



“Minimal-Advice” on Salt Intake: Results of a Multicentre Pilot Randomised Controlled Trial on Hypertensive Patients

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Abstract

Introduction A strong and well-known association exists between salt consumption, potassium intake, and cardiovascular diseases. MINISAL-SIIA results showed high salt and low potassium consumption in Italian hypertensive patients. In addition, a recent Italian survey showed that the degree of knowledge and behaviour about salt was directly interrelated, suggesting a key role of the educational approach.

Aim The present multicentre randomised controlled trial study aimed to evaluate the efficacy of a short-time dietary educational intervention by a physician, only during the first visit, on sodium and potassium intake in hypertensive patients.

Methods Two-hundred-thirty hypertensive subjects participating in the MINISAL-SIIA study were enrolled for this study. After the randomisation, the participants were stratified into the educational intervention (EI) group ($n=109$) and control group (C) ($n=121$). Anthropometric indexes and blood pressure (BP) measurements were taken in the single-centre, and 24-hour urinary sodium (UrNa) and potassium (UrK) excretion were centrally measured.

Results After 3 months, there was a reduction in BP, UrNa, and body weight, and an increase in UrK in EI. By contrast, a lower decrease in BP was found in the C group, and a slight rise in UrNa and no substantial change in UrK were revealed. BP changes were positively and significantly associated with changes in UrNa only in EI.

Conclusion The main results of this trial indicate that a single brief educational intervention by a physician can lead to a reduction in salt intake and BP, and increased potassium consumption in hypertensive patients, without adverse effects.

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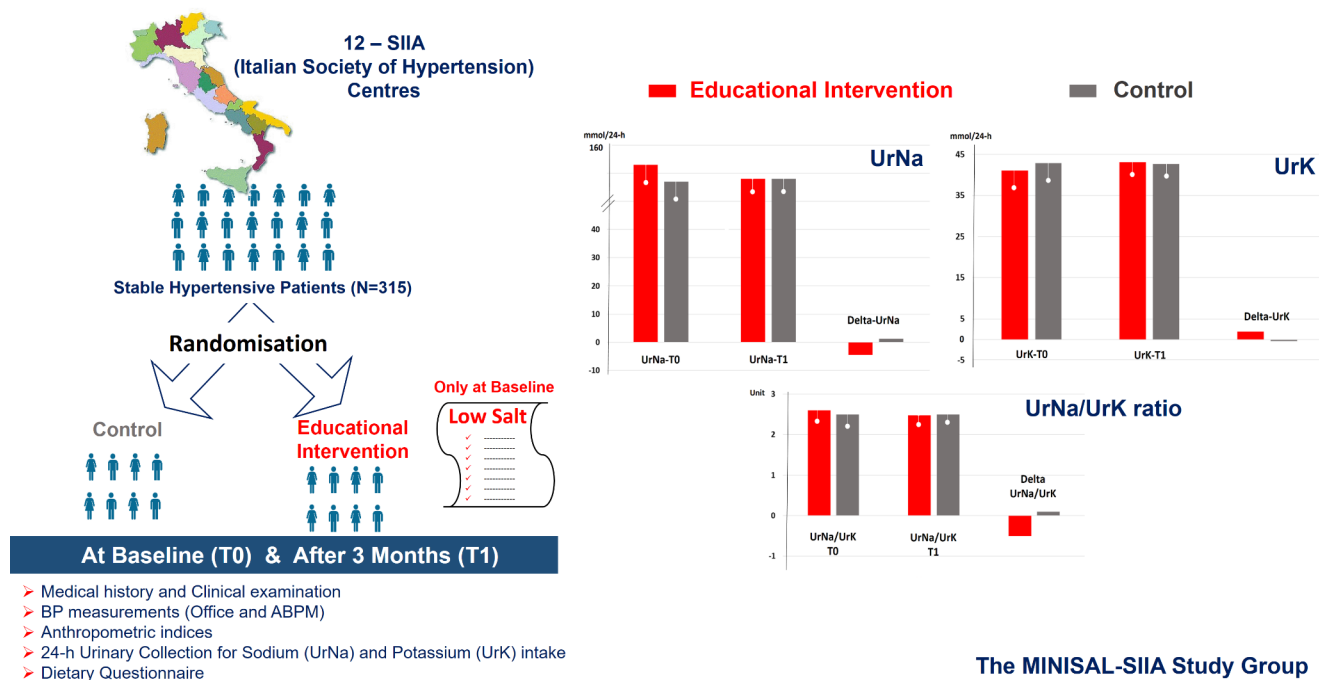
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Graphical Abstract The main findings of this randomised controlled trial on hypertensive patients indicate that a short-time dietary educational intervention during the baseline visit is associated with slight improvements in salt and potassium intake and a reduction in blood pressure after three months. These results highlight the importance of providing adequate dietary counselling during the patient's visits to help reduce cardiovascular risk in patients with hypertension.

