#### ARTICLE



# Effect of monitoring salt concentration of home-prepared dishes and using low-sodium seasonings on sodium intake reduction

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#### Abstract

**Background/objectives** Objective methods such as the monitoring of salt concentrations in home-prepared dishes may be effective in reducing salt intake. We investigated the effect of monitoring the salt concentration of home-prepared dishes (Monitoring) on salt reduction and change in taste threshold, and the effect of the simultaneous use of low-sodium seasonings (Seasoning) to compare the effect of Monitoring with the conventional method.

**Subjects/methods** We conducted a double-blind randomized controlled study using a  $2 \times 2$  factorial design with two interventions. A total of 50 participants (40–75 years-old) were recruited among residents of Niigata Prefecture, a high sodium-consuming population in Japan, then randomly allocated to four groups. After excluding participants with incomplete urine collection, change in salt intake was evaluated using 24-hour urinary excretion as a surrogate of intake for 43 participants. Change in taste threshold was evaluated in 48 participants after excluding those with incomplete threshold measurement.

**Results** The Monitoring intervention group showed a significant decrease in sodium intake (-777 mg/24 h), whereas the decrease in the Seasoning intervention group was not significant (-413 mg/24 h). Sodium intake did not statistically differ between the intervention and control groups (-1011 mg/24 h) and -283 mg/24 h for Monitoring and Seasoning, respectively). The changes in taste threshold measurement were very small and did not markedly differ between groups. **Conclusions** Monitoring the salt concentration of dishes had a potentially stronger salt-reducing effect than the use of low-sodium seasonings, a conventional method. Confirmation requires additional study with a larger sample size.

Ribeka Takachi is a principal investigator.

**Electronic supplementary material** The online version of this article (https://doi.org/10.1038/s41430-017-0053-2) contains supplementary material, which is available to authorized users.

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# Introduction

A high-salt intake remains a major risk factor for cardiovascular diseases such as hypertension, cardiac infarction, and stroke, as well as gastric cancer [1-3]. Mean salt intake among Japanese was recently calculated to be 10.2 g [4], a reduction from the mean of 14.5 g in the 1970s but still greater than in western populations (mean salt intake of

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United States [US] citizens, 8.5 g; National Health and Nutrition Examination Survey-NHANES, 2007–2008).

In 2010, the Institute of Medicine of the National Academies recommended strategies to ensure a major reduction in salt intake in the US [5]. The report proposed that including the salt content of processed and restaurant/foodsupply foods as a food additive under US Food and Drug Administration regulations would reduce salt intake. However, while approximately 80-85% of Americans' salt intake is derived from processed and restaurant foods [5], only about 30% of Japanese dietary salt intake is obtained via these routes [4], and it remains unclear whether adopting the same strategy for processed and restaurant foods (except for seasonings) in Japan, where home-cooking is still popular, would be as effective as in the US. Salt intake from salty seasonings, such as soy sauce and miso, account for 66.0% of the total intake among the Japanese, according to the National Health and Nutrition Survey in Japan [4], and the contribution in home-cooked meals is even higher for other Asian countries, such as in China (82.2%; vs. Japan 51.7%) [6]. Reducing salt intake by reducing intake of these seasonings might therefore help to achieve a total salt reduction in Asia. Novel methods are, therefore, needed to reduce intake in Asian populations, which predominantly use home-cooking.

Because salt intake derived from seasonings is based on factors such as individual preference and taste threshold [7– 9], self-recognition of taste preference can be difficult. Such difficulties might have hampered previous dietary education efforts aimed at salt reduction. Moreover, while tailored dietary education to reduce sodium based on individualized assessment by dietitians is effective [10], implementation of these methods on a population basis is difficult.

Self-monitoring of the salt concentration of a homecooked meal can aid recognition of actual saltiness preference, facilitating salt reduction. Given that Japanese have a higher mean salt intake than western populations, establishing an easy-to-implement, concrete, and reproducible method of salt reduction education will be crucial to the development of an efficient education plan for this population. Further, the basic statistics required to calculate the sample size necessary for interventional studies of this methodology have not yet been determined.

Here, we conducted a randomized controlled trial to evaluate the salt-reducing effect of monitoring the salt concentration of home-prepared dishes by comparison with the conventional method of using low-sodium seasonings. In addition, we evaluated the effect of these interventions on the taste threshold for saltiness. A further goal of this study was to obtain basic statistics for sample size calculation and evidence for reproducible, concrete, and easy-to-implement methods of reducing salt intake among Japanese.

