

ORIGINAL ARTICLE

Salt sales survey: a simplified, cost-effective method to evaluate population salt reduction programs—a cluster-randomized trial

Yuan Ma^{1,2,3}, Feng J He³, Nicole Li², Jesse Hao², Jing Zhang², Lijing L Yan^{2,4} and Yangfeng Wu^{1,2,5}

Twenty-four-hour urine collection, as a gold standard method of measuring salt intake, is costly and resource consuming, which limits its use in monitoring population salt reduction programs. Our study aimed to determine whether a salt sales survey could serve as an alternative method. This was a substudy of China Rural Health Initiative-Sodium Reduction Study (CRHI-SRS), in which 120 villages were randomly allocated (1:1:2) into a price subsidy+health education (PS+HE) group, a HE-only group or a control group. Salt substitutes (SS) were supplied to shops in the intervention groups; 24-h urine was collected from 2567 randomly selected adults at the end of the trial to evaluate the effects of the intervention. Ten villages were randomly selected from each group (that is, 30 villages in total), and 166 shops from these villages were invited to participate in the monthly salt sales survey. The results showed that during the intervention period, mean monthly sales of SS per shop were 38.0 kg for the PS+HE group, 19.2 kg for the HE only and 2.2 kg for the control group ($P < 0.05$), which was consistent with the results from the 24-h urine sodium and potassium data. The intervention effects of CRHI-SRS on sodium and potassium intake estimated from SS sales were 101% and 114%, respectively, of those observed from the 24-h urine data. Furthermore, the salt sales survey cost only 14% of the cost of the 24-h urine method and had greater statistical power. The results indicate that a salt sales survey could serve as a simple, sensitive and cost-effective method to evaluate community-based salt reduction programs in which salt is mainly added by the consumers.

Hypertension Research (2016) 39, 254–259; doi:10.1038/hr.2015.139; published online 10 December 2015

Keywords: China; methodology; salt intake; salt reduction; salt substitute

INTRODUCTION

It is well established that a high salt (sodium chloride, 1 g salt = 0.4 g sodium) intake is a major cause of high blood pressure and could lead to cardiovascular diseases.^{1–3} Salt reduction, which is one of the key targets of the World Health Organization (WHO),⁴ is a widely accepted, cost-effective population intervention to prevent cardiovascular disease worldwide.⁵ In China, the average salt intake in adults is ~12 g per day,⁶ which is more than double the WHO-recommended level of 5 g per day. With more than one in six adults having hypertension⁷ and with one of the world's highest morbidity and mortality rates owing to stroke,⁸ it is imperative for China to develop population-based salt reduction strategies to reduce the burden of disease attributed to hypertension and other related diseases. Although such strategies have been considered and developed in some areas,^{9–11} it remains unclear how to best measure their effects in a simple and reliable manner. Twenty-four-hour urine collection is the 'gold standard' method to measure the effects of salt reduction in

clinical trials and salt intake in epidemiological studies.¹² However, its complexity, high cost, high participant burden and the challenge of collecting and assessing 24-hour urine limit its application in large-scale population salt reduction programs, which often involve tens of thousands or even millions of participants.^{9,11} This in turn impedes the successful translation of effective salt reduction strategies into programs for large populations. Recently, much attention has been given to finding cheaper and less burdensome alternatives to 24-hour urine collection, such as spot urine,¹³ timed-spot urine^{14,15} and dietary methods;¹⁶ however, this issue remains controversial.^{17,18}

In this study, we aimed to determine whether a salt sales survey could serve as a simplified cost-effective method to evaluate large-scale community-based salt reduction programs at the population level.

METHODS

China rural health initiative-sodium reduction study

The China rural health initiative-sodium reduction study (CRHI-SRS) was a cluster-randomized controlled trial conducted in 120 villages in 10 counties

¹Department of Epidemiology and Biostatistics, Peking University School of Public Health, Beijing, China; ²The George Institute for Global Health, Peking University Health Science Center, Beijing, China; ³Wolfson Institute of Preventive Medicine, Barts and The London School of Medicine and Dentistry, Queen Mary University of London, London, UK; ⁴Global Health Research Center, Duke Kunshan University, Kunshan, China and ⁵Peking University Clinical Research Institute, Beijing, China

Correspondence: Dr Y Wu, The George Institute for Global Health, Peking University Health Science Center, Level 18, Tower B, Horizon Tower, No. 6 Zhichun Road, Haidian District, Beijing 100088, China.