“MINIMAL-ADVICE” ON SALT INTAKE: RESULTS OF A MULTICENTRE PILOT RANDOMISED CONTROLLED TRIAL ON HYPERTENSIVE PATIENTS



Keywords Salt · Sodium · Salt Awareness · Salt Behaviour · Potassium · Dietary Questionnaire · Hypertension · Urinary Sodium · Urinary Potassium

1 Introduction

High salt (i.e., sodium chloride, 1 g = 17.1 mmol of sodium) consumption is an important determinant of high blood pressure (BP) and cardiovascular diseases [1]. Several intervention studies showed that a reduction in salt consumption reduces BP [2, 3] and can reduce cardiovascular risk beyond the beneficial effect on BP in people with and without hypertension [4–6]. The World Health Organization (WHO) recommends that adults should consume no more than 5 g of salt daily [7]. However, the mean daily salt intake in most countries worldwide exceeds this recommendation [7, 8]. In contrast to salt, epidemiological and intervention studies suggest beneficial effects of dietary potassium on BP [9] and cardiovascular risk [1, 10–12]. This effect seems more

pronounced during high salt consumption [9]. The WHO currently also recommends that adults should consume not less than 90 mmol of potassium daily [13]. However, also for potassium the WHO recommendations are not generally met [13, 14].

Several countries have made some progress towards reducing habitual salt intake through a voluntary or regulatory approach, achieving a reduction of BP and cardiovascular disease in the young population [15–17].

Our previous observational data detected that Italian general population samples consumed high dietary salt and low dietary potassium [18], far from the WHO guidelines recommendation. Excess dietary salt intake in the hypertensive patients' population was observed in all age categories and there were no differences in salt intake among different

regions [19, 20]. Likewise, in the same hypertensive population the adequate potassium intake in both men and women, in all age categories, and in all the regions surveyed was much below the recommendation. These results point out the potential target to improve BP and cardiovascular risk, in particular in hypertensive patients.

An Italian survey of a large cohort of the general population showed that the degree of knowledge and behaviour about salt was directly interrelated [21]. These data suggested that an educational approach is crucial to improve the level of salt consumption. The reduction of salt intake has been recommended by WHO as a cost-effective action that should be undertaken. Hence, an intervention study targeted to reduce dietary salt intake and also to increase dietary potassium consumption by an educational intervention is needed.

Given these premises, the aim of the present intervention study was to evaluate the effect of a single very brief educational intervention "MINIMAL-ADVICE" by a physician at the first visit, for improving dietary salt and potassium intake in a hypertensive population. In addition, the effect of the educational intervention on BP in relation to the potential variation of salt and potassium intake was also evaluated.

2 Methods

2.1 Study Population

Adult hypertensive patients with essential hypertension - and assessment of organ damage - and stable antihypertensive treatment (lifestyle modifications and/or drug therapy) for at least 6 months were recruited. While, patients with alteration in nutritional and absorptive status, glomerular filtration rate lower than 60 ml/min/1.73 m², personal history positive for a recent cardiovascular event (less than 6 months), atrial fibrillation or flutter, frequent atrial or ventricular premature contractions were not recruited.

A total of 315 hypertensive patients were recruited in 12 Hypertension Clinics recognised by the Italian Society of Hypertension, and distributed in 9 Italian regions (Abruzzo, Calabria, Campania, Emilia Romagna, Lombardia, Piemonte, Puglia, Sicilia, Toscana) (between 2017 and 2020). Eventually, 230 patients (73% of all the participants involved in the study), who had a complete database at baseline and end of the observation period, were included in the analysis.

