# Effects of the 52% low-sodium salt applied to CM-DASH diet in hypertensive patients with type 2 diabetes:A Randomized Controlled Trial

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### Abstract

Background and Aims: The DASH diet have been proven to be effective in lowering blood pressure (BP), but it is rarely used in people with type 2 diabetes (T2D), especially in the Chinese population. We aimed to evaluate the effects of 52% low-sodium salt applied to CM-DASH diet in patients with hypertension and T2D. Methods and Results: This trial is a single-blind, randomized controlled study conducted from December 2019 to November 2020 at Chongqing, China. 61 participants were randomly allocated to intervention group or control group for 8 weeks.2 participants were lost, and 59 patients were finally included in the analysis. The systolic blood pressure (SBP) and diastolic blood pressure (DBP) of intervention group and control group were significantly decreased compared with baseline, but there was no difference between groups. The 24-hour urine Na+ and Cl- of the two groups decreased significantly after intervention, but the increase of 24-hour urine K+ and the decrease of Na+/ K+ ratio were only observed in the intervention group. Furthermore,the urine urinary albumin creatinine ratio (UACR) and serum creatinine of two groups also decreased from baseline. Conclusions: Following the CM-DASH diet in hypertensive patients with T2D has beneficial effects in improving SBP and DBP. and the application of 52% low-sodium salt has a significant effect in reducing sodium intake and increasing potassium intake.


## 1. Introduction

Hypertension and T2D has become a global public health concern in the 21st century.Both diseases lead to severe complications such as chronic kidney diseases[1]and cardiovascular[2],which increase the risk of death over a long period of time. Both of them related to lifestyles such as physical exercise[3],alcohol consumption[4] , and dietary habits[5,6]. Studies have found that about 50% of T2D patients have hypertension, and 20% of hypertensive patients have T2D[7]. Hypertension coexists with T2D, which increases the risk of cardiovascular-related events and makes BP management more complicated and difficult[8]. Drug use alone makes BP control hard to achieve, so lifestyle intervention (such as dietary intervention and exercise) is more needed.

The DASH diet was proposed by National Heart, Lung, and Blood Institute (NHLBI) in 1977 to control the BP of hypertensive patients. The DASH eating plan encourages the consumption of potassium-rich vegetables and fruits, including whole grains, poultry, fish, and nuts, and reduces sodium and saturated fat intake[9]. There is strong evidence that the DASH dietary pattern can lower BP[10,11], including patients with T2D and hypertension[12,13].However, as the DASH diet was designed for white ethnicity, it is difficult for Chinese people to follow the original DASH diet. In addition, Chinese people generally prefer salty foods.It is estimated that Chinese people consume an average of 12g of salt per day[14],but DASH diet requires a daily consumption of 2300 mg of sodium (equivalent to 5.8 g of sodium chloride) or less[10], which also makes it difficult for the DASH diet to be used in Chinese population. Among many salt reduction strategies, consuming low-sodium salt is a feasible and low-cost method. Numerous studies have shown that low-sodium salt can lower BP by reducing sodium and adding potassium[15,16],but it has not been used in the DASH diet so far.

Therefore, in this randomized controlled trial, we developed a modified DASH diet for the use of Chinese people, and we want to know the hypotensive effect of 52% low-sodium salt applied to CM-DASH diet in patients with hypertension and T2D.

## 2. Materials and Methods

### 2.1. Participants

$$n = 2\delta^2 * f(\alpha, \beta)/(\ u_1 - u_2)^2$$

Inclusion criteria: (1) aged [?] 35 and [?] 75 years; (2) no plan to move out of the community in the next three months; (3) agree to consume the salt and DASH meals we provide during the trial; (4) clinically diagnosed patients with hypertension and T2D,and the SBP is between 130-180mmHg, DBP is between 80-110mmHg (without antihypertensive drugs).Exclusion criteria:(1)serious complications of hypertension or T2D; (2) hypercortisolism or aldosteronism; (3) acute disease, such as upper respiratory infection, fever and diarrhea; (4) patients or family members has abnormal kidney function or use potassium-retaining diuretics; (5) patients or family members have abnormal liver function; (6) pregnant or others who are not suitable to consume low-sodium salt.