E-mail: ywu@georgeinstitute.org.cn

Received 27 May 2015; revised 15 September 2015; accepted 18 October 2015; published online 10 December 2015

from five provinces in northern rural China, the protocol of which has been published elsewhere.¹¹ The objective of this trial was to investigate whether population-level salt reduction could be achieved by the social marketing of a salt substitute (SS) in rural China. One hundred twenty villages were randomly allocated to either an intervention group (60 villages) or a control group (60 villages). In the intervention group, the SS (65% NaCl, 25% KCl and 10% MgSO₄) was made available to the village shops, and residents in the villages could choose to buy either regular salt or SS. In addition, health education that focused on salt reduction and targeted the whole village population was implemented by trained local health educators according to a standardized protocol. During the education, the health educators also described medical situations that were not suitable for using the SS. Within the intervention group, 30 villages were further randomized to receive price subsidy coupons that allowed families to buy SS at the same price as regular salt (PS+HE intervention group). The other 30 villages received the same intervention but were not provided with the coupons (HE intervention-only group). The 60 villages in the control group received no intervention. All the randomization was stratified by county (see Figure 1).

The first health education activities were launched in May 2011 and the last were held in September 2012; the supply of SS to the intervention groups began in May 2011 and continued until December 2012. To comply with government regulations, the SS was supplied to only registered shops holding a retail license.

To evaluate the effects of the CRHI-SRS interventions, a total of 2567 adults from the 120 villages (about 20 adults from each village) were randomly sampled with stratification by age and gender and were invited to collect one 24-h urine at the end of the intervention. Of those invited, 1903 participants had a 24-h urine sample collected that was complete and were included in the analysis according to the following criteria: urine samples were excluded if participants reported missing the first morning void, missing more than one void, a collection period less than 22 h or longer than 26 h, or spilling more than 10% of the total volume. Samples contaminated with feces were also excluded as were collections that had a volume of less than 500 ml or greater than 6000 ml, or a 24-h creatinine excretion of less than 4 mmol or greater than 25 mmol for women and less than 6 mmol or greater than 30 mmol for men.¹⁹

Salt sales substudy

As a substudy of the CRHI-SRS, we randomly selected 10 villages from each group, that is, 10 from the PS+HE group, 10 from the HE group and 10 from the control group with stratification by county (that is, one village from one county in each group, and 30 villages in total). The mean population was 1878 ± 604 per village. We also invited all the 166 village shops holding retail licenses in these 30 villages to participate in the SS sales survey. Of the 166 shops, 129 shops participated in the monthly telephone sales survey (see Figure 1 for details). All the shopkeepers were interviewed via monthly telephone calls by an independent researcher from Beijing using a structured questionnaire from July 2012 to June 2013. Data collected included the amount of SS in stock at the time of the phone call and the amount purchased by the shopkeeper since the previous phone call. The study design and participant flow chart for this substudy are shown in Figure 1. The SS sales for a specific month were defined by the following formula.

Formula 1: SS sale of month_n (kg) for Shop X = Amount of SS in stock at month_{n-1} (kg) – Amount of SS in stock at month_n (kg) + Amount of SS the shop purchased in the past month from salt suppliers (kg).

The amount of SS in stock at month_n was the amount of SS available in the shop at the time of the phone call in month_n. Similarly, the amount of SS in stock at month_{n-1} represented the SS available at the time of the previous month's phone call.

Ethics

This study was approved by the Peking University Institutional Review Board, and written informed consent was obtained from all the study participants.

Statistical methods

We compared the salt sales survey method to the gold standard method (that is, 24-h urine collection) in terms of validity, cost and statistical power to evaluate the salt sales survey.

