack group, *n* = 33)**	***p***
Age (y)	68.12 ± 3.95	70.00 ± 4.24	63.39 ± 6.83	67.21 ± 5.19	0.000[a*]
Male (*n*, %)	16 (47.1)	11 (36.7)	17 (51.5)	16 (48.5)	0.670[b]
Salt intake (g/day)	8.19 ± 3.35	9.00 ± 2.51	9.08 ± 3.43	8.40 ± 3.97	0.647[a]
Smoking (*n*, %)	3 (8.8)	1 (3.3)	4 (12.1)	2 (6.1)	0.594[c]
Drinking (*n*, %)	6 (17.6)	3 (10.0)	5 (15.2)	6 (18.2)	0.801[c]
Waist-to-hip ratio	0.92 ± 0.05	0.92 ± 0.05	0.90 ± 0.06	0.91 ± 0.06	0.623[a]
BMI, kg/m^2	24.96 ± 2.12	25.34 ± 3.09	25.46 ± 2.94	24.97 ± 4.42	0.719[a]
Age of hypertension (y)	11.28 ± 6.66	9.83 ± 7.11	10.23 ± 7.19	12.53 ± 9.06	0.513[a]
Family history of hypertension (*n*, %)	18 (60.0)	14 (53.8)	15 (51.7)	22 (81.5)	0.094[b]
SBP, mmHg	136.15 ± 15.39	139.72 ± 15.89	133.00 ± 14.48	135.70 ± 13.71	0.363[a]
DBP, mmHg	79.81 ± 7.90	79.07 ± 8.89	77.97 ± 7.48	77.42 ± 8.27	0.630[a]
Statin therapy (*n*, %)	14 (41.2)	8 (26.7)	10 (30.3)	17 (51.5)	0.159[b]
Aspirin medication (*n*, %)	8 (23.5)	5 (16.7)	6 (18.2)	8 (24.2)	0.840[b]
Age of diabetes (y)	8.18 ± 6.04	10.40 ± 7.61	10.56 ± 8.40	12.27 ± 7.67	0.179[a]
Family history of diabetes (*n*, %)	12 (35.3)	11 (36.7)	13 (40.6)	15 (48.4)	0.714[b]

Fasting blood sugar (mmol/L)	8.20 ± 2.18	8.64 ± 1.85	9.18 ± 2.92	8.97 ± 2.24	0.345[a]

BMI: body mass index; SBP: systolic blood pressure; DBP: diastolic blood pressure. [a]One-way analysis of variance. [b]Chi-square test. [c]Fisher's precision probability test. *There was difference between Group C and Group A (p = 0.031), and there was difference between Group C and Group B (p = 0.001).

Table III Changes in HSBP during the intervention period

	Group A (control group, *n* = 34)			**Group B (52 % salt group, *n* = 30)**			**Group C (23 % salt group, *n* = 33)**			**Group D (meal pack group, *n* = 33)**			$p^{†}$
	HSBP	**Change**	***p****	**HSBP**	**Change**	***p****	**HSBP**	**Change**	***p****	**HSBP**	**Change**	***p****	
Baseline	136.15 ± 2.60	-	-	139.72 ± 2.87	-	-	133.00 ± 2.48	-	-	135.70 ± 2.35	-	-	0.363
1 w	130.77 ± 3.43	-5.38 (-13.42, 2.66)	0.190	135.21 ± 2.83	-4.51 (-13.09, 4.08)	0.303	121.40 ± 2.87	-11.60 (-18.19, -5.01)	0.001	122.43 ± 2.29	-13.27 (-19.71, -6.83)	0.001	0.005[a]
2 w	130.33 ± 3.02	-5.82 (-12.70, 1.07)	0.098	132.19 ± 2.79	-7.53 (-16.04, 0.98)	0.083	126.53 ± 2.51	-6.47 (-11.65, -1.29)	0.014	123.58 ± 1.96	-12.12 (-17.49, -6.74)	0.001	0.096
3 w	127.90 ± 2.92	-8.24 (-15.26, -1.22)	0.021	130.87 ± 2.48	-8.85 (-16.92, -0.77)	0.032	126.57 ± 2.06	-6.43 (-11.26, -1.60)	0.009	122.47 ± 2.02	-13.22 (-18.56, -7.89)	0.001	0.115

