



A school-based education programme to reduce salt intake in children and their families (School-EduSalt): Protocol of a cluster randomised controlled trial

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A school-based education programme to reduce salt intake in children and their families (School-EduSalt): Protocol of a cluster randomised controlled trial

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ABSTRACT

Introduction: The current salt intake is very high for both children and adults in China. A reduction in salt intake is one of the most cost-effective measures to curb the rapidly growing disease burden attributed to blood pressure and cardiovascular disease in the Chinese population. A lower salt diet starting from childhood has the potential to prevent the development of such conditions. The School-EduSalt (**School-based Education Programme to Reduce Salt**) study aims to determine whether an education programme targeted at school children can lower salt intake in children and their families.

Methods and analysis: The study is designed as a cluster randomised controlled trial. The location is Changzhi, Shanxi province in northern China. The study population will consist of 28 primary schools with 280 children aged ≈ 11 years and 560 adult family members. Children in the intervention group will be educated on how to reduce salt intake. They will then be empowered to deliver the salt reduction message home to their families. In particular, children need to persuade the person who does the cooking to reduce the amount of salt used during food preparations. The duration of the intervention is one school term (≈ 4.5 months). The primary outcome is the difference between the intervention and control group in the change in 24-hour urinary sodium and the secondary outcome is the difference between the intervention and control group in the change of blood pressure. An economic evaluation will be undertaken to assess cost-effectiveness.

Ethics and dissemination: The study has been approved by The Queen Mary Research Ethics Committee (QMREC2012/81) and Peking University Health Science Centre IRB (IRB00001052-12072). Study findings will be disseminated widely through conference presentations and peer-reviewed publications.

Protocol Registration: Protocol Registered on ClinicalTrials.gov NCT01821144.

ARTICLE SUMMARY

Article focus

- This article describes the protocol of a cluster randomised controlled trial to test whether an education programme targeted at school children can lower salt intake in children and their families.

Key messages

- Salt reduction is one of the most cost-effective measures to prevent cardiovascular disease. A lower salt diet starting from childhood has the potential to prevent the development of hypertension and cardiovascular disease later in life. However, there is no strategy on how to keep children on a lower salt intake.
- Our study aims to determine whether the school environment can act as a vehicle to lower the salt intake in children and their families.
- The study will be carried out in primary schools in Changzhi, northern China where salt intake and the prevalence of hypertension and stroke are all very high.

Strengths and limitations of this study

- A unique feature of the study is to develop a new approach, i.e. using the primary school education system rather than the healthcare system to prevent hypertension and cardiovascular disease. This approach reaches a wide range of the population from children to adults and could have a greater impact.
- Although the study will be carried out in China, the method could be adapted by many other low- and middle-income countries where the majority of salt in the diet is added by consumers.

INTRODUCTION

Cardiovascular disease (CVD, i.e. strokes, heart attacks and heart failure) is the leading cause of death and disability worldwide. Approximately 80% of CVD deaths occur in low- and middle-income countries (LMICs).¹ Raised blood pressure (BP) is a major cause of CVD, accounting for 62% of strokes and 49% of coronary heart disease.² Dietary salt intake is the major factor that increases BP and is largely responsible for the rise in BP with age.^{3,4} There is compelling evidence in adults that a modest reduction in salt intake lowers BP and reduces cardiovascular risk.⁴⁻⁷ Indeed, salt reduction is one of the most cost-effective measures to prevent CVD in both high-income and LMICs.⁸⁻¹⁰

Although CVD events occur most frequently after the age of 40 years and the prevalence of overt hypertension is very low in children, the origins of hypertension and CVD occur in childhood.¹¹ Accordingly, the greatest long-term potential to reduce these conditions is to initiate prevention activities in youth. Such a public health strategy aimed at preventing or slowing the progression of rising BP altogether would have enormous benefits.