All participants gave their written informed consent to participate in the study. The local Ethics Committees

approved the study protocol. ClinicalTrials.gov registration number: NCT06651437.

2.2 Study Design

The study was designed as a multicentre parallel-group single-blind controlled randomised trial (Consort Statement-Online Resource 1) [22]. Anthropometric indexes and BP measurements were taken in the single-centre, and 24-hour urinary sodium (UrNa) and potassium (UrK) excretion were centrally measured.

2.2.1 Randomisation

After the inclusion, the randomisation procedure was carried out allocating the patients to the educational intervention (EI) or the control (C) group by a computer-generated schedule, with the number of individuals in each group balanced in blocks (10 individuals per block) for each study centre. The patients were blinded to the randomisation procedure and list.

2.2.2 Intervention

The baseline and follow-up examinations included: a fixed-sequence questionnaire about every participant's medical history and dietary salt intake; anthropometric indices and BP measurements; ambulatory blood pressure monitoring (ABPM); and 24-h urine collection (recognized gold standard for monitoring salt and potassium intake [23]). Only at the end of the baseline examination, EI participants received by a physician a brief dietary education (5 min) on the health damage due to excess salt consumption and on behavioural methods to gradually reduce dietary intake, for example at home, reduce the consumption of processed foods, do not bring salt shaker on the table, limit the use of condiments with a high sodium content; out of home, both when eating and when shopping, reduce the consumption of processed foods, check nutritional labels and choose products with lower salt content. In addition, written information was provided (Online Resource 2). By contrast, the C group did not receive any additional information on salt intake.

All participants were only clinically followed every month, with potential titration of the antihypertensive therapy. After 3 months of follow-up, the baseline measurements were carried out again.

During the entire study period, subjects were asked to maintain their lifestyle and to report the use of additional medications.

2.3 Study Procedures

2.3.1 Blood Pressure and Anthropometric Indices

Systolic and diastolic BP were measured with automatic validated devices, after having the participant sit for at least 10 min [24]. Three measurements of BP and heart rate were made at 2-minute intervals with the patient in the sitting position, and the average of the second and third readings was recorded. In addition, two measurements were made after 2 minutes in the standing position. Body weight and height were measured on a standard beam balance scale with an attached ruler. Body weight was measured to the nearest 0.1 kg, and body height was measured to the nearest 1.0 cm, with subjects wearing light indoor clothing without shoes. Body mass index (BMI) was calculated as weight (kg) divided by height squared (m²). Waist circumference (WC) was measured at the umbilicus level with the participants standing erect, the abdomen relaxed, arms at each side, and feet together. Measurements were performed with a flexible, non-extendable plastic tape to the nearest 0.1 cm.

2.3.2 Twenty-four-hour Urine Collection

After detailed and careful instructions on the day of the screening examination, participants provided a 24-hour urine collection at baseline and follow-up visits. Furthermore, the day of the screening examination they received a plastic container of 3 L. Once the collection was returned, the total volume of urine was recorded and four urine specimens were extracted after shaking. The specimens were immediately frozen: three of them were kept at -30 °C for measurement of UrNa (expression of salt intake), UrK (expression of potassium intake), and urinary creatinine (UrCr), and the fourth sample was preserved in case it was necessary to repeat the assay. The UrNa/UrK ratio was calculated by dividing UrNa by UrK. The central laboratory at "Federico II" University of Naples measured sodium, potassium, and creatinine [18]. Urinary sodium and potassium concentrations were measured by ion selective electrode potentiometry and urinary creatinine by a kinetic Jaffe reaction using an ABX Pentra 400 apparatus (HORIBA ABX, Rome, Italy). Quality control was effected using urine-specific reference samples from UrichemGol BIODÉV (Milan, Italy). Samples with a volume below 500 mL or under-collected (<22 h) / over-collected (>26 h) or with a creatinine content per kg body weight below 2 SD from the population mean were excluded from the analysis.