4 w	127.60 ± 2.62	-8.54 (-14.88, -2.21)	0.008	129.65 ± 2.12	-10.07 (-17.43, -2.70)	0.007	124.84 ± 1.85	-8.16 (-12.92, -3.39)	0.001	122.14 ± 2.05	-13.56 (-18.56, -8.56)	0.001	0.082
5 w	124.60 ± 2.29	-11.55 (-17.46, -5.64)	0.000	128.70 ± 2.25	-11.01 (-18.51, -3.51)	0.004	126.37 ± 2.02	-6.63 (-11.47, -1.78)	0.007	121.53 ± 2.12	-14.16 (-19.81, -8.51)	0.001	0.157
6 w	125.75 ± 2.32	-10.39 (-16.57, -4.22)	0.001	127.59 ± 1.83	-12.13 (-18.95, -5.30)	0.000	127.47 ± 1.93	-5.53 (-10.51, -0.55)	0.029	124.21 ± 2.03	-11.49 (-17.28, -5.69)	0.001	0.494
7 w	125.83 ± 2.48	-10.31 (-16.21, -4.41)	0.001	127.31 ± 2.13	-12.41 (-19.24, -5.58)	0.000	126.78 ± 1.85	-6.22 (-11.08, -1.35)	0.012	124.29 ± 2.00	-11.41 (-17.00, -5.82)	0.001	0.626
8 w	127.69 ± 2.38	-8.46 (-14.27, -2.65)	0.004	128.63 ± 1.93	-11.09 (-18.03, -4.14)	0.002	127.64 ± 2.26	-5.36 (-10.54, -0.17)	0.043	122.64 ± 1.86	-13.06 (-18.84, -7.64)	0.001	0.205

HSBP (m ± s); Change (MD, 95 % CI). *Generalized estimating equation adjusted for age, gender, smoking, drinking, family history of hypertension, age of hypertension, family history of diabetes, age of diabetes, waist-to-hip ratio, body mass index, statin and aspirin therapy. †Comparison between groups. [a]Group C vs. Group B, -13.80 (-25.91 to -1.71) mmHg, p = 0.017; Group D vs. Group B, -12.78 (-24.69 to -0.87) mmHg, p = 0.029.

Table IV. Changes in HDBP during the intervention period

	Group A (control group, *n* = 34)			**Group B (52 % salt group, *n* = 30)**			**Group C (23 % salt group, *n* = 33)**			**Group D (meal pack group, *n* = 33)**			***p*†**
	HDBP	**Change**	***p****	**HDBP**	**Change**	***p****	**HDBP**	**Change**	***p****	**HDBP**	**Change**	***p****	
Baseline	79.81 ± 1.33	-	-	79.07 ± 1.60	-	-	77.97 ± 1.28	-	-	77.42 ± 1.42	-	-	0.630
1 w	76.90 ± 1.58	-2.91 (-6.74, 0.92)	0.137	76.92 ± 1.98	-2.14 (-7.53, 3.24)	0.435	76.10 ± 1.84	-1.87 (-4.46, 0.71)	0.156	75.61 ± 1.31	-1.81 (-5.22, 1.59)	0.297	0.942
2 w	76.12 ± 1.44	-3.69 (-7.00, -0.39)	0.029	75.96 ± 1.94	-3.10 (-8.45, 2.24)	0.255	76.95 ± 1.63	-1.02 (-3.23, 1.20)	0.368	74.32 ± 1.25	-3.10 (-5.57, -0.63)	0.014	0.652
3 w	75.39 ± 1.55	-4.42 (-7.98, -0.86)	0.015	75.19 ± 1.86	-3.88 (-9.15, 1.40)	0.150	76.55 ± 1.74	-1.41 (-3.79, 0.96)	0.242	73.91 ± 1.35	-3.52 (-6.51, -0.53)	0.021	0.788
4 w	75.97 ± 1.47	-3.84 (-7.48, -0.19)	0.039	74.01 ± 1.54	-5.06 (-9.91, -0.20)	0.041	76.23 ± 1.42	-1.74 (-3.68, 0.21)	0.080	73.65 ± 1.44	-3.77 (-6.49, -1.05)	0.007	0.575
5 w	74.87 ± 1.32	-4.94 (-8.19, -	0.00	73.84	-5.23 (-10.23, -	0.04	74.89	-3.08 (-5.56, -	0.01	73.73	-3.69 (-6.78, -	0.01	0.74