Several lines of evidence from animal experiments, epidemiological studies and controlled trials demonstrate that salt intake plays an important role in regulating BP in children.¹² A meta-analysis of 10 trials in individuals aged 8-16 years showed that a modest reduction in salt intake for an average duration of 4 weeks reduced BP by 1.2/1.3 mmHg ($P < 0.0001$).¹² A lower salt diet, if continued, may lessen the subsequent rise in BP with age, which would have major public health implications in terms of preventing the development of hypertension and CVD later in life. Additionally, more recent studies have shown that, in children and adolescents, salt intake is a major determinant of sugar-sweetened soft drink consumption which in turn increases childhood obesity – an independent risk factor both for raised BP and for CVD.¹³

The current salt intake in children in most countries around the world is very high as it is in

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2
3 adults.^{14 15} However, there is no strategy on how to keep children on a lower salt intake and
4
5 there is little data available to formulate policy and engage key stakeholders. The School-
6
7 EduSalt (**School-based Education Programme to Reduce Salt**) study aims to determine
8
9 whether the school environment can act as a vehicle to lower the salt intake in children and
10
11 their families. The study will be carried out in Changzhi, Shanxi province in northern China.
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13

14 15 **Why is this research needed in China?**

16
17 China presents a huge opportunity to achieve major health gains from salt reduction because
18
19 (1) Salt intake is very high with an average intake of 14 g/d in men and 12 g/d in women as
20
21 measured by 24-hour urinary sodium excretion;¹⁶ (2) The prevalence of hypertension and
22
23 stroke, both of which are directly related to salt intake, are among the highest in the world.
24
25 Approximately 177 million people had hypertension in 2002 and raised BP attributed to 2.33
26
27 million CVD deaths in 2005.¹⁷ These figures are projected to increase rapidly due to the fast
28
29 economic and epidemiological transition occurring in China; (3) Healthcare resources are
30
31 limited. A reduction in salt intake is highly cost-effective;^{8 18} (4) The major sources of salt in
32
33 the Chinese diet are salt added by individuals during cooking and in sauces. Therefore, an
34
35 important strategy to reduce population salt intake is to encourage individuals to reduce the
36
37 amount of salt used during their own food preparations; (5) Salt intake in children is also
38
39 high. A study in 1986 indicated that salt intake in teenagers was around 10 g/d in rural
40
41 China;¹⁹ (6) China has a one-child policy and the “little emperors”, as they are often called,
42
43 have a special power in the family. This provides an excellent opportunity for children to
44
45 deliver the salt awareness education to and also make a significant impact on their families;
46
47 (7) School children in China are in a unique position for the proposed research to be carried
48
49 out because they are more disciplined, co-operative, and most likely to comply with the study
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51 protocol. Research undertaken in such an environment could provide definitive evidence
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3 which would drive widespread uptake of the intervention strategy both nationally and
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5 internationally.
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8 **Addressing system barriers**

9
10 In China and many other LMICs, the health services are less developed. The healthcare
11 system is very much oriented towards hospital-based care and treatment for individuals who
12 already have medical conditions. Such a system has little capacity for hypertension
13 prevention and control because (1) hypertension is a “silent killer” and 75% of the Chinese
14 hypertensive individuals are not aware that they have raised BP,²⁰ and (2) The majority of the
15 population in China and other LMICs can not afford life-long BP treatments. While it is
16 important to make the health services more affordable and accessible, a strategy targeted at
17 the whole population will have a greater potential. In the School-EduSalt study, we will
18 develop a new approach, i.e. through the primary school education system rather than the
19 healthcare system to prevent hypertension. This approach has the following advantages:
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32 (1) Because universal primary education is a common goal in most national education
33 policies, the School-EduSalt approach is likely to have a greater impact compared with the
34 “usual” healthcare system, which in many LMICs focuses on treatment only.
35
36
37

38 (2) The School-EduSalt method prevents hypertension from its root, i.e. childhood. Therefore
39 the long-term benefits will be greater than targeting adults alone.
40
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43 (3) The School-EduSalt approach reaches a wide range of the population from children to
44 adults. Such an approach will have an impact on hypertension prevention and control both in
45 the short- and long-term.
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50 **Salt substitution vs salt reduction**