To evaluate the validity of the proposed method, we first calculated the average monthly SS sales per shop (kg) using formula 1 for each of the three study groups (HE+PS, HE only and control) at each month to observe the possible intervention effects and any trends over the study period (see Figure 2). We further divided the whole study period into two phases. Phase 1 was

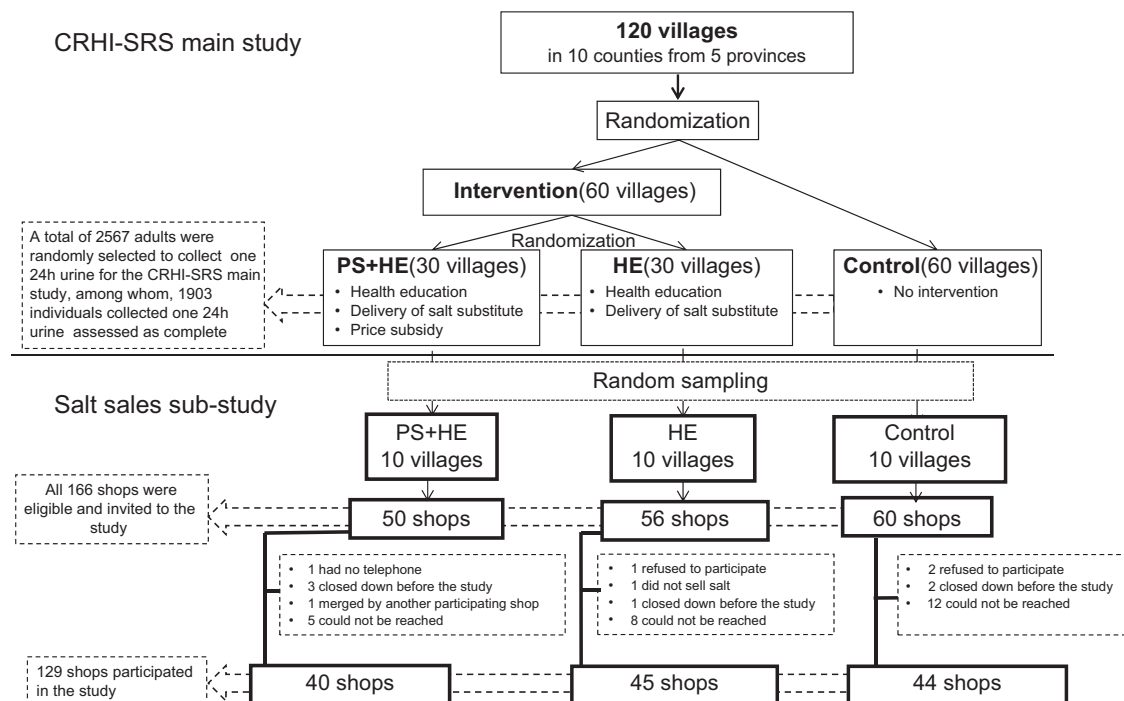


Figure 1 Trial profile. CRHI-SRS, China rural health initiative-sodium reduction study; PS+HE, price subsidy+health education.

defined as the intervention period, from August 2012 to January 2013 (1 month after the final delivery of subsidy coupons), during which the intervention took place. Phase 2 was defined as the post-intervention period, from February 2013 to June 2013, when the interventions had ended. The mean monthly SS sales per shop were further calculated and compared between groups for Phase 1 and Phase 2 respectively using a generalized linear mixed model to allow for the dependence of repeated measurements as well as a cluster effect, adjusting for village population in the model. The same model was used to compare the difference in 24-h urinary sodium and potassium excretion between the three groups. Urinary data of study participants from all the 120 villages and those from the 30 villages participating in the substudy were analyzed (Table 1 and Figure 3).