		1.70)	3	± 1.68	0.22)	1	± 1.67	0.51)	9	± 1.42	0.61)	9	6
6 w	75.22 ± 1.33	-4.59 (-7.92, -1.27)	0.007	72.75 ± 1.56	-6.32 (-11.29, -1.35)	0.013	75.07 ± 1.60	-2.90 (-5.59, -0.22)	0.034	74.78 ± 1.38	-2.64 (-5.48, 0.20)	0.068	0.692
7 w	74.42 ± 1.35	-5.39 (-9.14, -1.64)	0.005	73.41 ± 1.61	-5.66 (-10.69, -0.63)	0.027	75.30 ± 1.58	-2.67 (-5.24, -0.09)	0.042	74.48 ± 1.35	-2.95 (-5.79, -0.11)	0.042	0.858
8 w	74.93 ± 1.54	-4.88 (-8.53, -1.23)	0.009	73.94 ± 1.50	-5.13 (-9.96, -0.29)	0.038	74.55 ± 1.68	-3.42 (-6.19, -0.65)	0.016	73.86 ± 1.23	-3.56 (-6.36, -0.77)	0.013	0.797

HDBP (m ± s); Change (MD, 95 % CI). *Generalized estimating equation adjusted for age, gender, smoking, drinking, family history of hypertension, age of hypertension, family history of diabetes, age of diabetes, waist-to-hip ratio, body mass index, statin and aspirin therapy. †Comparison between group.

Table V. Changes in 24-hour urinary sodium and potassium during the intervention period

Norm	Group A (control group, n = 34)				Group B (52 % salt group, n = 30)				Group C (23 % salt group, n = 33)				Group D (meal pack group, n = 33)				p*	$p^{\dagger}$	$p^{\ddagger}$
	Baseline	**4th week**	**Intervention end up**	***p***	**Baseline**	**4th week**	**Intervention end up**	***p***	**Baseline**	**4th week**	**Intervention end up**	***P***	**Baseline**	**4th week**	**Intervention end up**	***p***			
24 h U K^+ (mmol/24 h)	49.54 ± 24.11	44.08 ± 13.32	45.01 ± 19.56	0.259	43.7 ± 18.27	44.37 ± 16.07	55.26 ± 24.76	0.001	45.2 ± 22.67	50.84 ± 17.19	55.80 ± 21.07	0.334	42.97 ± 23.07	71.25 ± 25.11	57.41 ± 20.21	0.001	0.694	0.001	0.082
24 h U Na^+ (mmol/24 h)	143.7 ± 58.34	121.4 ± 41.07	129.13 ± 54.17	0.078	153. ± 43.01	104.6 ± 30.96	130.54 ± 52.97	0.001	155.21 ± 58.55	131.51 ± 45.71	132.15 ± 64.85	0.042	147.4 ± 74.44	121.9 ± 52.15	131.36 ± 67.50	0.070	0.085	0.115	0.998
24 h U Na^+/K^+	3.29 ± 1.53	2.85 ± 0.97	3.09 ± 1.23	0.127	4.07 ± 1.98	2.53 ± 0.87	2.67 ± 1.40	0.001	3.93 ± 1.56	2.77 ± 1.11	2.47 ± 0.98	0.001	3.65 ± 1.51	1.85 ± 0.78	2.36 ± 1.05	0.001	0.072	0.926	0.424

*Comparison between groups at baseline; †Comparison between groups at week 4; ‡Comparison between groups after intervention.