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52 In China and many other LMICs where the majority of dietary salt comes from salt added by
53 consumers themselves, an important public health approach is to replace the usual salt (i.e.
54 sodium chloride) with a salt substitute (i.e. low in sodium and high in potassium). Previous
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3 studies have shown that such an approach lowers BP and reduces CVD mortality.^{21 22}
4
5 However, it has been realised that salt substitution alone is unlikely to bring the population
6
7 salt intake down to the recommended level of 6 g/d. This is because only $\approx 30\%$ of the sodium
8
9 chloride can be replaced with potassium chloride due to the metallic and bitter taste of
10
11 potassium chloride. In the China Salt Substitute Study²¹ which is the largest study using a salt
12
13 substitute, only 25% of sodium chloride was replaced with potassium chloride. In China, salt
14
15 intake is very high with an average of 12-14 g/d,¹⁶ and in some rural areas of northern China,
16
17 salt intake can be as high as 18 g/d. In order to achieve a substantial reduction in salt intake,
18
19 both salt substitution and a reduction in the amount of salt used during food preparations are
20
21 required, and the latter plays a crucial role.
22
23

24
25 The School-EduSalt study is to develop a new method to reduce salt intake in children and
26
27 their families. During the study, we will not provide salt substitute to the participants,
28
29 however, those in the intervention group will be given the information about the salt
30
31 substitute and they could purchase it themselves if they wish.
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33

34 35 **Methods of measuring salt intake**

36
37 Several methods have been used in previous studies to assess dietary intake of salt in both
38
39 children and adults. These include dietary methods (i.e. dietary record, dietary recall, Food
40
41 Frequency Questionnaires (FFQ)), and urine collections (i.e. spot urine, overnight urine and
42
43 24-hour urine).^{14 15} Most of these methods are unreliable in estimating salt intake. The dietary
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45 methods are well known to underestimate the actual amount of salt consumed, particularly as
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47 they do not include salt added during cooking or at the table. In China, the majority of salt in
48
49 the diet is added by consumers during cooking or in sauces, therefore, the dietary methods are
50
51 of little use under such circumstances. Among the urine collection methods, 24-hour urine
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53 collection is the most reliable method for estimating salt intake and overnight urine is not as
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55 accurate as 24-hour urine, due to the diurnal variation in sodium excretion. Spot urinary
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3 sodium has been shown to have a poor agreement with the 24-hour urinary sodium.²³ In our
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5 study, we will use 24-hour urinary sodium to assess salt intake throughout the study. The
6
7 baseline 24-hour urinary sodium could provide valuable data on the current salt intake in
8
9 children and adults.
10

11 12 13 **METHODS AND ANALYSIS**

14 15 **Study hypothesis**

- 16
17 • Children's salt intake can be reduced through an education programme.
- 18
19 • Children, if taught properly, can deliver the salt reduction message home to their
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21 families, therefore, the whole family's salt intake can be reduced.
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28 29 **Aim and objectives**

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31 The overall aim of the School-EduSalt study is to develop an innovative, feasible, affordable
32
33 and sustainable education programme for school children to reduce dietary intake of salt for
34
35 both children and their families. This programme will ultimately prevent or slow the rising
36
37 BP that accompanies aging and thereby preventing the development of hypertension and
38
39 CVD. There are four specific objectives:

- 40
41 (1) To develop an education programme for school children to reduce their salt intake.
- 42
43 (2) To empower children to educate their family members, particularly the person who
44
45 does the cooking, on reducing the amount of salt used at home.
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- 48
49 (3) To test whether the education programme can lower salt intake in children and their
50
51 families by carrying out a cluster randomised controlled trial.
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- 53
54 (4) To implement the education programme nationwide by incorporating it into the national
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56 school curriculum, although subsequent funding will be sought for widespread
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58 implementation.
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Study design

The study is designed as a cluster randomised controlled trial (Figure). A total of 28 primary schools in urban Changzhi will be recruited into the study. The reason for excluding rural schools is to avoid contamination from school meals because some children in rural schools have lunch and dinner at school due to the long distance of their home from school, whereas, in urban schools most children have both lunch and dinner at home.

