

BMJ Open An Application-based programme to reinforce and maintain lower salt intake (AppSalt) in schoolchildren and their families in China

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ABSTRACT

Introduction Salt intake is very high in China, with ~80% being added by the consumers. It is difficult to reduce salt in such settings. Our previous study (School-based Education programme to reduce Salt(School-EduSalt)) demonstrated that educating schoolchildren, who then instructed their families to reduce the amount of salt used at home, is effective in lowering salt intake in both children and adults. Our team also developed an app called 'KnowSalt', which could help individuals to estimate their salt intake and the major sources of salt in the diet. Building on School-EduSalt and KnowSalt, we propose to develop a new app (AppSalt) focusing on salt reduction through education, target setting, monitoring, evaluation, decision support and management to achieve a progressive lower salt intake for long term. To evaluate the effectiveness of the AppSalt programme, we will carry out a cluster randomised controlled trial.

Methods and analysis We will recruit 54 primary schools from urban and rural areas of three provinces in China. A total of 594 children aged 8–9 years and 1188 adult family members will be randomly selected for evaluation. After baseline assessment, schools will be randomly allocated to either the intervention or control group. Children in the intervention group will be taught, with support of AppSalt, about salt reduction and assigned homework to get the whole family involved in the activities to reduce salt consumption. The duration of the intervention is two school terms (ie, 1 year). The primary outcome is the difference between the intervention and control group in the change of salt intake as measured by 24-hour urinary sodium.

Ethics and dissemination The study has been approved by Queen Mary Research Ethics Committee and Peking University Health Science Centre IRB. Results will be disseminated through presentations, publications and social media.

Trial registration number ChiCTR1800017553.

INTRODUCTION

Cardiovascular disease (CVD; ie, strokes, heart attacks and heart failure) is the leading cause of death and disability worldwide. Approximately 80% of CVD deaths occur in

Strengths and limitations of this study

- Our study will develop a new approach to achieving a sustainable progressive lower salt intake for long term.
- The study will use an innovative smartphone application through estimation of salt intake, education, target setting and monitoring, decision support and management to implement a salt reduction programme.
- The study covers a wide range of the population including children and adults in diverse settings, for example, rural and urban, northern, central and southern China.
- The results should generally be applicable to the whole Chinese population.
- The study will be carried out in China only; however, the method could potentially be adopted by many other developing countries where most of the salt in the diet is added by the consumers.

developing countries.¹ Raised blood pressure (BP) is an important risk factor for CVD, accounting for 62% of strokes and 49% of coronary heart disease.² High salt intake is the major cause of raised BP.³ Randomised trials have demonstrated that a reduction in salt intake lowers BP in both hypertensive and normotensive individuals, in both adults and children.^{4–6} There is also compelling evidence that a lower salt intake is associated with a reduced risk of CVD and total mortality.^{7,8} Indeed, salt reduction is one of the most cost-effective measures to prevent hypertension and CVD.^{3,9} The WHO has recommended a 30% reduction in population salt intake by 2025 and also set a target of <5g/d for all adults and lower levels for children.¹⁰ Many developed countries have started salt reduction initiatives.¹¹ Salt intake has been successfully reduced in Finland and the UK, accompanied by falls in population

BP and CVD mortality.¹² Developing countries, however, are lagging behind.

China is the largest developing country with one-fifth of the world population. Salt intake in China is very high with an average of 12–14 g/d in adults,^{13–15} and in some rural areas of northern China, salt intake could be as high as 18–20 g/d.¹⁶ Approximately 80% of the salt in the Chinese diet is added by the consumers during cooking or in sauces.¹⁷ It is extremely challenging to reduce salt intake in such settings due to the difficulty in changing individuals' dietary behaviours. Our previous study (School-based Education programme to reduce Salt (School-EduSalt)) has developed a novel and effective approach to reducing salt intake in northern China.¹³ In School-EduSalt, primary schoolchildren aged ≈10 years were educated about the harmful effects of salt on health and how to reduce intake during the school's usual health education lessons. Children then instructed their families to reduce salt. The results showed that, over one school term (≈3.5 months), salt intake was reduced by ≈25% in both children and adults as measured by 24-hour urinary sodium excretion. The reduction in salt intake led to a significant fall in systolic BP of 2.3 mm Hg in adults.¹³ It was estimated that, if School-EduSalt was implemented and sustained, it would prevent ≈400 000 stroke and heart attack events per year in China.