In theory, if total salt (regular salt+SS) consumption remained unchanged and regular salt sales were replaced by the same amount of SS during the intervention period, we would be able to calculate the effect of the CRHI-SRS intervention (differences in sodium intake between groups) from the SS sales data (that is, the differences in SS sales between groups). Thus, to understand the validity of the salt sales survey method, we compared the effect of the CRHI-SRS intervention estimated from the SS sales survey (afterwards referred to as 'estimated effect') with the effect observed using 24-h urine collection (referred to as 'observed effect'). To perform this comparison, SS sales data collected at the same time as the 24-h urine collection (from September 2012 to November 2012) was used, and the estimated effect on mean sodium and potassium intake per person per day (mmols per person per day) was defined as the difference between intervention and control villages in the mean amounts of sodium and potassium sold. These amounts were derived from the mean SS sales per shop per day, the number of shops per village and the number of population per village using the following formulae.

Formula 2: Estimated mean potassium intake (mmol per day per person) = mean SS sales per shop per day (g per day) \times 5.5 (number of shops per village) \div 1878 (mean population size per village) \times 25% (the proportion of potassium chloride in the study SS) \div 74.5 (molecular weight of potassium chloride, g mol^{-1}) \times 1000.

Similarly, the calculation of mean sodium intake was as follows:

Formula 3: Estimated mean sodium intake (mmol per day per person) = mean SS sales per shop per day (g per day) \times 5.5 (number of shops per village) \div 1878 (mean population size per village) \times 35% (1 - proportion of sodium chloride in the study SS) \div 58.5 (molecular weight of sodium chloride, g mol^{-1}) \times 1000.

Next, the estimated difference in daily potassium and sodium intake between the intervention and control villages (the estimated effect) was calculated and compared with that derived from the 24-h urine collection (the observed effect).

The observed potassium and sodium intake per day for each individual was calculated from 24-h urine collection by the following formulae.

Formula 4: Observed potassium intake (mmol per day per person) = concentration of potassium (mmol l^{-1}) \times total volume of 24-h urine (l) \times (24 \div actual total hours of urine collection).

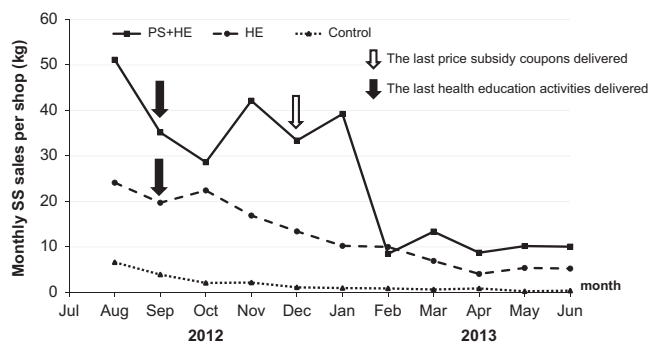


Figure 2 Trends in salt substitute (SS) sales by group over the study period. PS+HE, price subsidy+health education.

Formula 5: Observed sodium intake (mmol per day per person) = concentration of sodium (mmol l^{-1}) \times total volume of 24-h urine (l) \times (24 \div actual total hours of urine collection).

To validate the salt sales survey method, we also examined the correlations between the estimated and observed mean daily sodium and potassium intake at the village level using Spearman's correlation.

We compared the cost of the two methods based on our original study design. The cost of collecting one 24-h urine sample from 2400 individuals in 120 villages was compared with the cost of conducting the monthly telephone salt sales survey, which covered all the shops in the 30 villages for the entire study period, including the baseline and post-intervention period, that is, 24 months in total.

Finally, we conducted a power analysis for the two methods and compared their ability to detect the same intervention effect size if the same study design as CRHI was used.

Data analyses were performed using SAS 9.4 software (SAS Institute, Cary, NC, USA) and power analysis was conducted using PASS 11 software (NCSS, LLC, Kaysville, UT, USA).

RESULTS

Monthly SS sales per shop in the three study groups and their temporal trends

Figure 2 shows the monthly SS sales per shop in each of the three study groups (HE+PS, HE only and no intervention) from August 2012 to June 2013. The time of the last intervention activity is also given. It is clear that during the intervention period, SS sales per shop in the PS+HE group were significantly higher than in the HE group, and SS sales were also significantly higher in the HE group than in the control group (Table 1). One month after the intervention activities ended, the SS sales in both the HE+PS and HE only groups began to decrease. Approximately 3 to 6 months after the last delivery of intervention activities, the SS sales leveled off and became stable. The differences in sales remained significantly higher in both the PS+HE and HE groups compared with the control group even post intervention (Table 1).