Following baseline assessments, schools will be randomised to either the intervention or control group. The salt reduction education programme will be implemented in the intervention group. The duration of the intervention is one school term (≈ 4.5 months).

Participants and recruitment

In primary schools in Changzhi, there are 6 grades in total, with age ranging from 7 to 12 years. For practical reasons, the School-EduSalt study will be carried out in grade 5 children (age ≈ 11 years). It is considered that younger children may not be able to deliver the salt awareness education to their families and children in grade 6 are usually very busy with their final year exams before entering high schools.

In total, there are 36 primary schools in urban Changzhi, among which three are special Muslim schools and will be excluded. Among the remaining 33 schools, we will recruit 28 schools whose headteachers agree to take part in the study. To recruit schools, we will firstly contact the local education authority (i.e. Changzhi Education Bureau) to gain their opinion, support and approval. The Changzhi Education Bureau will then send a letter to the headteachers of the schools encouraging them to take part in this project. Our research team will then contact the headteachers asking for their participation in the study.

In most schools, there are more than one class in Grade 5. In such schools, one class will be selected. We will discuss with the headteacher to choose a class whose teacher in charge is willing to collaborate with the researchers. From each class, we will randomly select 10

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3 children for evaluation. Therefore, a total of 280 children from 28 schools will be recruited
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5 into the study for evaluation. Additionally, adult family members will be invited to take part
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7 in the study. We will recruit two adult members from each child's family, e.g. grandparents,
8
9 parents, uncles and aunties, who live and have meals at the child's home.
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12 ***Inclusion/Exclusion criteria:*** All children in Grade 5 are eligible for the study, however,
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14 children who do not have lunch or dinner at their own home or who live far from the school
15
16 (>3 km) will be excluded. All adult family members who share the same meals with the child
17
18 are eligible for the study. If more than two adults in one family agree to take part in the study,
19
20 we will select two of them (i.e. one male and one female) in the order of grandparents,
21
22 parents, uncles and aunties.
23
24

25 26 27 **Randomisation procedures**

28
29 Randomisation will be stratified by the level of schools (i.e. belonging to city or district
30
31 government) and the size of class. Among the schools in urban Changzhi, the size of the class
32
33 varies from 13 children/class to ≈ 80 children/class. Usually, a larger class size indicates that
34
35 the school is at the upper level of the league table in terms of exam results. Therefore, parents
36
37 are more likely to send their child to such schools. The randomisation will be carried out
38
39 using computer generated random number system by a researcher who is not involved in the
40
41 study and is blind to the identity of the schools.
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45 46 47 **Intervention description**

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49 Our target is to lower salt intake by a minimum of 20% for both children and their families.
50
51 The intervention will be delivered to the whole class in spite of only 10 children being
52
53 selected for evaluation. The salt reduction education includes two main components.
54

55 ***(1) Classroom component:*** Children will be educated at 2-week intervals throughout the
56
57 study. Education curriculum and materials will be developed around the following "key
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59
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1
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3 messages": (a) Harms of salt- "More salt, less health; less salt, more health"; (b)
4
5 Recommended salt intake - "Less than 6 g/d"; (c) Methods of reducing salt intake - "Add less
6
7 salt in cooking and eat less pickles". Our slogan is "Small hands leading big hands, together
8
9 let's reduce salt".
10

11
12 Lessons will support other classroom disciplines and activities, and resources provided will
13
14 be mapped to complement activities in the curriculum, in particular, health education lessons.
15
16 Materials will be designed to provide a low-cost and sustainable intervention that could
17
18 ultimately be used as a resource for teachers in the future. The material will consist of lesson
19
20 plans, activity worksheets and homework assignments. Other teaching methods to engage
21
22 students will include demonstrations, food preparation activities, case studies and group
23
24 projects. Programme materials will be developed around cartoon characters. Role plays and
25
26 student presentations will be some of the activities included. Children will be encouraged to
27
28 express their own ideas and initiatives on how to cut down the amount of salt. They will be
29
30 invited to design their own programmes for their family. Essay competitions on salt or
31
32 drawing competitions are other ways to actively involve children. Each lesson will build on
33
34 what has been taught in the previous lessons to ensure that there is a clear progression in
35
36 learning and understanding.
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39
40 School teachers will be involved in all activities. They will coordinate all events and check
41
42 students' homework. Posters will be put up in the classroom.
43
44