Previous studies have shown that salt reduction achieved by dietary advice attenuates over time and maintaining a lower salt intake long-term remains a challenge.⁴ The School-EduSalt was successful over one school term of ≈3.5 months. The question is how to continue and reinforce the salt reduction education to achieve a sustainable, progressive lower intake to achieve the WHO's target.

Mobile technology is increasingly used in health education.¹⁸ Recent studies have suggested that game-based intervention has great potential in changing behaviours due to the popularity of gaming.¹⁹ China has the largest and fastest growing mobile internet population with 802 million people using the internet and mobile phone penetration reached 98.3% of the population by June 2018.²⁰ Mobile-based decision support system has been shown to be effective in increasing medication use in individuals with high CVD risk in rural China.²¹ Our team has recently developed a smartphone application (KnowSalt), which can be used by individuals to estimate their salt intake and the major sources of salt in the diet. The methodology underpinning KnowSalt application had been validated in a pilot study in primary schoolchildren and their families.¹⁶

Our proposed study building on School-EduSalt and KnowSalt app will develop an innovative smartphone application focusing on salt reduction (AppSalt) through functional modules of education, evaluation, target setting and monitoring, decision support and management, with the aim of reinforcing School-EduSalt to achieve a progressive lower salt intake for long term. To evaluate the effectiveness and cost-effectiveness

of the AppSalt programme, we will carry out a cluster randomised trial.

METHODS AND ANALYSIS

The project consists of two phases: (1) developing AppSalt platform and (2) carrying out a cluster randomised controlled trial (RCT).

Phase 1—development of AppSalt platform

AppSalt platform comprises a smartphone application named AppSalt (family end) and a WeChat mini app (teacher end). The AppSalt consists of four core procedures (ie, education, evaluation, decision support and reminding) and three supportive modules (ie, Competition & Award, Supervision & Communication and SaltSwitch) (figure 1).

Core procedures

1. 'Education' is to educate the families about the harmful effects of salt on health and how to reduce salt intake. Nine lessons are developed, each starting with a 10-min lecture on salt reduction, followed by a few questions to test whether the families have understood the content. At the same time, the questions and answers will re-enforce the key messages. Following each lesson, the families are required to complete a practical session, which is designed to help the families to prepare foods with reduced salt at home and choose lower-salt foods when shopping.
2. 'Evaluation' is to estimate salt intake and the main sources of salt for every member of the family. After completing a simple questionnaire, the family will be provided with the information on the top three contributors of salt in their diet. This will help the family make a decision on how to effectively reduce salt intake. Evaluation of the top three contributors (ie, top three sources of dietary salt) will be based on a 7-day salt surveillance method. Participants will record frequency of dining out, consumption of processed foods and the amount of salt added during cooking. The added salt will be assessed by weighing salt, soy sauce and other primary salty condiments on the first and last day of the evaluation period.¹⁶
3. 'Decision support' will set target for total salt intake and specific targets for top three contributors. Lower-salt sample recipes and specific measures, for example, reducing the amount of salt used during cooking by 50%, will be recommended. The recommended measures will be customised as an action plan.
4. 'Reminding' will remind the family how far their salt intakes are away from the targets set and highlight further action plans.

Supportive modules

1. 'Supervision & Communication' module: The teachers and researchers will use the function 'Supervision' to announce instructions, newsletters and school canteen