Comparison of between-group patterns of differences in SS sales and 24-h urine sodium and potassium levels

Figure 3 shows SS sales and parallel 24-h urine sodium and potassium levels by group. The results showed that the mean 24-h sodium excretion level was the lowest in the PS+HE group (231.5 ± 95.2 (s.d.) mmol per day) and the highest in the control group (250.5 ± 94.0 mmol per day; $P = 0.004$ for HE+PS vs control) at the end of the intervention. The mean amount of 24-h potassium excretion was the highest in the PS+HE group (54.5 ± 25.7 mmol per day) and was the lowest in the control group (45.4 ± 18.97 mmol per day; $P < 0.0001$ for HE+PS vs control). The corresponding urinary data from the 30 villages participating in the substudy showed the same between-group trends (PS+HE $<$ HE $<$ control for mean sodium excretion and PS+HE $>$ HE $>$ control for potassium excretion), although most of the between-group comparisons were not statistically significant owing to a smaller sample size. These patterns are consistent with those of the SS sales (PS+HE $>$ HE $>$ control).

Comparison between observed effect size and estimated effect size of CRHI intervention

As shown in Figure 4, the observed effects in potassium intake and sodium intake between the intervention groups (PS+HE and HE) and the control were 7.0 mmol per day and 14.1 mmol per day, respectively, using 24-h urine data. The effect sizes estimated from SS sales, on the other hand, were 8.0 mmol per day for potassium intake

Table 1 Monthly sales (kg) of salt substitute per shop in each group and the comparison between the three groups

	Mean (s.e.)			PS+HE vs HE		PS+HE vs Control		HE vs Control	
	PS+HE	HE	Control	Difference (95% CI)	P-value	Difference (95% CI)	P-value	Difference (95% CI)	P-value
Intervention period ^a	37.96 (5.36)	19.16 (5.26)	2.16 (4.99)	18.80 (3.42 ~ 34.18)	0.017	35.80 (21.54 ~ 50.06)	<0.0001	16.99 (2.66 ~ 31.33)	0.020
Post-intervention period ^a	9.79 (1.62)	6.68 (1.53)	0.55 (1.47)	3.12 (-1.45 ~ 7.68)	0.181	9.25 (4.98 ~ 13.51)	<0.0001	6.13 (1.92 ~ 10.34)	0.004

Abbreviations: CI, confidence interval; PS+HE, price subsidy+health education.

^aIntervention period was from August 2012 to January 2013 and post-intervention period from February 2013 to June 2013.

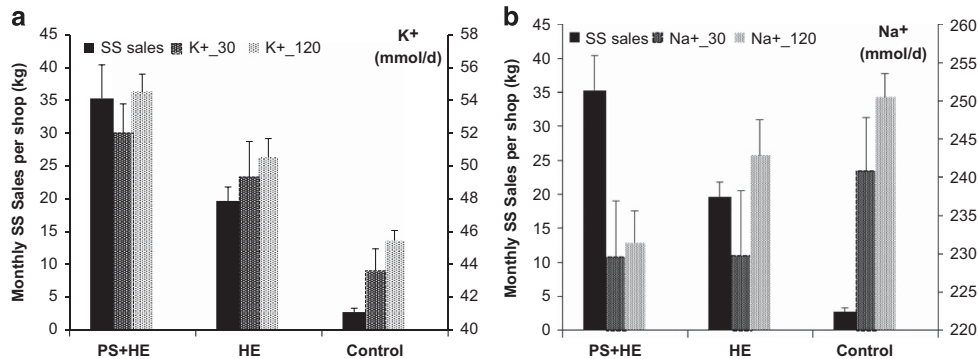


Figure 3 Salt substitute (SS) sales with urinary potassium excretion (a) and sodium excretion (b). PS+HE, price subsidy+health education.