2.3.3 Ambulatory Blood Pressure Monitoring

ABPM was performed at baseline and follow-up visits by validated devices [24]. An appropriate-size BP cuff was applied to the non-dominant arm of each participant. Participants were encouraged to avoid strenuous activity during the period of ABPM. The device was programmed to record BP for 24 h, at 15-minute intervals during daytime (06:00–23:00 h) and 20-minute during night-time (23:00–06:00 h). A minimum of 70% usable BP recordings were considered for a valid ABPM measurement session. Mean arterial pressure (MAP) and standard deviation (SD) of the parameters were automatically provided by the software of the devices. The pulse pressure (PP) was obtained from the following formula: $PP = \text{systolic} - \text{diastolic BP}$. The degree of night-time BP dipping was calculated as $(\text{daytime MAP} - \text{night-time MAP}) * 100 / \text{daytime MAP}$.

2.3.4 Dietary Questionnaire

A validated multiple-choice questionnaire was used to comprehensively explore the knowledge (5 questions) and behaviour (10 questions) for salt and the Mediterranean diet (MD) adherence (4 questions), using a user-friendly freely accessible online survey [21]. Scores were imputed to the different possible answers in the range 0–2. The knowledge section score could range from 0 to 28, the behaviour score from 0 to 26 and the MD adherence score from 0 to 8. The higher the score the better the result.

2.4 Statistical Analysis

All statistical analyses were performed using the SPSS software (version 29.0, SPSS inc, Chicago, Ill).

The distribution of the variables was tested by Kolmogorov–Smirnov test. The Student's T-test (for normal distribution) or Mann-Whitney's test (for skewed distribution) were utilised to assess differences between baseline continuous variables. The chi-squared test was used to evaluate differences between categorical variables. Within-group and between-group comparisons of variables measured at baseline and the end of intervention were investigated using paired Student's t-test, or a non-parametric equivalent (Wilcoxon signed ranks). Pearson's or Spearman's correlation was performed to detect possible associations between the variables under study. The results were expressed as percentage or mean or geometric mean and standard deviation (SD) or (SE) as appropriate unless otherwise indicated. A two-sided p-value less than 0.05 was considered statistically significant.

Table 1 Baseline characteristics of the total study participants, and stratified by intervention

	Total	[EI]	[C]
N. of participants	230	109	121
Gender [m/f] n (%)	128 (56%)/102 (44%)	59 (54%)/50 (46%)	69 (57%)/52 (43%)
Age (yrs)	57.5 (10.6)	57.5 (10.6)	57.5 (10.6)
BMI (kg/m ²)	28.0 (3.9)	28.3 (3.9)	27.5 (3.8)
Excess body weight (%)	76	83*	70
Waist circumference (cm)	96.8 (11.5)	98.0 (10.7)	95.7 (12.1)
Central obesity (%)	54	57	52
Systolic BP (mmHg)	129.7 (13.7)	129.8 (13.2)	129.7 (14.1)
Diastolic BP (mmHg)	79.4 (10.1)	79.2 (10.0)	79.5 (10.2)
Heart rate (bpm) [†]	70.8 (10.7)	70.0 (9.7)	71.5 (11.5)
Diuretic therapy (%)	29.7	28.8	30.4

Data are expressed as means (SD) or as percentages; EI: educational intervention group; C: control group; BMI: body mass index; BP: Blood Pressure

[†]Analysis performed by the Mann–Whitney U test. *[EI] vs. [C]: $p < 0.05$

It was estimated that a total of 209 participants for each group with a similar number of men and women and balanced among centres (allowing 10% drop-out rate) was needed in this study (power: 80%, alpha error: 5%) to detect a statistically significant difference in 1 g/day of salt intake (UNa: 17.1 mmol/day, standard deviation: 60 mmol/day).

Table 2 Changes (Δ) in the participants’ main characteristics stratified by intervention

	[EI]	[C]
Participants (n)	109	121
BMI (kg/m ²)	-0.22 [0.06]*	-0.03 [0.07]
Waist circumference (cm)	-1.15 [0.37]*	-0.26 [0.30]
Systolic BP (mmHg)	-4.23 [0.92]*	-3.25 [1.07]*
Diastolic BP (mmHg)	-1.82 [7.47]*	-1.79 [7.73]*
Heart rate (bpm) [†]	-0.17 [0.76]	0.34 [0.76]

Data are expressed as means and [standard error]; BMI: body mass index; BP: Blood Pressure. EI: educational intervention group; C: control group