The Ethics Committee of CQMU (Chongqing Medical University) has approved the experiments, including any relevant details(20/03/2020) which means that all experiments were performed in accordance with relevant guidelines and regulations,and all participants provided written informed consent before enrollment in the trial.

### 2.2. Study design

We used a randomized controlled parallel-design. After completing the baseline questionnaire and physical checkup, participants were randomly assigned to intervention group (CM-DASH diet +52% low-sodium salt) or control group (CM-DASH diet +common salt) for 8 weeks with a random number table,and participants do not know which group they are assigned to. The present study is divided into 3 phases(2 weeks of CM-DASH diet adaptation + 2 weeks of CM-DASH diet feeding + 4 weeks of CM-DASH diet behavior intervention), and two dietary intervention methods have been adopted. In phase 1 and phase 3, we designed a 7-day menu of Chinese food that met the nutrient criteria of the DASH diet. At the same time, we also provide salt (52% low sodium salt or common salt), and the participants cooked at home according to the menu we provided .In phase 2, patients are required to consume the CM-DASH diet provided by us at a uniform location. All participants were told not to change their previous exercise habits and drug use during the intervention.

Participants were followed up in the hospital once a week to collect information on OBP, salt and drug use. In addition, for trial safety, patients were examined at baseline, 4 weeks after the intervention and the end of the trial.

### 2.3. CM-DASH

We have developed a modified DASH diet that we called CM-DASH. CM-DASH is tailor-made according to Chinese dietary habits, with the same nutritional content as the original DASH diet, and is generally better accepted by Chinese people.The general requirements of food selection are as follows: rice is the staple food mixed with coarse grains;white meat (chicken and fish) accounts for the majority of meat;low-fat milk is used; more green leafy vegetables and fruits with low sugar;moderate intake of nuts;daily cooking oil(plant oil) $<$

30g and salt $< 5$g. Compared to the original DASH diet, the modified diet contains less total fat,saturated fatty acids and calories.The CM-DASH diet for one person is shown in Table 1.

### 2.4. Salt

In this study, 52% low sodium salt of "Gu Da Chu" was developed by Shanghai Institute of Ecological Health Sciences. Name: solid compound condiment, standard of execution: Q/BAAM0009S, food production license number: SC10334042205441, and the main ingredients include potassium chloride (31%), sodium chloride (52%). Common salt of "Jing Xin" was developed by Chongqing salt industry group Co., Ltd. Name: purified salt, product standard: NY/T1040, and the content of sodium chloride content>99%. In Phase 1 and Phase 3, we used 52% low-sodium salt or common salt to completely replace the salt in the participants' homes,and we also provided a quantitative pot and a quantitative spoon to allow participants to control the amount of salt used in the family(<5g per person per day). In addition, we use an electronic scale(Precision:0.1g) to weigh the salt consumption every week , and estimate the daily salt consumption of each person according to the family population.

### 2.5. Blood pressure measurement

Participants were followed up in the hospital once a week to collect information on OBP. OBP was measured by trained professionals, and 3 measurements was required to be completed between 8-9 am, interval of about 2 min,and the average of the last two BP measurements was used for analysis. The BP measuring instrument adopt validated automated upper-arm cuff devices that operate through the oscillometric technique (Manufacturer:Omron,Dalian,Co.,Ltd. Product name:"Omron" electronic sphygmomanometer. Model: HEM-7130).

### 2.6. Laboratory Measurements

Laboratory measurements included 24-hour urinary electrolytes, blood electrolytes, blood lipids, liver function, renal function, urinary creatinine and urinary albumin. All indexes were tested in the Second Affiliated Hospital of CQMU, and we reported the results to patients in a timely manner.

### 2.7. Statistical analysis

Statistical analysis was carried out using SPSS 24.0 (IBM, Armonk, NY, USA). Quantitative normal distribution data was described by mean and standard deviation, and T test was used to compare the difference between the intervention group and the control group. Qualitative data is described by frequency, and the Pearson's chi-square test is used to compare the differences between groups. Non-positive distribution data are expressed in median and quartiles, and Friedman's Rank Test was used. Repeated measures analysis of variance (RMANOVA) was used to analyze the changes of physical examination indexes during the intervention.The Generalized Estimating Equation (GEE) was used to compare the changes in blood pressure during each week, and Bonferroni method was used for comparison between groups. P values <0.05 were considered statistically significant.