45 **(2) Family Component:** Children will be empowered to persuade their family members,
46
47 particularly, the person who does the cooking and prepares food, to reduce the amount of salt
48
49 used at home. Additionally, there needs to be a significant reduction in the amount of soy
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51 sauce and bean paste used as well as a reduction in the consumption of pickles, salted eggs,
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53 salted peanuts, etc. Garlic, ginger and herbs will be recommended for enhancing food
54
55 flavour. We will recommend replacing pickles with fresh vegetables, and replacing salted
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3 eggs and peanuts with unsalted ones. We will encourage participants to replace the usual salt
4
5 with a mineral salt which is low in sodium and high in potassium. However, the important
6
7 message is to reduce the total amount of salt used even with a salt substitute.
8

9
10 In view of the fact that the prevalence of stroke is very high in northern China and many
11
12 people have witnessed the debilitating impact of a stroke on individuals and their families,
13
14 our education materials will emphasise the effect of salt on stroke. For parents and
15
16 grandparents, we will use their special love towards the only child in the family to persuade
17
18 them to reduce the amount of salt used at home. The key message is “Do you know children
19
20 who have high salt intake are more likely to develop hypertension and stroke when they grow
21
22 up?”
23

24
25 To engage the family, some school activities will be organised with the family as a unit.
26

27
28 Additionally, parents will be provided with educational materials in the form of a newsletter
29
30 on a bi-weekly basis. The newsletter will cover topics such as salt and its effect on BP and
31
32 CVD (particularly stroke), the major sources of salt in the diet, and cooking with reduced salt.
33
34 The newsletter will also have a question and answer column and a family quiz. Homework
35
36 set for the students will be related to the newsletter.
37

38 39 ***Salt reduction target – minimum reduction 20%***

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41 To reduce salt intake from the current level of 12-14 g/d¹⁶ to the recommended 6 g/d, it is
42
43 essential to implement a step-wise reduction in the amount of salt used, i.e. 10 to 20%
44
45 reduction and repeated at 1-2 year intervals. Such reductions are not detectable by human salt
46
47 taste receptors.²⁴ In view of this, we have set a target of minimum 20% reduction which
48
49 represents an important step towards achieving the overall goal and, importantly, this
50
51 represents a realistic and achievable target.
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55 56 ***Working towards 50% reduction in order to achieve the minimum 20% reduction in salt*** 57 58 ***intake***

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3 From our previous experience of salt reduction trials, to ensure that a minimum of 20%
4
5 reduction in salt intake can be achieved, a strategy towards a 50% reduction should be
6
7 implemented. Based on the dietary data collected from northern China in the INTERMAP
8
9 (INTERnational collaborative study of MAcronutrients, micronutrients and blood Pressure)
10
11 study,²⁵ we have developed a salt reduction strategy (Table). Due to a lack of such data in
12
13 children, our strategy is based on the data in adults. However, in northern China, children's
14
15 eating patterns are very similar to that of their parents and, therefore, this strategy also applies
16
17 to children with a proportional reduction in all items.
18
19

20
21 From the sources of sodium reported in the INTERMAP study,²⁵ we calculated the amount of
22
23 salt (1g sodium=2.5g salt) and the percentage contribution of each food category to total salt
24
25 intake. We then worked out the reduction needed for each food category in order to achieve a
26
27 reduction of $\approx 50\%$ in total salt intake (Table). With this strategy, the total salt intake, on
28
29 average, will be reduced by 45%.
30
31