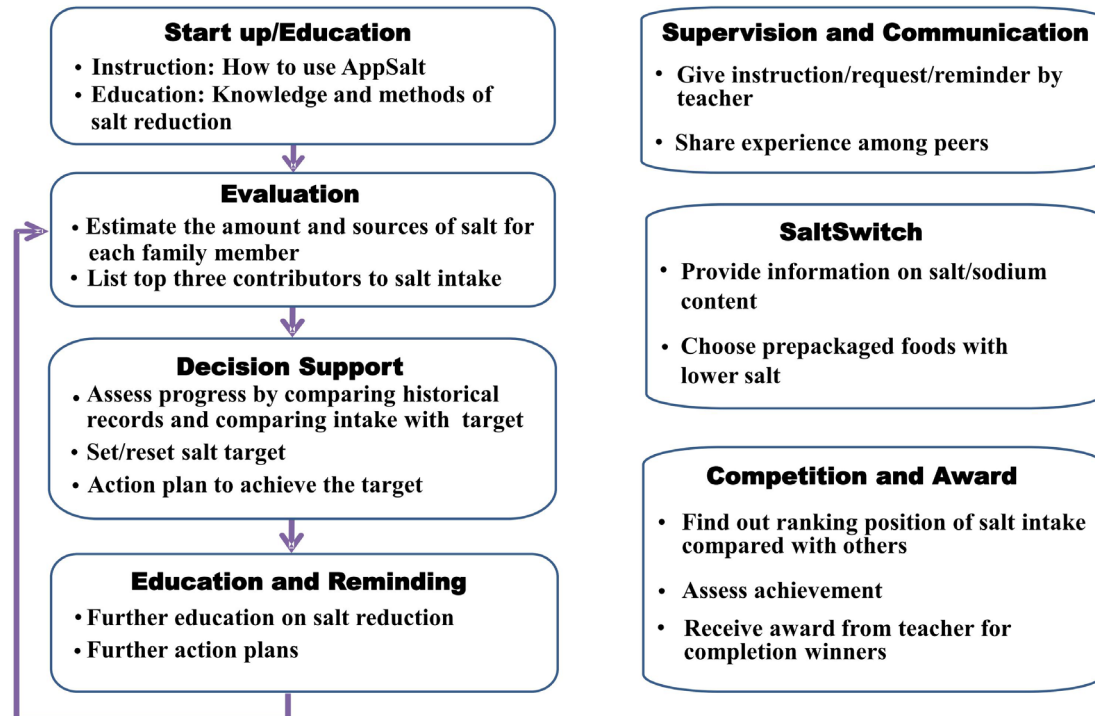


Figure 1 AppSalt core procedures and modules.

menus, as well as providing answers to any queries. The participants will use the function ‘Communication’ to ask any questions and also exchange experience and knowledge with other participants.

2. The ‘SaltSwitch’ module will help the participants to choose prepackaged foods with lower salt. ‘SaltSwitch’, as a subfunction of ‘FoodSwitch’²² integrated into the AppSalt, has a database of over 50 000 prepackaged foods collected by The George Institute (TGI) China. By scanning the barcode of the prepackaged foods, the ‘SaltSwitch’ will provide information on salt/sodium content and compare it with other similar products based on products’ labelling.
3. The ‘Competition & Award’ module will help the participants to find out their own ranking position assessed by salt intake level and the extent of salt reduction among all participants (NB: only their own ranking will be displayed, and other participants’ ranking will not be revealed to them). The family with the lowest salt intake and the family who achieve the greatest reduction in salt intake will be the winners of competition. They will be awarded an honorary title like ‘Salt Reduction Pacesetter’ and get a small gift.

AppSalt will be installed in the smartphone of adult family members. Children are only allowed to use AppSalt accompanied by their adult family members to complete AppSalt core procedures as required. New features with a variety of presentation styles on salt reduction education will be added to keep the programme attractive to the participants.

The school teachers will use the WeChat mini app (teacher end) to send messages to the families, provide timely feedback to any queries and check families’

progress and ensure all families complete the procedures in time. The teachers will also report any issues to the site managers and the research team where appropriate.

Phase 2—cluster RCT

To test the effectiveness and cost-effectiveness of the AppSalt programme, we will carry out a cluster RCT (figure 2).

Study setting and participants

Considering the geographical location, economic level and dietary habit, our study will be undertaken in selected primary schools from urban and rural areas of three provinces in northern (Hebei), central (Sichuan) and southern (Hunan) China.