* $p < 0.05$ final vs. baseline

[†]Analysis performed by the Wilcoxon test

3 Results

The baseline characteristics of the whole sample and stratified by intervention are reported in Table 1. A total of 230 hypertensive participants (EI: 47%, men/women: 56%/44%) were finally included in the analysis. The sample had a mean age of 57.5 years, 76% in excess body weight, 54% with abdominal obesity, and 29.7% were taking diuretics. Moreover, UrNa was 150.3 mmol/24-h (more than 5 g of daily salt intake=90%), UrK 62.1 mmol/24-h (more than 90 mmol of daily potassium intake=31%), UrNa/UrK ratio 2.5, and a mean urinary volume of 1.8 L/24-h. At baseline, EI had a percentage of excess body weight higher

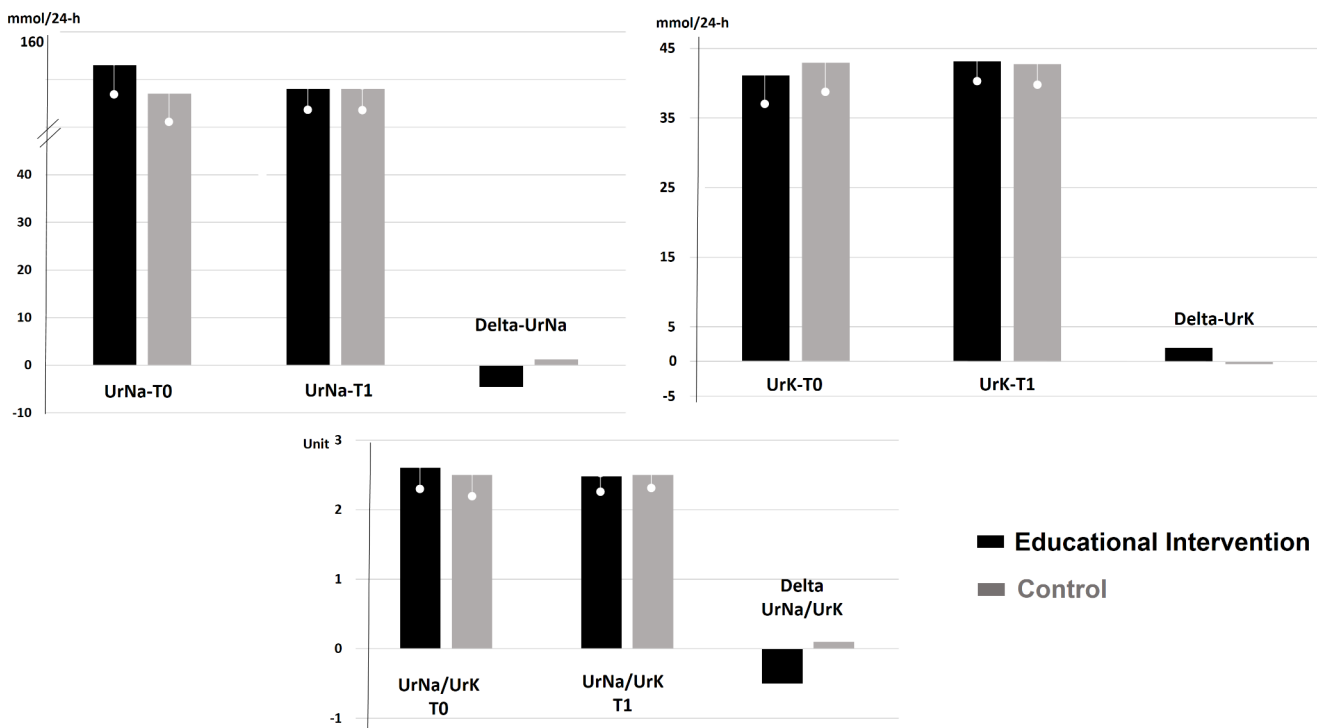


Fig. 1 Twenty-four-hour urinary excretion of sodium (UrNa), potassium (UrK), and the UrNa/UrK ratio at baseline (T0), follow-up (T1), and their changes (Delta). C: Control; EI: educational intervention.