# Subjects and methods

# Study design and participants

A pilot study for a randomized, controlled, cross-over study was conducted from November 2013 to August 2014. Participants of the study were volunteers aged 40-75 years who were living in Niigata Prefecture and did not have sov allergy or use anti-hypertensive medication. We dispensed flyers inviting participation through public health centers, local co-op societies, and so on. For sample size calculation, we tentatively presumed a reduction in sodium of 750 mg, based on the target value in Health Japan 21 (second term) determined by the Japanese government, as well as the values used by previous observational and intervention studies [9-12]. We calculated that 100 subjects would be necessary to demonstrate a 750-mg decrease in sodium intake, assuming an  $\alpha$  error = 0.05,  $\beta$  error = 0.20, and dropout rate of 10% after randomization. We, therefore, recruited 50 participants, given that the sample size would be doubled by the cross-over design. All participants gave written informed consent to participate in this randomized intervention study for low-sodium seasoning. Simple randomization was made using random numbers generated by an SAS function. The study was double-blinded so that neither the participants nor investigators knew the allocation of intervention during the intervention, evaluation, and analyses. The random allocation sequence was generated by one of the co-authors (MI) who was not involved in the conduct of the study, while the enrollment and assignment of participants to inventions was done by the research coordinating office of Niigata University. The random allocation was sent to this office as an electric file, and was implemented and maintained by a research coordinator until all procedures of the trial were completed, including statistical analysis.

This study was registered with the UMIN clinical trials registry (UMIN-CTR, identification number UMIN000012560). The study received approval from the institutional review board of Niigata University School of Medicine and the National Cancer Center, Tokyo, Japan (No. 1698, on 10 July 2013).

## Intervention

The study used a  $2 \times 2$  factorial design with two types of intervention: (1) monitoring of salt concentration of homecooked dishes (Monitoring); and (2) use of low-sodium seasoning without regard to the amount (Seasoning). We randomly allocated the 50 subjects who consented to participate into four groups, as follows: Monitoring salt concentration and use of low-sodium seasoning; Monitoring salt concentration and use of regular seasoning; No monitoring of salt concentration and use of low-sodium seasoning; and No monitoring of salt concentration and use of regular seasoning (Figs. 1 and 2). Family members of the same household were allocated to the same group.

We provided a measuring instrument (Digital Salt Meter Model SK-5SII; Sato Keiryoki Mfg. Co., Ltd., Tokyo, Japan) to the Monitoring intervention group and asked these participants to use this instrument to measure the salt concentration of home-cooked soup dishes, with a focus on miso soup, at least once a week. We instructed participants on how to use the measuring instrument at baseline, and to use it after receipt at their convenience once a week. Regardless of grouping, all participants were given general education on salt reduction [13]. In the Seasoning intervention group, commercially available low-sodium seasoning was provided to the intervention group, and regular sodium seasoning was provided to the control group as placebo. Salt concentrations of the low-sodium miso and soy sauce were approximately 7% each, vs. concentrations in regular miso and soy sauce of 11–12% and 14.5%, respectively. During the intervention period, the participants were instructed to use these monthly-delivered seasonings when preparing dishes.



Fig. 1 Study scheme (urinary excretion as outcome)



Fig. 2 Study scheme (taste threshold as outcome)

Table 1 Characteristics of study participants at baseline

	Monitoring			Low-sodium seasoning			
	Intervention $(n = 28)$	Control $(n = 22)$	<i>p</i> -value <sup>a</sup>	Intervention $(n = 24)$	Control $(n = 26)$	<i>p</i> -value <sup>a</sup>	
Sex (% female)	67.9	72.7	0.71	75	65.4	0.46	
Age (years) <sup>b</sup>	55.9 (7.9)	50.1 (7.7)	0.03	54 (9.4)	53.5 (7.1)	0.83	
Weight (kg) <sup>b</sup>	59.5 (10.3)	58.5 (12.3)	0.75	59.2 (11.1)	58.9 (11.3)	0.94	
Current smokers (%)	10.7	27.3	0.13	12.5	23.1	0.33	
Alcohol drinkers (%)	67.9	68.2	0.98	62.5	73.1	0.42	
Use of medications (%)	32.1	13.6	0.13	29.2	19.2	0.41	
Other intervention (%) <sup>c</sup>	50.0	45.5	0.75	58.3	53.8	0.75	

 $^{a}p$ -value for comparison between groups was performed using the Chi-square test. Age and weight p-value for comparison between group was performed using the *t*-test

<sup>b</sup>Values are means (standard deviation)

<sup>c</sup>Percentage of Low-sodium seasoning group within the groups of Monitoring, or vice versa

To blind the intervention, participants were not informed about which type of seasoning they received. All seasonings included a label with an expiration date and the manufacturer, but no information regarding sodium content so that the participants would not find out which type of seasoning they received. We also informed participants that the primary purpose of the intervention was the intervention for Seasoning, and not Monitoring. We suggested that they started using the measuring instrument when they received it at some time during the study. In fact, the intervention group received the instrument before the intervention started, and the control group did so after the final evaluation. We also asked participants not to exchange information with other participants.