To recruit schools, we will first contact the local education authority through local Health/Education Bureau or Centre for Disease Control to gain their opinion, support and approval. We will then contact schools’ headteachers to request their participation in the study. In each school, there are six grades with age ranging from 7 to 12 years, and our study will be carried out in grade 3 (age 8–9 years). Head-teacher will choose one class whose teacher in charge is willing to collaborate with the researchers. From each class, we will randomly select 11 children and 22 adult family members (ie, one child and two adults per family) for evaluation. The inclusion criteria are (1) children and their adult family members have to eat homemade meals at least four times per week; (2) one of the adults in the family has a mobile device with access to Internet; (3) if more than two adults in one family agree to take part in the evaluation, we will select two in the order of grandparents, parents, uncles

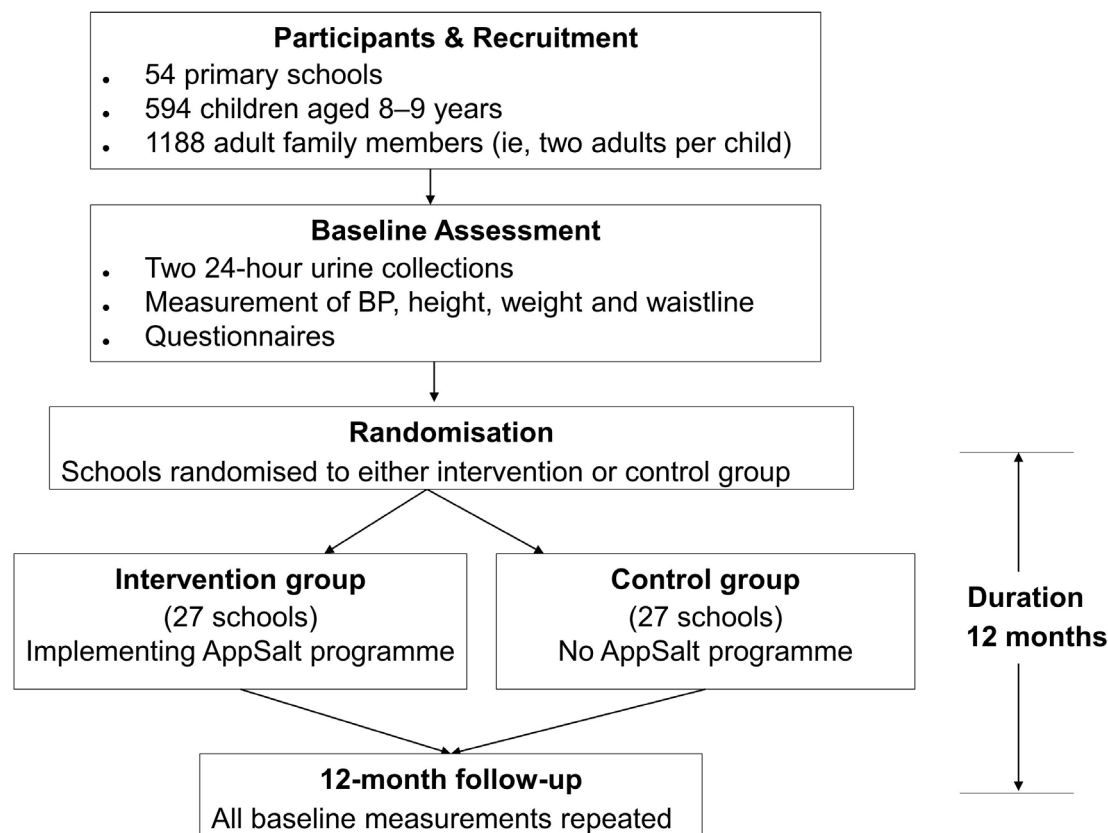


Figure 2 AppSalt trial design. BP, blood pressure.

and aunties; (4) participants have been local residents for over 6 months, without moving plan within 24 months. We will exclude the individuals who cannot or refuse to collect 24-hour urine.

Randomisation

Schools (clusters) will be randomly assigned (1:1) to either the intervention or the control group. Randomisation will be stratified by the location of schools (ie, south or north, urban or rural) and the size of the class. The randomisation will be carried out using computer-generated random number by an independent statistician who is blind to the identity of the schools. The randomisation will take place after baseline data collection has completed. Therefore, the participants, school-teachers and local investigators who undertake recruitment and data collection, will be unaware of the allocation until the point prior to the commencement of the intervention.