Data were reported as median and standard error. The data were compared by the Wilcoxon test

than C (Table 1). By contrast, no significant difference was detected for age, BP, heart rate, WC, diuretics use, UrNa, UrK, UrNa/UrK ratio, and percentage of the dietary recommended intake of salt (EI: 91% vs. C: 89%) and potassium (EI: 30% vs. C: 32%) (Table 1; Fig. 1). UrNa and UrK significantly correlated in EI ($r=0.45$) and C ($r=0.42$).

After 3 months, there was a significant reduction in body weight, WC, and BP (without change in pharmacological treatment) in EI (Table 2); while a non-significant reduction in UrNa (-4.5 mmol/24-hour), increase in UrK (+1.9 mmol/24-hour), and accordingly a reduction in UrNa/UrK ratio (-0.14) were detected (Fig. 1), without adverse effects. By contrast, only a significant reduction in BP was found in the C group (Table 2), and a slightly non-significant increase in UrNa (+1.2 mmol/24-hour) and no substantial change in UrK (-0.2 mmol/24-hour), and consequently an increase in UrNa/UrK ratio (+0.07) were revealed (Fig. 1). All of these changes were not statistically different between EI and C ($p>0.05$); nevertheless, the higher BP change found in the EI group was also confirmed after adjustment for weight (or WC) at baseline and its changes during the trial (EI: -4.27 mmHg vs. C: -3.20 mmHg). Similar non-significant trends were also found after stratification by gender and baseline excess body weight or abdominal obesity or non-controlled hypertension (systolic BP/diastolic BP: $\geq 140/90$ mmHg, EI: 26% vs. C: 28%, $p>0.05$), and changes in BMI or WC at follow-up ($p>0.05$). Furthermore, no difference between EI and C in the percentage of participants with salt intake lower than 5 g/day or potassium intake more than 90 mmol/day ($p>0.05$).

Additional analyses on ABPM results confirmed the BP decreases in the EI, in total, daytime and night-time (Table 3), with a non-significant greater change than in the C group (Table 3). No difference in dipping status at baseline, follow-up and changes over the time was detected (Table 3). Of note, ABPM - BP changes were positively and significantly associated with changes in UrNa only in EI (Total MAP: $r=0.28$; day-MAP: $r=0.30$; Total systolic BP: $r=0.28$; Total diastolic BP: $r=0.34$; Day-systolic BP: $r=0.25$; Day-diastolic BP: $r=0.35$), but not in C. Similar results were also found for the relationship between UrNa/UrK ratio and ABPM-BP change values in EI (Total MAP: $r=0.25$; day-MAP: $r=0.27$; Total systolic BP: $r=0.26$; Total diastolic BP: $r=0.26$; Day-systolic BP: $r=0.23$; Day-diastolic BP: $r=0.26$). By contrast, no correlation was found with UrK.

At baseline, the scores of the questionnaire were 18.9 for knowledge, 15.0 for behaviour, and 5.2 for adherence to the Mediterranean diet. These scores were not statistically different between EI and C groups ($p>0.05$). After 3 months

Table 3 Baseline and changes in ambulatory blood pressure monitoring (ABPM) data stratified by intervention

(mmHg)	Educational intervention		Control	
	Baseline	Changes	Baseline	Changes
Total systolic BP	127.1 (10.3)	-2.0 (10.0)	125.7 (10.6)	-1.9 (9.0)
Total diastolic BP	78.3 (8.6)	-1.6 (6.5)	77.8 (7.9)	-0.7 (6.1)
Total MAP	94.7 (8.0)	-1.9 (7.4)	93.9 (7.8)	-1.1 (6.8)
Total PP	48.7 (8.0)	-0.3 (5.7)	47.9 (8.1)	-1.2 (5.1)
Day- systolic BP	130.7 (11.3)	-2.3 (11.0)	129.4 (10.8)	-2.3 (9.4)
Day- diastolic BP	81.5 (9.2)	-1.8 (7.0)	81.0 (8.4)	-0.9 (6.8)
Day- MAP	98.0 (8.5)	-2.2 (7.9)	97.2 (8.1)	-1.4 (7.4)
Day-PP	49.3 (8.5)	-0.4 (6.4)	48.4 (8.3)	-1.3 (5.3)
Night- systolic BP	117.2 (10.6)	-1.9 (10.1)	115.5 (12.3)	-0.8 (10.3)
Night- diastolic BP	70.1 (8.6)	-1.8 (7.0)	69.2 (8.7)	-0.8 (10.6)
Night- MAP	85.9 (8.1)	-1.6 (7.6)	84.9 (8.9)	-0.4 (8.2)
Night- PP	47.1 (7.9)	-0.1 (5.5)	46.3 (8.6)	-0.1 (9.3)
Dipping (%)	12.1	-0.4	12.4	-0.9