The intervention periods were 3 months for each crossover period, with a 1-month washout period between. After the completion of the first period of the cross-over, the second period followed. During the washout period, we asked participants to discard all seasonings provided during the first cross-over period and use their usual seasonings at home. We collected outcome data (24-h urine sample, taste threshold measurement, anthropometric and lifestyle information) at baseline and after each intervention (three times in total). We used the second outcome data after the first cross-over period as a baseline for the second cross-over period.

# **Evaluation methods**

As primary outcome, we used 24-h urinary sodium excretion as a surrogate for salt intake. Urine was sampled using a 24-h urine proportional collecting device (1/50 portion of the total urine volume; U-container, Precise Urine Measurement Device, Sumitomo Bakelite Co., Ltd., Tokyo, Japan) [14].

As secondary outcome, we used the taste threshold for saltiness as an index of taste preference change. Evaluation was done 1-2 h after a meal using filter papers impregnated with 13 different concentrations of salt (NaCl) at 0-1.6 mg/ cm<sup>2</sup> (Salsave<sup>®</sup>; Toyo Roshi Kaisha, Ltd., Tokyo, Japan) as previously described [15, 16]. We specially ordered concentration of NaCl at 0.05, 0.1, 0.2, 0.3, 0.4, and 0.5 mg/ cm<sup>2</sup> in addition to the commercially available Salsave<sup>®</sup> (0.6 to  $1.6 \text{ mg/cm}^2$  by 0.2-unit increments) to try to capture the subtle taste threshold change for healthy subjects who had low to normal taste thresholds. We asked participants to fast for 1-2 h before they arrived at the test site and confirmed the time of their last meal. We also asked smokers to avoid smoking for at least 1 h before the test and checked the time point at which they had last had a cigarette. Participants rinsed their mouths with water before testing and placed a strip saturated with sodium chloride on their tongue for 3 s. We then asked them if they recognized saltiness, sourness, sweetness, bitterness, umami (savory taste), spiciness, or no taste (actual option was only saltiness). We started with a 0% concentration and then increased the salt concentration of the strip until participants detect saltiness twice in a row. We prepared a manual for the procedure and trained several staff to administer the test. The trained staff did not know the allocation of the intervention.

Other outcome measures included changes in taste preference and salt intake habits before and after the interventions, assessed using a questionnaire, as well as any changes in body weight.

## **Statistical analysis**

We compared the difference in changes after each intervention between the intervention and control groups with regard to salt intake reduction and taste threshold changes. and

Table 2 Means of sodium intake and taste threshold at baseline and post-intervention, change between baseline and post-intervention, and difference in change between the intervention

control groups in monitoring and low-sodium intervention (period 1)

	Inte	rvention group			Cont	rol group			Difference <sup>a</sup>
	и	Baseline <sup>b</sup>	Post-intervention <sup>b</sup>	Change <sup>c</sup>	и	Baseline <sup>b</sup>	Post-intervention <sup>b</sup>	Change <sup>c</sup>	
Sodium (mg/24 h)									
Monitoring	25	4880 [330]	3844 [321]	-777 [-1838, -285]	18	4170 [371]	4197 [475]	235 [-985, 1455]	-1011 [-2285, 263]
Low-sodium seasoning	21	4658 [381]	3781 [322]	-413 [-1601, 776]	22	4658 [381]	3781 [322]	-129 $[-1190, 931]$	-283 $[-1495, 928]$
Taste threshold (mg/cm <sup>2</sup> )									
Monitoring	26	0.590 [0.129]	0.735 [0.141]	-0.117 [ $-0.504$ , $0.270$ ]	22	0.916 [0.153]	0.893 [0.143]	-0.345 [ $-0.751$ , $0.061$ ]	0.228 [-0.244, 0.700]
Low-sodium seasoning	23	0.698 [0.133]	$0.884 \ [0.148]$	-0.129 [ $-0.522$ , $0.264$ ]	25	0.778 [0.152]	0.736 [0.137]	-0.332 [-0.712, 0.048]	0.203 [-0.232, 0.639]
<sup>a</sup> Change in group difference	s is ind	licated by the lea	ist squares mean [959	% confidence interval]					
<sup>b</sup> Sodium intake and taste th	resholc	I (unadjusted val	ues) for baseline and	post-intervention are indic	cated	by mean [standa	d error]		