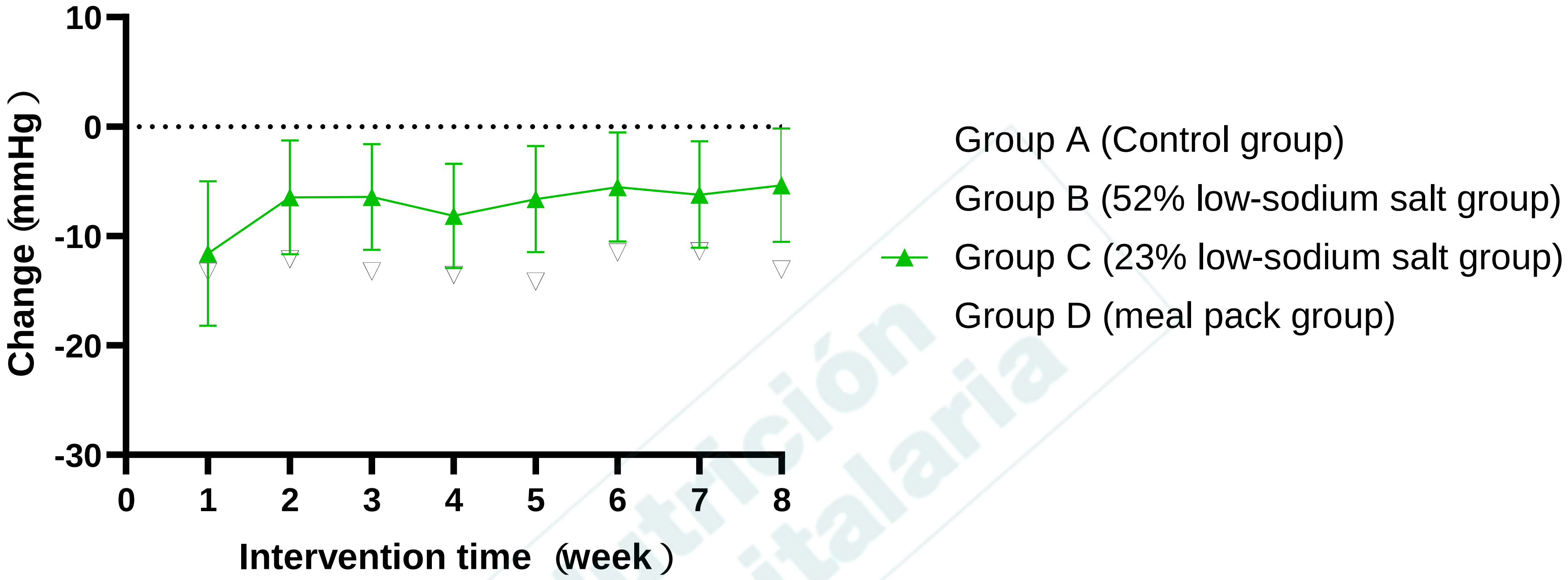

Figure 1. Changes in HSBP during the intervention period.

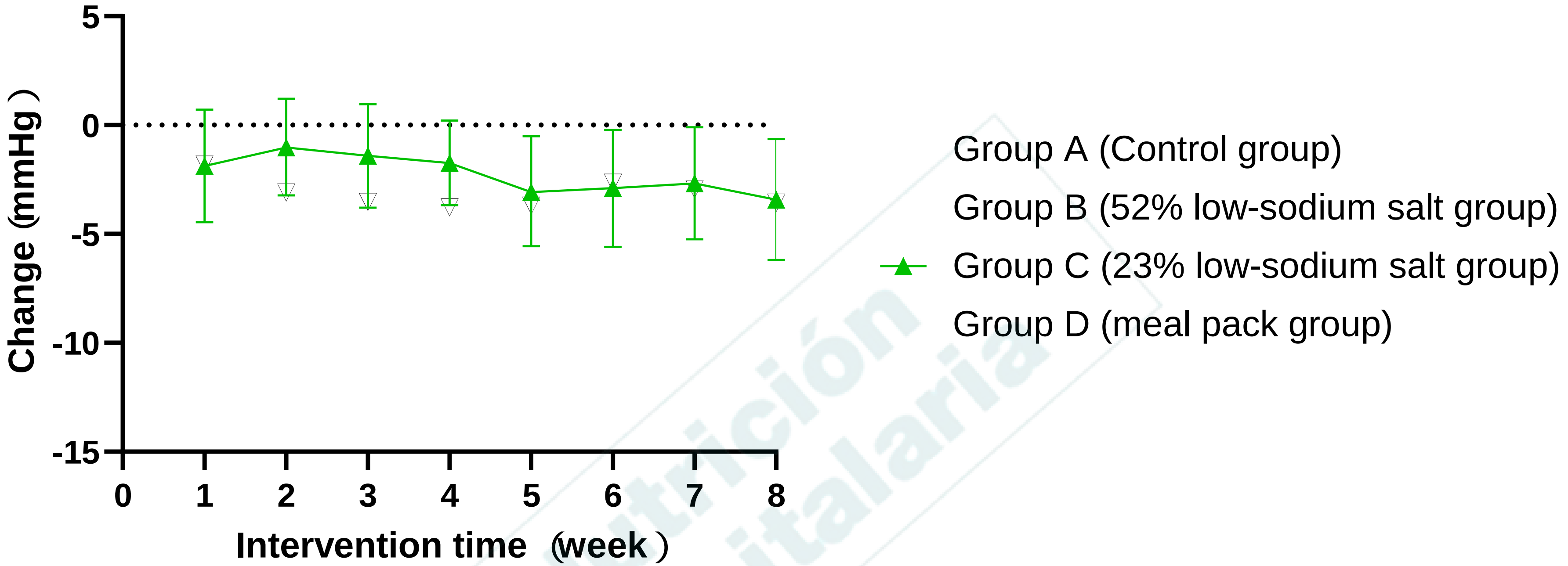

Figure 2. Changes in HDBP during the intervention period.