Data are expressed as means and (standard deviation); BP: blood pressure; MAP: mean arterial pressure; PP: pulse pressure

of intervention, the scores improved in both groups, but without significant differences ($p>0.05$). Of note, the score of behaviour increased more in EI than C, although not significantly (1.9 vs. 1.3, $p>0.05$), and these changes were inversely and significantly associated with UrNa at baseline ($r= -0.34$) and at final examination ($r= -0.30$) only in EI.

4 Discussion

To our knowledge, this trial is the first to investigate the effects of a single very brief counselling by a physician for improving salt and potassium intake. The main results of this RCT indicate that this educational intervention can lead to a reduction in salt intake and BP, and increased potassium consumption in hypertensive patients, without adverse effects. However, the intervention did not produce significant changes, and these results could be due to the small sample size and the short observation period. Most likely, the enrolment of around 200 participants for each group would achieve a study power of 80%, and an extension of the observation period to at least 6 months would allow consolidation of the improvements noted at 3 months.

Adequate dietary counselling led to a reduction of 1 mmHg in office systolic BP, a decrease of 5.7 mmol/24-h in salt UrNa (i.e. 0.3 g of salt intake), an increase of 2.1 mmol/24-h in UrK (i.e. 3 mmol of potassium intake), to consequent a lower UrNa/UrK ratio of 0.21. Moreover, the

analysis showed a decrease in body weight in the group of intervention, which did not affect the changes in BP. Analyses of ABPM data confirmed the results found in the office BP, to which it is added a direct significant relationship between these latter data with UrNa and the UrNa/UrK ratio. The results also suggest a better improvement of the behaviour on salt intake in EI than in the C group; this improvement was confirmed by the inverse association with salt intake.

These results are strengthened by: (a) the study design, i.e. randomised controlled trial; (b) the multicentre study enrolment; (c) the careful standardization of data collection at both baseline and final examination; (d) the use of a single very short-time dietary educational intervention delivered by a physician; (e) the measurement of 24-h urinary sodium and potassium, a recognised gold standard for monitoring salt and potassium intake [23]; (f) the ABPM availability at baseline and after 3 months of intervention; (g) the use of validated questionnaire to evaluate knowledge and behaviour about salt intake at both examinations; (h) stringent inclusion criteria; (i) no bias by pharmacological treatment (i.e., there were no changes in treatment during the trial, and the use of diuretics did not affect the results).

Salt excess is a well-known worldwide risk factor for non-communicable diseases [1]; indeed, the Global Burden Disorders Diet Collaborators indicated that high sodium intake was the leading dietary risk factor globally and in many countries [8]. In this context, a lot of studies showed the effectiveness of reducing salt intake and the cost-saving of different dietary interventions to reduce salt intake at the population level [25–27], among which are educational campaigns and food and menu labelling.

Unfortunately, despite these initiatives over the years, the average daily salt intake of the Italian general adult population remains higher than the recommended level [18, 28], even if slightly reduced in the past ten years [29], as well as that of hypertensive individuals [19, 20] and confirmed by our results (90% of the participants daily consumed more than 5 g of salt). At the same time, despite campaigns in favour of increasing the consumption of fresh plant-based foods (i.e. potassium-rich foods) to prevent cardiovascular diseases [30], dietary potassium intake was not increased in general and hypertensive people [19, 31], as well as confirmed in our sample (only 31% of the participants daily consumed more than 90 mmol of potassium). Therefore, in addition to the government initiatives aimed at the reduction of salt and increase potassium intake at the population level, the implementation of the support in this way at visit examination plays a key role, in particular in patients with cardiovascular risk (e.g. hypertensive patients). Indeed, our

results point out the benefits of a single very short-time dietary educational intervention delivered by a physician, during the first visit, on salt and potassium intake, as well as the favourable effect on BP and, hence on cardiovascular risk.