Intervention

Our goal is to lower salt intake (measured by 24-hour urinary sodium) by a minimum of 15% (≈ 1.5 g salt) for both children and their families. To achieve this goal, a strategy towards a 50% reduction should be implemented. To make the decision-support algorithm simple in the AppSalt, we will set targets for the top three contributors to salt intake, such as cooking salt. Targets and priority actions will be individualised depending on the sources of salt in the individual's diet, which will be provided by AppSalt. During the education

lessons delivered through AppSalt, the participants will be taught the methods on how to effectively reduce salt intake, for example, reducing the amount of salt, soy sauce and bean paste used during cooking. Garlic, ginger and herbs are recommended for enhancing food flavour. We also recommend replacing pickles with fresh vegetables and replacing salted eggs and peanuts with unsalted ones.

In the intervention group, the AppSalt intervention package will be delivered to all children and their families in the whole class, despite only 11 children and their families being randomly selected for evaluation. The adult family members will be authorised to install and operate the AppSalt programme, while children will be assigned homework to get the whole family to reduce salt with the support of AppSalt. Children's homework will include (1) helping the family to set salt reduction target and reminding the whole family of this target on a regular basis; (2) getting the whole family involved in salt reduction activities and persuading the person who does the cooking to reduce the amount of salt used during food preparations at home; (3) working with their family members to complete the AppSalt core procedures, including education, evaluation, target setting and monitoring. In addition to the online lessons, school teachers will organise three face-to-face seminars for both children and adults during the 1-year intervention period. This will provide an opportunity for the participants to share experiences and discuss challenges and solutions. These

seminars will be integrated into the schools' routine parent meetings.

Trained teachers will provide guidance on AppSalt utilisation, assign and check children's homework including monitoring the progress of salt reduction. They will also create salt-reduction environment, for example, putting up posters in classroom, campus and canteens. The AppSalt will be activated at the beginning of the intervention for all families in the intervention group. Throughout the study, participants will receive salt reduction messages and newsletters via AppSalt on a monthly basis. Participants will be encouraged to use AppSalt and communicate with the teachers and other families to share experiences. The mandatory tasks for the participants include completing the online lessons and the related questions and answers at baseline and every month thereafter and completing the core procedures, that is, salt intake estimation, target setting at baseline and every 3 months thereafter. In addition to the mandatory tasks, the participants are encouraged to repeat the core procedures as often as they wish in order to monitor their progress and achieve progressive reductions in salt intake. Based on the progress monitored from the WeChat mini application, the teachers will remind children that they should complete their homework, which is to help the family complete the AppSalt procedures in time and to instruct the family members to reduce salt to the target.

The records from AppSalt, for example, salt intake and how far the intake is different from the target set, will be used to monitor compliance. During follow-up, the participant who fails to achieve the salt reduction target will be sent a specially designed message via AppSalt and a letter to the child through his/her teacher to remind the family of the salt reduction target.

The intervention duration is two school terms, that is, 1 year. Children in the control group will carry on with their usual health education lessons as in the curriculum. After the trial is completed, we will introduce the AppSalt to all schoolchildren and their families including those in the control group.

Sample size calculation

Based on the School-EduSalt trial,¹³ assuming an SD of 24-hour sodium excretion is 85 mmol/d, and intraclass correlation coefficient is 0.05, we estimate that a sample size of 594 children from 54 schools (18 primary schools from each province in both urban and rural area and 11 children per school) would provide a power of 80% (with a two-sided $\alpha=0.05$) to detect a difference in mean 24-hour urinary sodium ≥ 26 mmol/d (1.5 g/d salt) between intervention and control groups, allowing for a 15% drop-out rate of participants. We aim to recruit two adults per family; therefore, 1188 adults will be recruited into the study for evaluation.

Outcome measures

The primary outcome is the difference between the intervention and control groups in the change of salt intake as

measured by 24-hour urinary sodium from baseline to the end of the trial. The secondary outcome is the difference between the two groups in the change of systolic BP for adults.

Outcome assessments

All outcome measurements and assessments will be carried out at baseline and at the end of the trial in exactly the same way in all schools for all participants, irrespective of their assignment to intervention or control group.