<sup>c</sup>Change values are the least squares mean [95% confidence interval]. Values were obtained by subtracting baseline values from post-intervention values for each

Although we planned to combine data from both periods for the analysis, we were unable to do so because of the carrying effect in the second half, and analysis was, therefore, restricted to data from the first half-period only. The results of the second half-period are shown in the Supplemental Tables 1 and 2.

To analyze the urinary excretion of sodium, we excluded participants with two or more missing urine samples. We excluded seven participants with incomplete urine collection as it was pre-defined in the study protocol in accordance with that of our previous study [9] (Fig. 1). For the taste threshold, we used the lowest salt level a participant identified as salty at least twice in the test as the effective value. Test data from two participants were incomplete and, therefore, excluded from analysis (Fig. 2).

For the statistical analysis, we used SAS 9.3 for Windows (SAS Institute Japan Ltd., Tokyo, Japan) and R software, version 3.4.0 (www.r-project.org). Participant characteristics were analyzed using the  $\chi^2$  test and *t*-test. The differences in changes after the interventions were calculated as the least squares mean, and we performed an analysis of variance (ANOVA) adjusted for sex, age, smoking habit, alcohol drinking, current medications except for anti-hypertensive medications, other interventions, and interaction term of the interventions. Significance level was set at < 5%.

# Results

Characteristics of the study participants are described in Table 1. A significant difference was observed in the mean age of intervention and control participants in Monitoring. No statistically significant differences in any other variables were found for either of the interventions.

Unadjusted difference (standard deviation: SD) in sodium intake between the intervention and control groups was -1063 (1943) and -559 (1943) mg/24 h for Monitoring and Seasoning, respectively (data not shown). The changes in sodium intake and taste threshold after the Monitoring and Seasoning intervention and the differences between the intervention and control groups are indicated by least squares mean in Table 2. The Monitoring intervention group showed a significant decrease in sodium intake (-777 mg/24 h), whereas that for the Seasoning intervention group was -413 mg/24 h. Sodium intake between the intervention and control groups did not statistically differ (-1011 mg/24 h and -283 mg/24 h for Monitoring and Seasoning, respectively). The changes in taste threshold measurement were very small and did not markedly differ between the control and intervention groups.

Results from ANOVA indicated that neither Monitoring nor Seasoning produced a statistically significance effect on

	Coefficient	Sum of squares	df	Mean square	F- value	p value
Sodium intake <sup>a</sup>						
Monitoring (ref = none)	66.96	18543525.5	2	9271762.7	2.69	0.08
Low-sodium seasoning (ref = none)	795.11	12760884.8	2	6380442.4	1.85	0.17
Sex (ref = male)	614.72	2279720.6	1	2279720.6	0.66	0.42
Age	75.5	13506767.5	1	13506767.5	3.92	0.06
Smoking status (ref = none)	1722.8	9572145.2	1	9572145.2	2.78	0.10
Alcohol consumption (ref = none)	-998.69	103786.8	1	103786.8	0.03	0.86
Medications (ref = none)	-115.51	5473740.3	1	5473740.3	1.59	0.22
Monitoring*Low-sodium seasoning	-2156.75	10226249.7	1	10226249.7	2.97	0.09
REGRESSION	_	41398282.6	8	5174785.3	1.5	0.19
ERROR	_	117237683.3	34	3448167.2	_	_
Taste threshold <sup>b</sup>						
Monitoring (ref = none)	-0.0947	1.535667324	2	0.767833662	1.59	0.22
Low-sodium seasoning (ref = none)	-0.2983	1.195254618	2	0.597627309	1.23	0.30
Sex (ref = male)	-0.0684	0.028212826	1	0.028212826	0.06	0.81
Age	-0.0181	0.746799034	1	0.746799034	1.54	0.22
Smoking status (ref = none)	-0.9152	2.701280205	1	2.701280205	5.58	0.02
Alcohol consumption (ref = none)	0.307	0.694098706	1	0.694098706	1.43	0.24
Medications (ref = none)	-0.0157	0.001342525	1	0.001342525	0	0.96
Monitoring*Low-sodium seasoning	0.7029	1.061483702	1	1.061483702	2.19	0.15
REGRESSION	_	6.083370567	8	0.760421321	1.57	0.17
ERROR	_	15.98621277	33	0.48443069	_	_

Table 3 ANOVA summary table: effects of monitoring and low-sodium seasoning intervention on sodium intake and taste threshold (period 1)

<sup>a</sup>Change in sodium intake was used as the dependent variable

<sup>b</sup>Change in taste threshold was used as the dependent variable

sodium intake and taste threshold (Table 3). There were no interactions between interventions (Monitoring and Seasoning) in both salt intake and taste thresholds.