## 3. Results

### 3.1. Baseline Characteristics

In this study, 61 were included in the intervention, 2 participants withdrew from the trial due to personal reasons, and finally 59 completed the intervention and were included analysis. (Figure 1) The baseline features of hypertensive patients with T2D are shown in Table 2. There were no differences between the intervention and control groups regarding demographic features, lifestyle characteristics ,anthropometric indices, 24-hour urine sodium and potassium values and OBP values. In addition, the use of antihypertensive drugs was not different between groups.

### 3.2. Urine test result

Analysis of RMANOVA for repeated measures indicated that 24-hour urine Na+(Intervention: -49.29mmol/24h,$P$ <0.001; Control:-27.62mmol/24h, $P$ =0.015; between groups:21.67mmol/24h,$P$

=0.123)and 24-hour urine Cl-(Intervention: -35.50mmol/24h, $P$ =0.002; Control:-26mmol/24h,$P$ =0.017; between groups:9.51 mmol/24h,$P$ =0.514)decreased significantly in both groups after 4-week dietary intervention.However, 24-hour urine Na+(+25.88mmol/24h, $P$=0.006)and 24-hour urine Cl – (+26.11 mmol/24h, $P$ =0.005 )in the intervention group increased again from the 4th week. The increase of 24-hour urinary K+( $P$ =0.020) and the decrease of Na+ / K+ ratio ($P$ <0.001)were observed in the intervention group, but not in the control group($P$ >0.05). In addition, the UACR ($P$ =0.017) of two groups decreased from baseline(Table 3).

3.3. Serum test result

Compared with baseline, the changes of $Na^+$, $K^+$, $Cl^-$ and $Ca^{2+}$in serum electrolytes concentration were observed in the intervention group and the control group, and the change trend was the same as that of 24-hour urine electrolytes. There was no significant change in AST(Alanine aminotransferase), ALT(Aspartate aminotransferase), UA(Uric acid) and Creatinine during the study .However, serum lactate and creatinine were significantly lower than baseline(Table 4).

3.4. BP Measurements During the Study

The results of GEE showed that after one week of intervention, the SBP of the intervention group and the control group (intervention group:-12.17 mmHg, 95% CI: -19.72 ~ -4.62, $P$<0.001; control group:-7.16 mmHg, 95 %CI: -13.53 ~ -0.78, $P$ =0.012) was significantly lower than the baseline. The DBP of the two groups also decreased significantly from baseline after one week of intervention (intervention group: -7.25mmHg, 95%CI: -0.61 ~ -3.89, $P$<0.001; control group: -5.29mmHg 95%CI: -8.55 ~ -2.04, $P$ <0.001). At the end of the intervention, the SBP of the intervention group decreased by an average of 14.32 mmHg from the baseline (95%CI: -21.80 ~ -6.83,$P$ <0.001), and the DBP was decreased by an average of 6.32 mmHg from the baseline (95%CI: -9.55 ~ -3.08,$P$ <0.001), the SBP of the control group decreased by an average of 10.98 mmHg from the baseline (95%CI: -18.26 ~ -3.71, $P$ <0.001), and the DBP was decreased by an average of 5.24 mmHg from the baseline (95%CI: -9.23 ~ -1.25, $P$ =0.001). However, from baseline to the end of the intervention, the changes in SBP and DBP were not statistically significant between the intervention group and the control group (SBP: -0.28mmHg, 95%CI: -6.42 ~ 5.86, $P$=0.929; DBP: -3.32 mmHg, 95%CI: -7.21 ~ 0.56, $P$=0.093) (Table 5. Table 6).

3.5. Safety

No serious adverse events occurred during the intervention. Other adverse events included: 1 weeks after intervention, 2 patients developed fatigue and dizziness. At the third week of intervention,2 patients developed mild diarrhea.

## 4. Discussion

Large number of studies has repeatedly demonstrated that consumption of the DASH diet could decrease BP in hypertensives[10,11],but it has been less commonly used in hypertensive patients with T2D. In the study by Azadbakht et al.[13], after 8 weeks of DASH diet intervention among patients with T2D, the intervention group had a significant BP reduction compared with the control group. Paula et al.[12]also had a similar conclusion, but in the study of Hashemi et al.[17], there was no significant difference in the reduction of BP between the DASH diet and the control diet. To the best of our knowledge, this is the first study evaluating the effects of DASH eating pattern on BP among Chinese patients with hypertension and T2D.

