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Journal:	<i>BMJ Open</i>
Manuscript ID	bmjopen-2019-033842
Article Type:	Protocol
Date Submitted by the Author:	27-Aug-2019
Complete List of Authors:	Zhang, Xiaochang; Chinese Center for Disease Control and Prevention Hu, Xiao; Beijing Center for Diseases Prevention and Control, Ma, Jixiang; Chinese Center for Disease Control and Prevention Zhang, Puhong ; The George Institute at Peking University Health Science Center, Diabetes Program Li, Yuan; The George Institute for Global Health, Peking University Health Science Centre Luo, Rong; The George Institute for Global Health at Peking University Health Science Center, He, Feng; Queen Mary University of London, Wolfson Institute of Preventive Medicine MacGregor, Graham; Queen Mary University of London, Wolfson Institute of Preventive Medicine Wang, Jinglei; Chinese Center for Disease Control and Prevention Yin, Zhaoxue; Chinese Center for Disease Control and Prevention
Keywords:	Protocols & guidelines < HEALTH SERVICES ADMINISTRATION & MANAGEMENT, PUBLIC HEALTH, Salt reduction

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Protocol for a cluster randomized controlled trial of home cook intervention to reduce salt intake in China

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ABSTRACT

Introduction Salt intake in China twice the upper limit recommended by WHO, and nearly 80% is added during cooking. This study will develop a salt reduction package targeting home cooks and evaluate its effectiveness and feasibility for scale-up.

Methods and analysis A cluster randomized controlled trial (cRCT) design was adopted in this study. The cRCT is conducted in six provinces covering the north-, south-, and west-China. For each province, 10 communities/villages (clusters) was selected with 13 families (one cook and one adult family member) in each cluster for evaluation. In total, 780 home cooks and 780 adult family members were recruited. The home cooks in the intervention group will be provided with the intervention package, which includes community-based standardized offline and online health education and salt intake monitoring. The duration of the intervention is one year. The primary outcome is the difference between the intervention and the control group in the change of salt intake as measured by 24-hour urinary sodium from baseline to the end of the trial

and the secondary outcome is the difference between the two groups in the change of salt related KAP and blood pressure.

Ethics and dissemination The study has been approved by The Queen Mary Research Ethics Committee (QMERC2018/13) and Institutional Review Board of Chinese Center for Disease Control and Prevention (No.201801). The study findings will be disseminated widely through conference presentations and peer-reviewed publications and the general media.

Trial registration number CiChR1800016804.

Strengths and limitations of this study

- The study will develop a new approach to achieving a sustainable progressive lower salt intake for long term.
- The study will use an special intervention method which is family 7-day salt intake monitoring activity to estimate and monitor salt intake, which can support study population to implement a salt reduction programme.
- The study covers a special population which is home cooks in diverse settings, for example, 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.

INTRODUCTION

Excess dietary salt consumption is an important risk factor for high blood pressure, stroke, cardiovascular disease and other adverse health outcomes¹⁻³. As a result, in 2003 the World Health Organization (WHO) and the United Nations Food and Agriculture Organization (FAO) issued a joint report calling for a reduction in population salt intake to less than 5 g per day (<2,000 mg sodium)⁴. It has been estimated that mean salt consumption in 181 of 187 countries exceeded the daily intake of salt recommended by WHO in 2010, and 51 of these countries reported mean intakes greater than double the recommended amount⁵. In April 2019, the

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4 *Lancet* published the latest series of studies on the global burden of disease⁶,
5 which found that 3 million deaths were attributable to high-salt diet in 2017.
6 Salt reduction is highly cost-effective worldwide⁷⁻⁸. It has been estimated
7 that a regulatory intervention to reduce salt intake by 3 g per day would
8 save 194,000 to 392,000 quality-adjusted life-years and \$10 billion to \$24
9 billion in health care costs every year in the USA⁹. At the United Nations
10 General Assembly in 2011, the WHO has identified population salt
11 reduction as a priority intervention for ameliorating the global burden of
12 non-communicable diseases (NCDs)⁴. In 2013, the WHO member states
13 agreed on a global target of a 30% relative reduction in population salt
14 intake to be achieved by 2025¹⁰. Many developed countries have
15 introduced programmes that seek to reduce population-level salt intake,
16 including the UK, Finland, Japan, the US and Canada¹⁰.