Two consecutive 24-hour urine collections will be made at each time point, using the stringent protocol which we developed in the School-EduSalt study.¹³ Although there are other more convenient methods for assessing salt intake, for example, a food diary, they are not reliable, and the most accurate method is 24-hour urine collection.²³ Our previous studies have shown that it is entirely feasible to collect 24-hour urine in both children and adults.¹³ The participants will be carefully instructed on how to accurately collect 24-hour urine by trained research staff. On the first day, the participants will be asked to come to the schools. The researchers will ask the participants to empty bladder and discard the urine. The researchers will record the start time and date of the 24-hour urine collection. They will then give the participants the collection equipment including containers and collection aids such as carrier bags. The participants will be instructed to collect all subsequent urine voids over the next 24-hour period. On the second day at the same time, the participants will be asked to bring the urine collection bottles back to the schools, and they will be asked to pass the last urine into the container. The researchers will record the finish time of the first 24-hour urine collection. The researchers will then give the participants the collection equipment for the second 24-hour urine collection and repeat the process. During the 24-hour urine collection period, the participants will be asked to take spare urine containers with them when they go to school or work. Spare collection equipment will also be available in the schools, in case children forget to bring them. In the case that the participant misses one or more urine voids or spillage occurs, the participant will be asked to do a further 24-hour urine collection. The 24-hour urine collections will be made either at weekdays or weekends. For each participant, the 24-hour urines will be collected on the same days of the week for baseline and follow-up at the end of the trial.

We will measure urine volume, sodium, potassium and creatinine. Ion-selective electrode method will be used for sodium and potassium analysis and enzymatic method for creatinine assay. Twenty-four-hour urinary creatinine together with urine volume will be used to determine if the collection is likely to be complete. The biochemist who performs the measurements of urinary electrolytes will not be told to which group the participant is allocated.

In addition to 24-hour urine collection, we will measure BP and heart rate using a validated automatic machine with the appropriate size of cuff. Three readings will be

taken in the right arm at 1- to 2-min intervals at sitting position after the participant has had 10-min rest in a quiet room. Body weight, height and waist circumference will also be measured. Survey on Knowledge, Attitude and Practice (KAP) related to salt will be completed via questionnaire.

Data collection, management and analysis

Data collection

Our study will have two major data outputs. One is the 'App Data' generated automatically when the AppSalt platform is used by the families in intervention group to support salt reduction. The App Data includes information on demographic characteristics, eating habits, amount and sources of salt in the diet, as well as information (or App logs) on the use of AppSalt. The other data output is the 'RCT Data', which is generated by both intervention and control groups during the RCT. The RCT Data will be collected through a specially designed mobile device-based electronic data capture system (mEDC) by well-trained field investigators. The mEDC has been validated and widely used in other clinical trials²⁴ with more advantages on process and quality control compared with traditional EDC. The RCT Data includes information on demographics, social-economic information, KAP, measurement of height, weight, waist circumference, BP, heart rate, 24-hour urine volume and electrolytes, as well as information on costs for all the components of intervention conducted through the AppSalt programme.

Data management

All cleaned and locked datasets together with the study design, questionnaire, code list and definition of database and variables will be stored with a unique ID number attached but no personal identifiers, in TGI, following an established standard operating procedure for data security. To guarantee the data security, the mobile app developer (ie, the Information Technology (IT) team at Beihang University) must follow the 'Mobile Application Information Service Regulation' issued by the Cyberspace Administration of China in 2016. Although personal data are accessible to app developer, disclosure of such information is prohibited. In addition to the development and maintenance of the AppSalt and mEDC, IT team will also provide data management service during the study to guarantee the safety, integrity and proper use of the data collected through AppSalt and mEDC.

Statistical analysis

Data analyses will be performed according to the intention-to-treat approach. The effect of the intervention on the outcomes will be tested using linear mixed models with participants nested within family units and families nested within schools. We will include group (intervention, control), time (baseline, end of trial) and time×group interaction, with the time×group interaction term indicating differential change by group from baseline to the end of the trial. We will adjust for the

stratification variables at randomization and potential confounding variables. Various sensitivity analyses will be carried out to examine the robustness of the conclusions of the primary analysis. Results will be reported as mean, SD, SE, and 95% CI where appropriate. All analyses will be two sided, and $p < 0.05$ is considered significant. SAS will be used for the analyses.