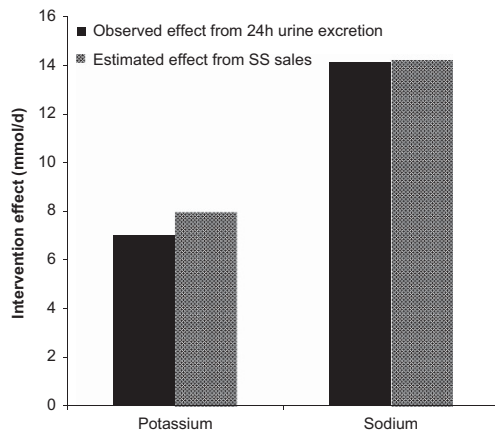


Figure 4 Comparison of the observed intervention effects on 24-h urinary sodium and potassium levels and the corresponding effects estimated from SS sales. SS, salt substitute.

and 14.2 mmol per day for sodium intake. The results showed that the SS sales survey could precisely estimate the mean effects of the interventions.

Correlation between mean 24-h urine potassium excretion and corresponding mean daily SS sales among villages

A significant correlation ($r=0.534$, $P=0.007$) between the mean monthly SS sales and the mean 24-h urinary potassium excretion at the village level was observed. However, the correlation between SS sales and mean 24-h urinary sodium excretion was not significant ($r=-0.219$, $P=0.305$).

Cost analysis

In our study, the estimated total cost of the salt sales survey over 24 months (from April 2011 to March 2013) in 30 villages was around

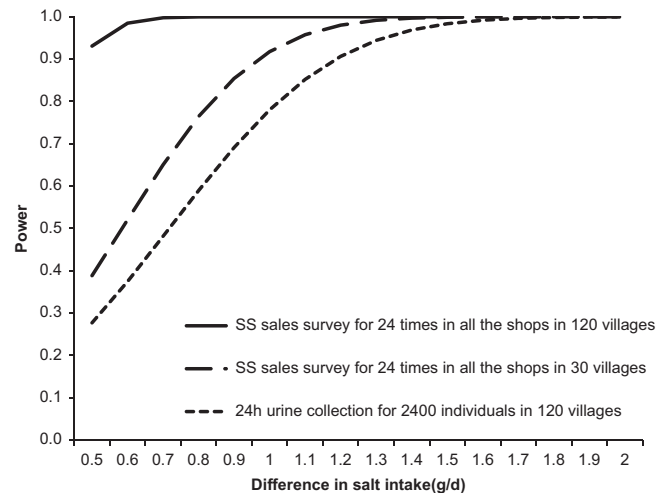


Figure 5 Statistical power comparison between the 24-h urine collection method and the SS sales survey. SS, salt substitute.

¥57 000, whereas the cost of collecting only one 24-h urine sample for 2400 participants in the main study was ¥420 000; this was 7.4 times as high as the cost of the sales survey. If the study had collected both baseline and post-intervention 24-h urine sample, the cost would have been almost 14 times higher than that of the simple salt sales survey. This clearly shows that the salt sales survey is highly cost-effective compared with 24-h urine collection. Costs such as staff training, quality control, participant recruitment, participant incentives, data collection and sample analysis were taken into account when calculating the cost of both methods.

Power analysis

As shown in Figure 5, the statistical power for varied effect sizes were compared between the 24-h urine collection method and the SS sales

survey using the current study design (2400 individuals with one 24-h urine test from 120 villages and a monthly salt sales survey for all the shops in the 30 villages as well as in the 120 villages overall for 24 months). This comparison indicated that the SS sales survey had a greater power to detect an equivalent effect size of salt intake compared to 24-h urine collection.