We modified the original DASH diet according to the dietary habits of Chinese people, and formed CM-DASH diet. Participants had high compliance during the intervention, and no one dropped out because of diet,which indicated that CM-DASH diet was meets the dietary preferences of Chinese people.Our study revealed that hypertensive patients with T2D who followed a CM-DASH diet during an 8-week period had a major reduction in SBP and DBP. From baseline to 8 weeks later, the mean SBP had decreased by 14.32 mmHg in intervention group,10.98mmHg in control group and ,the mean DBP had decreased by 6.32 mmHg in intervention group,5.24 in control group.The largest reduction in BP was observed in SBP at the end of week 4, approximately 18 mmHg in the intervention group, 12mmHg in the control group.

Sodium reduction was considered to be a factor underlying the hypotensive effect observed in this study. The baseline mean salt consumption of participants in this study was 8.94g per day, but with the CM-DASH diet, the mean salt intake of participants was reduced by approximately 4g per day. As the golden criteria to determine the intake of sodium, 24-hour urine electrolyte electrolytes has been widely used in scientific research[18].Our results shows that after the intervention of CM-DASH diet, the 24-hour urine $Na^+$ of the intervention group and the control group both decreased significantly, which indicated that CM-DASH diet had a marked effect on reducing the sodium intake of the participants. Studies have shown that high dietary sodium intake can lead to high BP by inhibiting the activity of $Na^+$ - $K^+$ - ATPase pumps in cell membrane[19], damaging vascular endothelial function[20]and activating RAAS (Renin-Angiotension-Aldosterone System)[21]. There is substantial evidence that reducing sodium intake lowers BP in persons with hypertension. We also found similar hypotensive effects in patients with hypertension and diabetes.

Contrary to the effect of sodium on BP, potassium can lower BP by stimulating $Na^+$ - $K^+$ - ATPase pumps and the opening of potassium channels in vascular smooth muscle cells and adverse nerve receptors[22].The DASH diet also recommends reducing dietary sodium and consuming more potassium-rich fruits and vegetables[9], but it is hard to achieve the desired effect by supplementing potassium with food. Studies have shown that increasing potassium intake by consuming low sodium salt is an effective and economical way[23]. We used low-sodium salt with a sodium chloride content of 52% and a potassium chloride content of 31% in the intervention group, while the control group used common salt with a sodium chloride content of >99%. Our results showed that there were significant changes in 24-hour urinary $K^+$and $Na^+$ / $K^+$ ratio in the intervention group, but not in the control group. Although there is no significant difference in BP drop between the intervention group and the control group, we observed that the decrease of SBP in the intervention group appeared earlier and more significantly than that in the control group. In view of previous studies[24,25] suggest that the high level of potassium in the DASH diet is important for its hypotensive effects,we still consider that the application of low-sodium salt in the DASH diet may have more beneficial effects on BP reduction in hypertensive patients with T2DM, and a significant difference may be found by increasing the intervention time and expanding the sample size.

It was considered that the high potassium content of the low-sodium salt could result in hyperkalemia and safety monitoring was conducted. During the study period,

no serious adverse events occurred, and the safety of the participants was monitored and confirmed throughout the study period. Serum test results showed that there was a slight increase in potassium during the intervention period, but it was still within the normal range. In addition, there is no significant difference in the changes of AST, ALT, UA, Urea. However, urine UACR and serum creatinine showed a significant decrease compared with baseline in two groups , which may be related to the reduced sodium intake in the CM-DASH diet. Studies have reported that excessive salt intake is associated not only with high BP but also target organ damage[26].There is an association between high salt intake and UACR independent of BP, and oxidative stress is a modifying factor between them[27].The research of Feng J. He et al. showed that with the salt reduction, the urine albumin and UACR also decreased significantly[28]. In view of these results, we believe that short-term CM-DASH diet and sodium reduction feeding trials may have beneficial effects on the improvement of renal function.