Economic evaluation and process evaluation

Economic evaluations will be carried out from health sector perspective to compare the m-Health strategy with usual care, and it will entail two components: a trial-based economic evaluation and a modelled economic evaluation of long-term costs and outcomes. Intervention costs will include those in running the programme but exclude any research and development costs. The trial-based economic evaluation will be assessed initially in terms of incremental cost per unit reduction in salt intake and systolic BP. The modelled economic evaluation with discounting will examine the cost, survival, quality of life over lifetime, via capturing various health states (including death and CVD events) to estimate incremental cost per life year saved and cost per Quality-Adjusted Life Year gained. The transition probabilities across health states and costs attached to various health states will be based on literature and the long-term effects of the reduction in salt intake or systolic BP will be derived from the trial findings and/or literature of disease progression. Sensitivity analyses will be carried out to estimate uncertainty about the primary findings associated with varying key parameters.

Mixed-method process evaluations will be conducted during and at the end of the study using data from AppSalt, key informant interviews with researchers and teachers and focus groups interviews with participants. This will help understand the barriers and facilitators of the intervention as well as the acceptance and effect of the AppSalt programme.

Project status and timelines

Recruitment of schools and participants started in September 2018. Baseline assessments were carried out between September and December 2018. As the intervention duration is 1 year, the final follow-up assessments will be carried out between September and December 2019.

Expected outcome and potential impact

The study will provide a novel, feasible and effective approach to achieving a sustainable reduction in salt intake in both children and adults. The use of AppSalt platform in delivering health education lessons is particularly advantageous over the traditional school education method in terms of reducing the burden on teaching staff. Furthermore, our study covers a wide range of the population (children and adults, rural and urban, north and south), the results should therefore be generally applicable to the whole Chinese population. If the programme is implemented and sustained across China, it will reduce

population salt intake and thereby prevent hundreds of thousands of strokes, heart attacks and heart failure each year, and lead to major cost-savings to individuals, their families and the health service.

Although our study will be carried out in China, the AppSalt programme could potentially be adopted by many other countries. Additionally, our model on salt reduction could possibly be adapted for other dietary and lifestyle changes to prevent CVD and other non-communicable diseases, which will have major public health implications.

Patient and public involvement

During the development of the study protocol, we had two round-table meetings with six head teachers from three different cities and several telephone meetings with teachers and children's parents to gain their opinion, particularly on the feasibility of carrying out the study in school settings and how to incorporate the intervention programme into the school curriculum. During the study, school teachers will assign and check children's homework. Both teachers and head teachers will be informed of the study progress by monthly communication via newsletters, WeChat and website. On completion of the study, we will disseminate the results to head teachers, teachers, children and their parents. We will also discuss with them and other stakeholders on how to translate research findings into practice.

ETHICS AND DISSEMINATION

Written consent will be obtained from all participants according to well-established practices. For children, participant assent and parental written consent will be obtained. All participants will be free to discontinue their participation at any time with no explanation required.

The findings of this study will be disseminated widely through conference presentations, peer-reviewed publications, press release and social media. Furthermore, the results will be disseminated worldwide through World Action on Salt and Health,²⁵ which is a global non-profit organisation with 600 members from 100 countries with the mission to improve the health of populations by reducing salt intake worldwide.

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Contributors FJH and PZ conceived the project and contribute equally to the work. FJH, PZ, YLi and RL designed the study and oversaw the conceptualisation and development of the app. PZ, YLi, RL, FC, YZ, WZ, DL, HC, TW, JY, JL and SZ facilitates Patient and Public Involvement and were responsible for setting up the study in each site. YLiu and RL are leading the development and maintenance of the app. XL and CW contributed to sample size calculation and analysis plan. All authors contributed to the development of the intervention and evaluation. FJH wrote the first draft of the manuscript, and PZ, YLi, RL, CW and GAM revised the draft. All authors contributed to the refinement of the study protocol and approved the final manuscript.

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Competing interests None declared.

Patient consent for publication Not required.

Ethics approval The study has been approved by Queen Mary Research Ethics Committee and Peking University Health Science Centre Institutional Review Board.

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