DISCUSSION

Our study is the first to test the reliability of a salt sales survey as a method to evaluate large-scale population-based salt reduction programs. The results showed that the salt sales survey could precisely estimate the intervention effect size calculated from 24-h urine collection with much less cost, less resources and greater statistical power. Furthermore, the salt sales survey provided time-sensitive insight into the intervention effect size and its changes over time, which could inform efforts to improve intervention strategies in long-term pragmatic trials in routine environments.²⁰

Our study had several strengths. First, salt sales data were collected by a researcher who was not involved in the main study and was blinded to the allocation of groups. This minimized any potential observer bias. Second, 24-h urine collection, the gold standard method of assessing salt intake, were made, enabling validation of the effect size estimated from the sales survey data. Third, the monthly sales survey continued until 6 months after the intervention had ended; this not only enabled us to observe the carryover effects of the intervention but also allowed us to understand the comparability of the recruited shops between the study groups.

The salt sales survey method proposed in this study has demonstrated several advantages over other alternatives to 24-h urine collection. Although much attention has been drawn to random spot urine and timed-spot urine collection, spot urine reflects sodium intake only over a few hours because of the dramatic diurnal and day-to-day variations in urine sodium,¹⁷ and it remains controversial whether to use spot urine to monitor salt reduction programs. On the other hand, salt sales could assess a more stable intervention effect over a longer period of time (~1 month). Furthermore, as sales recordings are part of most business' routines, it is easier to collect salt sales continuously throughout an intervention to provide insight into the dynamic changes in the effects of salt reduction interventions.

Our study has several limitations. First, as our survey began after the onset of the intervention, the baseline salt sales levels of the three study groups were unknown. However, the post-intervention total salt sales in the study shops did not differ significantly between the groups (41 kg for PS+HE, 54 kg for HE only and 50 kg for control; $P=0.31$ for PS+HE vs HE, $P=0.44$ for PS+HE vs control and $P=0.74$ for HE vs control), indicating good comparability between the groups. Second, as only shops holding a retail license were selected to be in the sales study, this limited the precise estimation of sodium intake at the village or individual level because the number of shops selling regular salt without a retail license were unknown. We believe this may be the reason why the correlation between 24-h urinary sodium levels and the SS sales was not significant. However, because we had reliable data on SS sales (the supply of SS was limited to our study shops), our estimations based on SS sales should be reliable. Our study found that SS sales from these registered shops predicted ~101% of the between-group differences in sodium intake estimated by 24-h urine collection. This result as well as others, for instance, the total salt and regular salt sales were not significantly different between groups and the proportion of individuals using SS was much higher in the PS+HE group (PS+HE: 79% > HE: 53% > control: 7%; $P<0.05$), fully supported our assumption that the effect of the salt reduction intervention was

mainly achieved through substitution with SS. Further studies that included all the shops in a village would enable the precise estimation of sodium intake at the community level, and, therefore, the method proposed in this study could also be suitable for studies in which reduction of regular salt consumption is used as the main intervention strategy. Third, the study was conducted in rural China where residents in the villages were relatively stable and the main customers of village shops were residents in the village. Future studies should investigate whether this method could be used in urban areas, particularly those with a large mobile population.

Currently, 24-h urine collection remains the 'gold standard' method to evaluate the absolute salt intake of individuals and should be conducted to monitor the salt intake of both individuals and the population when the budget permits. However, it is not feasible to collect 24-h urine samples in large population intervention programs, especially in resource-limited areas. The salt sales survey provides a much more affordable and practical method to evaluate the effect of salt reduction programs at the community or population level, and hence would enhance the population salt reduction programs in rural China as well as other similar populations in which the main source of salt is discretionary salt added by consumers.

CONFLICT OF INTEREST

YM is sponsored by the China Scholarship Council. LLY is supported by the National Natural Sciences Foundation of China grants (71233001 and 71490732), UNFPA and the NIH (R01AG023627). The remaining authors declare no conflict of interest.

ACKNOWLEDGEMENTS

We are very grateful to the participants in our study and to Professor Kiang Liu for his helpful advice on the manuscript. This project has been funded in part with Federal funds from the National Heart, Lung and Blood Institute; National Institutes of Health; Department of Health and Human Services; and National Center for Chronic Disease Prevention and Health Promotion (CDC), under Contract No. HHSN268200900027C. Additional support has been received from the UnitedHealth Group Chronic Disease Initiative.

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