32 ***Monitoring family salt consumption***

33
34 Each child will be given a salt container and a salt-control spoon (2 g salt) to take home.
35
36 Parents are requested to put salt into the container provided and use salt in this container
37
38 only. Parents are asked to use the salt-control spoon provided as well so that they know the
39
40 approximate amount of salt used. Children will be asked to take the salt container to school
41
42 every two weeks and the teacher will weigh it. The reduction in the weight will therefore
43
44 indicate the amount of salt consumed by the household for those two weeks.
45
46

47
48 Children will also be asked to record whether they and their family members eat salted food
49
50 weekly, including pickles, salted eggs, salted peanuts, processed meat, sauces, processed
51
52 bean curd products, instant noodles, crisps or chips, and salted fish or seafood.
53
54

55 The above data recorded along with the number of people in the household will be entered
56
57 into a computer using specially designed software which will automatically give the
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1
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3 information on how far each family's salt consumption is different from the target level set.
4
5 This information will be provided to the parents every two weeks in a format of feedback
6
7 letter to guide salt reduction in order to reach the target.
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9

10 **Control group**

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12 Children in the control schools will carry on with their usual health education lessons as in
13
14 the curriculum. After the whole study is completed, participants in the control group will
15
16 receive summary information on dietary salt intake and educational materials utilised in the
17
18 intervention group.
19
20

21 **Outcome evaluation**

22
23 All outcome assessments will be carried out at baseline and at the end of follow-up in exactly
24
25 the same way in all schools for all participants selected for evaluation, irrespective of their
26
27 assignment to intervention or control group.
28
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30
31 Two consecutive 24-hour urine collections will be made for the measurement of urine
32
33 volume, sodium, potassium and creatinine. Participants will be carefully instructed on how to
34
35 accurately collect 24-hour urine by research staff. Twenty-four hour urinary creatinine
36
37 together with urine volume and participants' report will be used to determine if the collection
38
39 is likely to be complete. The biochemist who performs the measurements of urinary
40
41 electrolytes will not be told which group the participant is allocated.
42
43

44
45 BP and pulse rate will be measured using a validated automatic BP monitor (Omron HEM-
46
47 7301-IT) with the appropriate size of cuff. Three readings will be taken in the right arm at 2
48
49 minute intervals at sitting position with arm supported at heart level, after the participant has
50
51 had 10 minutes' rest in a quiet room. The average of the last 2 measurements will be used for
52
53 the analysis. Body weight and height will also be measured.
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3 A brief interviewer-administered questionnaire will be completed to collect data on
4 demographics, participants' dietary habit such as frequency of eating out, knowledge and
5 practices related to salt. For adults, disease history and medications will also be recorded.
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7
8
9 Additionally, a questionnaire on quality of life assessment (EQ5D)²⁶ will be completed for all
10 participants.
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13 14 15 **Outcomes**

16
17 The primary outcome is the difference between the intervention and control group in the
18 change in 24-hour urinary sodium from baseline to the end of follow-up for children and for
19 adults. The secondary outcome is the difference between the intervention and control group
20 in the change of BP.
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27 **Economic evaluation**

28
29 An economic evaluation will be performed to assess the cost-effectiveness of the
30 intervention. The perspective to be adopted will be societal. Costs to be assessed will include
31 costs in establishing and running the programme including the costs incurred by the
32 educational authorities and teachers involved in the programme, but excluding protocol
33 driven costs associated with conducting research. These data will be extracted from financial
34 statements from the project and partner organisations (e.g. the education bureau and schools).
35
36 Cost effectiveness will be assessed initially in terms of incremental cost per unit reduction in
37 urinary sodium and BP, but modelled to estimate cost per life year saved and cost per
38 Disability Adjusted Life Year (DALY) averted.²⁷ These estimates will be based on evidence
39 from the literature of disease progression and long term effects of salt reduction. Extensive
40 sensitivity analyses will be carried out to estimate uncertainty about the primary findings
41 associated with varying key parameters.
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57 **Sample size**

