Impact of Salt Substitute and Stepwise Reduction of Salt Supply on Blood Pressure in the Elderly in Nursing Homes (DECIDE-Salt Trial): Protocol and Baseline Characteristics (P13-022-19)

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Objectives: The aim of this study is to evaluate efficacy, safety, and cost-effectiveness of two sodium reduction strategies, salt substitution and stepwise reduction of salt supply, separately or in combination, on blood pressure (BP) in the elderly in nursing homes in northern China.

Methods: The study is a cluster randomized controlled trial with a two-by-two factorial design conducted in four areas from three northern Chinese provinces. Within each area, nursing homes were randomly assigned (1:1:1:1) to four groups: (1) both replacing normal salt with salt substitute (SS) and training the nursing home manager to reduce 5–10% of salt supply every 3 months (stepwise reduction of salt supply, SRSS), (2) SS only (no SRSS), (3) SRSS only (no SS), or (4) neither SS nor SRSS (control). With a sample size of 1080, 270 in each group, the study would have 80% power to detect a net reduction of 3.0 mmHg in systolic BP, assuming that the standard deviation is 18 mmHg, $\alpha = 0.05$, intraclass correlation coefficient = 0.02, number of clusters = 36, and participants loss to follow up = 20%. The study began in late 2017 and the interventions will last for two years. The primary outcome will be the changes in mean systolic BP from baseline to 24 months, analyzed by a generalized estimating equations extension of the linear regression model to account for cluster effect. The secondary outcomes will include changes in diastolic BP, incidence of hypertension, 24-hour urinary sodium and potassium excretions, all-cause mortality and incidence of hyperkalemia. Economic evaluations will be conducted as well.

Results: A total of 48 nursing homes were recruited in the study. The baseline examination has been completed. A total of 1598 study participants aged 55 to 102 years old were enrolled. The demographical characteristics of the study population, including baseline systolic and diastolic BP, are shown in Table 1.

Conclusions: The study is well powered to evaluate the effect of the three study interventions in lowering systolic BP in the elderly. It is expected to provide solid evidence for policy development regarding sodium reduction strategies in prevention and control of hypertension and its related diseases in the elderly.

Funding Sources: The study is supported by National Key R&D Program of China.

Supporting Tables, Images and/or Graphs

	SS+SRSS (n=390)	SRSS only (n=441)	SS only (n=406)	Control (n=361)	*P* value
Female, %	24.9	27.0	22.7	19.4	0.08
Age, year	70.9 ± 9.6	72.2 ± 9.8	70.8 ± 9.2	70.1 ± 9.1	0.01
Systolic BP, mmHg	137.5 ± 20.9	137.2 ± 20.9	137.3 ± 22.8	139.3 ± 20.7	0.49
Diastolic BP, mmHg	80.6 ± 11.3	79.7 ± 11.3	80.5 ± 12.3	82.5 ± 11.8	0.01

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