Of note, several experimental approaches have been adopted to achieve improvement in salt and potassium intake with reasonable results, among which one of the most promising seems to be the use of potassium-enriched salt substitutes (75% sodium chloride and 25% potassium chloride) in place of sodium chloride salt (100% sodium chloride), which proved to be associated with a reduction in cardiovascular events in large populations [32].

The results of the questionnaire about salt confirm the beneficial trend of the educational intervention, given that knowledge is essential to put in practice healthy diets [33]. In particular, the results of the questionnaire show that baseline knowledge and behaviour about salt intake are substantially similar to the general population [21]. While, after the educational intervention there was a non-significant improvement of the behaviour score greater in EI than C. Of note, this effect was supported by the inverse and significant association with UrNa only in EI.

A recent trial explored the effect of self-performed dietary sodium reduction in hypertensive people (Intervention $n=48$ vs. control $n=24$) after an oral dietary advice and written material on how to decrease sodium intake [34]. The main results showed a significant decrease in 24-hour BP of 9/5 mmHg compared with a control group, after 4 weeks. In addition, a significant reduction in UrNa and increased UrK were revealed. Also, body weight was affected, indeed a significant weight reduction was achieved in the intervention than control group. Our results are consistent with those of Duus et al.; however, their study primarily focused on evaluating changes in BP, while our first purpose was to improve salt and potassium intake. In addition, to enhance adherence, participants in the intervention group were contacted by phone once a week, whereas our findings are based on a single brief counselling session. Furthermore, the smaller sample size, different inclusion criteria, and randomisation module, the very short follow-up period, and the relatively extended duration of oral dietary advice in Duus et al.'s study prevent us from directly comparing the main results. Finally, their paper provided no information regarding the relationship between UrNa or UrK and BP changes.

Our results, however, have some limitations to highlight: (i) the small sample size did not permit the achievement of a statistically significant difference, because it may cause an underestimation of the effect - of note, the restrictions of the COVID period affected the recruitment

and the management of the study [35] -; (ii) the UrNa and UrK were assessed only before and after, and not during the intervention; (iii) no definitive conclusions about the long-term effects of sodium intake restriction and increase in dietary potassium on cardiovascular risk can be drawn; (iv) finally, the exclusion of patients with glomerular filtration rate < 60 ml/min/1.73 m² may also represent a limitation; however, the different sodium handling in these individuals compared to those with a glomerular filtration rate > 60 ml/min/1.73 m², together with the specific dietary recommendation (i.e., restricted protein and sodium intake) could have introduced a bias [36]. Indeed, the results of a randomized trial in chronic kidney disease patients confirm this difference, demonstrating that an intervention of dietary sodium reduction guided by self-measurement of urinary chloride produced a significant but modest difference in UrNa between the intervention and the control arm and no difference in ABPM and in-office BP [37].

5 Conclusions

The results of our multicentre randomised controlled trial indicate that a single very short-time dietary educational intervention delivered by a physician or general healthcare worker can improve salt and potassium intake, and reduce BP. These data support the importance of adequate dietary counselling during the visit to contribute to the reduction of cardiovascular risk in hypertensive patients, suggesting that educational advice is crucial for the implementation of a therapeutic approach.

Although our intervention did not achieve significant changes in salt and potassium intake, and BP, the positive trends support and encourage the initiatives aimed at the reduction of salt intake and the increase of dietary potassium intake both at the population level and in the management of patients with cardiovascular risk. Nevertheless, further randomised controlled trials with a greater sample size and with a long length of intervention are needed to confirm this trend.

Supplementary Information The online version contains supplementary material available at <https://doi.org/10.1007/s40292-025-00704-1>.

Author contributions Conceptualization: FG, PS, LD; Data acquisition: all authors; Data curation: LD, FG; Formal analysis: LD, FG; Methodology: LD; Project administration: FG; Software: LD; Supervision: FG; Validation: FG; Visualization: LD, FG; Writing—original draft: LD, FG; Writing—review & editing: all authors; full approval of the manuscript: all authors.

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Declarations

Conflict of interest The authors declare that they have no conflict of interest.

Ethics Approval The study protocol was approved by the local Ethics Committees (“Federico II” University of Naples - Ethics Committee, registration number: 55/16).

Consent to Participate All participants gave their written informed consent to participate in the study.

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