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3 **Children:** We anticipate that there will be a difference in salt intake between the intervention
4 and control group at the end of the follow-up. A 20% difference would be considered
5 significant from a population viewpoint. This is equivalent to a reduction in salt intake of 1.0
6 g/d from ≈ 5 g/d. To detect this difference with a power of 90% and $\alpha=0.05$, we would require
7 a sample size of 196 children, given a SD of 2.15 (from a pilot study, unpublished data).
8 Taking into account of clustering (cluster size=10 and ICC=0.01) and allowing a 10% drop-
9 out rate,¹⁹ the sample size would be 235 children from 24 schools. To ensure that the study
10 has a sufficient power, we will recruit a total of 280 children from 28 schools (i.e. 14 schools
11 with 140 children in the intervention group and 14 schools with 140 children in the control
12 group).

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25 **Adults:** We will recruit 2 adult family members per child and therefore a total of 560 adults
26 will be recruited into the study. With this sample size, we would have a power of greater than
27 95% to detect a difference in salt intake of 2 g/d (i.e. 20% reduction from 10 g/d, SD=3.5²⁸).
28 With a sample size of 560, we would also have a power of 80% and $\alpha=0.05$ to detect a
29 difference of 2.6 mmHg in systolic BP (SD=10²⁸) in adults.

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32 For both children and adults, we will recruit equal number of male and female participants.

33 34 35 36 37 38 39 40 **Data analysis**

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43 Data analyses will be performed according to the intention-to-treat approach. Statistical
44 comparisons between intervention and control groups for 24-hour urinary sodium and other
45 continuous variables will be made using regression analysis with robust standard errors
46 accounting for clustering.

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52 **Adjusting for potential confounding factors:** Our study is a school-based cluster randomised
53 trial and schools will be randomised to either intervention or control group. For children, it is
54 anticipated that the two groups will be comparable in baseline characteristics. For adults,
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3 however, there is a possibility for a difference between the two groups in factors that predict
4 our secondary outcome, i.e. blood pressure (BP). For example, age and baseline BP level
5 have been shown to be important factors predicting the change in BP with salt reduction. If
6 there is a difference between the intervention and control group in such factors, statistical
7 adjustment will be made when analysing the data.
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13 14 **Project timelines**

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16 Recruitment of schools and participants started on 21 May 2013. Baseline assessments are
17 underway and scheduled to complete in early July, i.e. before the school exams begin.
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20 Randomisation will take place during summer holiday in August. Intervention will start at the
21 beginning of September when the new school term commences. Final follow-up assessments
22 will be carried out at the end of the school term in January 2014.
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32 **ETHICS AND DISSEMINATION**

33 34 **Ethics**

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36 The study has been approved by The Queen Mary Research Ethics Committee
37 (QMREC2012/81) and Peking University Health Science Centre IRB (IRB00001052-12072).
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39 Written consent will be obtained from all participants according to well-established practices.
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41 For children, written consent from both parent/guardian and child will be obtained. All
42 participants will be free to discontinue their participation at any time with no explanation
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52 **Dissemination**

55 The findings of this study will be disseminated widely through conference presentations and
56 peer-reviewed publications. Furthermore, the results will be disseminated worldwide through
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3 WASH (World Action on Salt and Health)²⁹ which is a global non-profit organisation of 527
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5 members from 98 countries with the mission to improve the health of populations throughout
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7 the world by achieving a gradual reduction in salt intake.
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10 11 12 13 **DISCUSSION**