# Discussion

We conducted a pilot study for a randomized controlled cross-over trial to evaluate the salt-reducing effect of monitoring the salt concentration of home-cooked dishes and the use of low-sodium seasoning on the change in sodium intake and taste preference for saltiness. The saltreducing effect achieved by monitoring the salt concentration of home-prepared dishes was stronger than that by the consumption of low-sodium seasoning. Neither intervention had any marked effect on taste threshold.

Although salt intake decreased with both interventions, the degree of reduction was greater with the Monitoring. We observed a reduction in salt after 3 months with the Seasoning intervention, which was consistent (approximately 550 mg/24 h Na reduction, equivalent to 1.4 g salt, unadjusted value) with a 1-week seasoning intervention in a previous study [17]. To our knowledge, this is the first report to indicate that monitoring salt concentration at home may be an effective method for reducing salt intake, even compared with conventional salt reduction methods such as the use of low-sodium seasonings. Although the effect was not statistically significant with either intervention because of the exploratory pilot design of the study, with sample size calculated based on tentative statistics, the present findings will be useful for determining the optimum sample size and study design of future studies.

Previous cross-sectional studies have measured taste threshold using salt-impregnated filter paper as a simple evaluation method [15, 16, 18]. Taste threshold at baseline in the current study was slightly lower than the values noted in these previous studies (this study: 0.79 mg/cm<sup>2</sup>, Maruyama et al.: 0.97 mg/cm<sup>2</sup>) [15]. Changes in taste threshold did not markedly differ between groups with either intervention in the present study, likely because the variation ranges were small. However, self-reported measurement of threshold is rather subjective, which potentially hampers the clear identification of changes over such a short period. Relatively few studies have examined the association of salt intake with taste threshold and salty taste preference [9, 19– 21], and further studies on methods of altering the sense of taste may be necessary.

The findings of this study suggest that monitoring salt concentration in home-cooked foods is an objective, reproducible, and easy-to-implement method for reducing salt intake among those who eat at home. We also obtained basic statistics for determining sample size in future studies on the efficacy of monitoring in reducing salt intake. Because this was the first study to investigate the effect of Monitoring, basic statistics to calculate sample size were not available prior to the study. In fact, one of the purposes of this pilot study was to obtain the mean difference of change and standard deviation to calculate sample size. Using the mean difference (-1063 mg Na/day) and SD (1943) of change in the monitoring of salt concentration between groups from the current study, we determined that a sample size of 168 participants would be required for future studies ( $\alpha$  error = 0.05, power = 90%). We also identified an exclusion rate of 14%, giving a necessary sample size of 198 (data not shown).

Several limitations of our study warrant mention. First, the sample size was too small, which resulted in insufficient power in the statistical analyses. Because of the carrying effect produced by the learning effect from the intervention in the first half of the cross-over among the Monitoring arm subjects, we were unable to use the data of the second half of the cross-over, which ultimately gave us half the sample size that we originally planned. Through this experience, we learned that future studies should not involve a cross-over design for this particular intervention. Second, the participants in the present study were from Niigata Prefecture, which is well-known for excessive salt intake. Most families in this area follow traditional Japanese dietary habits: meals are primarily prepared at home, and eating out is relatively infrequent. This background may restrict the generalizability of this salt reduction method to more urbanized areas of Japan. Further investigation of the effects of this method on salt intake in other populations may be necessary.

In conclusion, monitoring the salt concentration of home-prepared dishes and the use of low-sodium seasonings are feasible and objective methods of reducing salt intake in Japanese. We found that monitoring the salt concentration of dishes had a potentially stronger saltreducing effect than the use of low-sodium seasonings, which is a known method for reducing sodium intake. In addition, the study provided basic statistics of the saltreducing effect achieved by monitoring salt concentration using a salinometer. Taken together, our findings suggest that the monitoring method is likely to be effective in reducing salt intake in Japanese population.

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#### Compliance with ethical standards

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

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