Most evidence for the DASH diet comes from short-term feeding studies[10,29] or dietary behavioral intervention studies[30],but both methods were used in this study. Interestingly, although the dietary and salt requirements for participants during the dietary behavior intervention were the same as those during the feeding trial, we still observed a small increase in BP in phase 3, which was also confirmed by the changes in urine $Na^+$ and $K^+$ in 24 hours. Cooking meals that meet dash nutritional requirements at home is affected by many interference factors, which makes it difficult for participants to strictly comply with our recommendations. On the other hand, CM-DASH diet menu contains coarse grains, low-fat milk and nuts, which is difficult for Chinese people to consume on a regular basis. It will take longer to change the eating habits of Chinese people that have lasted for thousands of years. In the future, we should strengthen health education on diet to change the dietary behavior of Chinese people with hypertension and T2D.

In conclusion, The results of the present study demonstrated that 52% low-sodium salt applied to the CM-DASH diet is an effective nutritional strategy for the control and management of BP in Chinese people with hypertension and T2D.

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**Competing interests:** The authors declare no competing interests.

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**Figure legends**

Table 1. A Chinese modified daily DASH diet for one person

Table 2. Baseline Characteristics of hypertensive patients with type 2 diabetes

Table 3. Changes of Urine Test Results During the Study

Table 4. Changes of Serum Test Results During the Study

Table 5. Changes in SBP From Baseline During the Study

Table 6. Changes in DBP From Baseline During the Study

Figure 1. Flow diagram of trial participants

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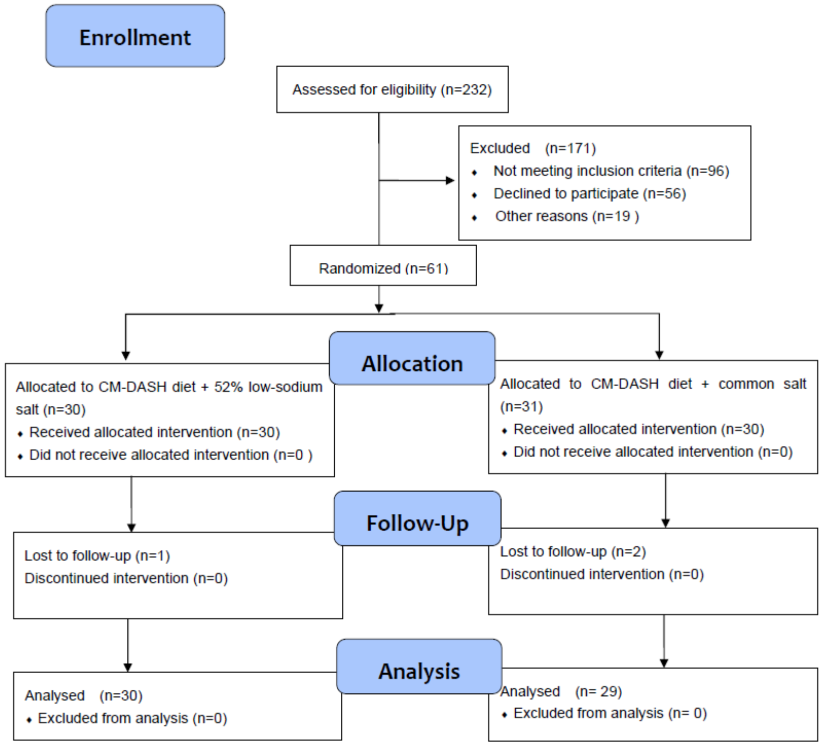
Enrollment
Assessed for eligibility (n=232)
Excluded (n=171)
Not meeting inclusion criteria (n=96)
Declined to participate (n=56)
Other reasons (n=19 )
Randomized (n=61)
Allocation
Allocated to CM-DASH diet + 52% low-sodium salt (n=30)
Received allocated intervention (n=30)
Did not receive allocated intervention (n=0 )
Allocated to CM-DASH diet + common salt (n=31)
Received allocated intervention (n=30)
Did not receive allocated intervention (n=0)
Follow-Up
Lost to follow-up (n=1)
Discontinued intervention (n=0)
Lost to follow-up (n=2)
Discontinued intervention (n=0)
Analysis
Analysed (n=30)
Excluded from analysis (n=0)
Analysed (n= 29)
Excluded from analysis (n= 0)