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17 The School-EduSalt study offers a unique approach towards hypertension prevention and
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19 control. The approach of using the primary school education system rather than the healthcare
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21 system has the potential to achieve the greatest long-term benefit as it prevents hypertension
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23 from its roots (i.e. starting from childhood). Although the study will be carried out in China,
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25 the method could be adapted by many other LMICs where the majority of salt in the diet is
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27 added by consumers. A modest reduction in salt intake across the whole population even by a
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29 small amount could have major beneficial effects on health along with major cost-savings.
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33 It is important that the reduction in salt intake achieved during the trial is sustained over the
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35 years after the study. Furthermore, our ultimate aim is to incorporate the education
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37 programme into the national school curriculum which all schools will follow. A key to
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39 success for such a large scale implementation is to monitor the progress. Repeated
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41 measurements of 24-hour urinary sodium at 3-4 year interval is essential to this process.
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44 Further funding will be sought for the widespread implementation and for the monitoring
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46 programme.
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3 **Contributors:** FJH, YW and GAM conceived the project and designed the study. FJH and
4
5 YW contribute equally to the work. FH wrote the first draft of the manuscript. JM, HW and
6
7 YY designed the education materials. YLL and SJ contributed to the economic evaluation.
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9 All authors contributed to the refinement of the study protocol and approved the final
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11 manuscript.
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34
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36
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39 Wu and Graham MacGregor).
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48 **FIGURE LEGEND**

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52 Figure. Summary of the School-EduSalt trial design.
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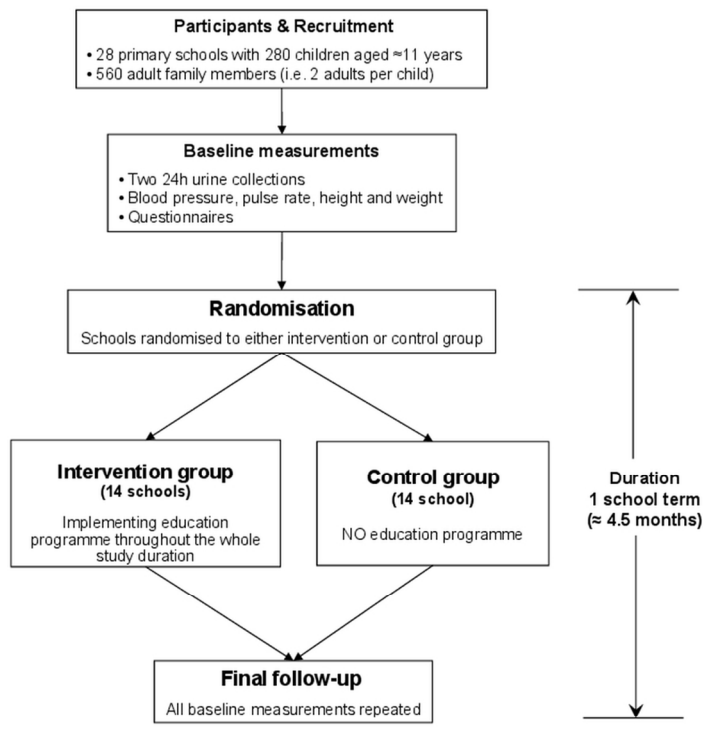
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Table. Strategy for achieving ≈50% reduction in salt intake

Source	Sodium* (g/d)	Salt (g/d)	Percentage contribution to total salt intake	Reduction Needed (Salt)	
				Reduction (%)	Reduction (g/d)
Salt (added in cooking)	3.614	9.04	76.4	50% reduction in the amount of salt used during food preparation.	4.52
Soy sauce	0.260	0.65	5.5	50% reduction in the amount of soy sauce used. Using garlic, herbs, ginger, 13 spices powder, vinegar.	0.33
Mustard, pickles	0.142	0.36	3.0	90% reduction in the amount of pickles eaten. Replacing pickles with fresh vegetables.	0.32
Breads (eg, mantou)	0.133	0.33	2.8	No reduction	0
Noodles (homemade)	0.131	0.33	2.8	No reduction	0
Salted eggs, sausages	0.049	0.12	1.0	100% reduction. Replacing salted eggs with unsalted eggs.	0.12
Salted peanuts	0.032	0.08	0.7	100% reduction. Using unsalted peanuts.	0.08
Sodium bicarbonate	0.147	-	-	No reduction	0
Monosodium glutamate	0.012	-	-	No reduction	0
Others		0.43	3.6	No reduction	0
Natural		0.50	4.2	No reduction	0
Total	4.733	11.83	100.0	45% reduction	5.37

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School-EduSalt trial design



90x127mm (300 x 300 DPI)