17
18 In China, the current situation of salt intake is not satisfactory. High salt
19 intake is the third leading risk factor contributing to death and DALYs¹².
20 A cohort of 16,869 Chinese adults aged 20–60 years over the period 1991–
21 2009 indicated that salt intake remains at high levels, double those of
22 World Health Organization recommendations¹³. A study used two methods
23 (24-hour urine collection and 24-hour dietary recall) to measure salt intake
24 in rural China, the results showed that mean 24-hour urinary sodium
25 excretion was 13g and 24-hour dietary salt intake was 10g¹⁴. Report on
26 Chinese residents' chronic diseases and nutrition showed that the average
27 daily salt intake for Chinese adults was 10.5g in 2012 which using dietary
28 survey method¹⁵.

29
30 In contrast with western countries, most dietary salt in China comes from
31 salt and high-salt condiments added during cooking. The main sources of
32 salt intake from weighed condiments recorded were from home cooking
33 salt (74.7%) followed by soy sauce (15.0%)¹⁶.

34
35 The Chinese government has been making great efforts in salt intake
36 surveillance and salt reduction interventions. Shandong-MOH Action on
37 salt and Hypertension (SMASH) project¹⁷ and Healthy Lifestyle for All
38 initiative¹⁸ were two representatives. Culturally-tailored salt reduction
39 interventions have been applied in various groups and sites, including
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4 distributing salt restriction spoons and encouraging people to use the
5 minimum order to reduce the amount of salt added during cooking¹⁹.
6 However, the effect of such interventions needs to be evaluated in a more
7 rigorous way²⁰.
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10 Since cooking salt is the biggest source of salt intake in China, home cooks,
11 who are responsible for purchasing food and preparing meals for their
12 family, should be given special attention during intervention activities. In
13 Japan, cooking classes for housewives effectively reduced salt intake from
14 9.57g/d to 8.95g/d after two months' intervention²¹. In China, studies
15 specifically focusing on salt reduction among housewives are scarce and it
16 is still unclear that which intervention is effective for family salt reduction.
17 Hence, this study will be undertaken among home cooks in six provinces
18 of China to explore the feasibility of reducing salt intake by means of
19 community-based intervention, which if proven successful, will be applied
20 to a broader scale.
21

22 **Study objectives**

23 The primary objective is to increase salt awareness in home cooks, and to
24 reduce the amount of salt used during cooking, thus helping the population
25 to reduce salt intake by at least 1 g/day. The specific objectives include:
26 (1) To develop a package of salt-reduction interventions through home
27 cook applicable for community families; (2) To evaluate the effectiveness
28 of intervention package by carrying out a cluster randomized trial with
29 intervention duration of 12 months.
30

31 **METHODS AND ANALYSIS**

32 **Overall Study design**

33 Using a cluster RCT design, 60 communities will be selected from 6
34 provinces. A baseline survey will be carried out before randomization
35 among 1560 participants recruited from the 60 communities. The
36 communities will be allocated into intervention or control group randomly.
37 Information of salt related Knowledge-attitude-practice (KAP), blood
38 pressure and 24-h urinary sodium will be collected. The intervention group
39 will receive the salt reduction education for 1 year. (Figure 1)
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Study Setting

Considering the geographical location, economic level and dietary habit, our study will be undertaken in selected counties from six provinces in Qinghai, Hebei, Heilongjiang, Sichuan, Jiangxi and Hunan. The interventions are targeted on all the home cooks and their family members in the selected communities.

Outcomes

Our primary outcome is the difference between the intervention and the control group 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 salt related KAP and blood pressure.

Study Population

Selection of communities

A County/District will be selected from each province. And ten communities will be selected from each County/District. For the selection of communities, we will take into consideration of geographical area, urbanization, size of the populations, age structure of populations, economic status, health service resources, etc. to ensure all the communities with similar characteristics. The selected communities should have local workers to carry out the intervention activities from primary health service and supported by Neighborhood Committee (Women's federation workers). The community involved in other salt-reduction projects should be excluded.

Selection of participants

Participants will be randomly selected according to age and sex. Inclusion criteria for participants include: (1) age: 18-75 years; (2) two family members from each family are included; one of them is the major cook, and the other is selected by the order of spouse, other adult family member (adult with opposite gender); (3) both eat home-made meals at least 4 days per week; (4) participants have lived in the community for more than 6 months and have no relocation plan in the next 24 months. The exclusion criteria include: (1) women in pregnant or lactation period; (2) individuals

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4 currently participate in any other clinical trial; (3) individuals who cannot
5 or refuse to collect 24-hour urine.
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7 **Randomization**

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9 60 communities (clusters) will be randomly assigned (1:1) to either the
10 intervention or the control group. Randomization will be stratified by the
11 geographical area (urban or rural), size of populations, economic status,
12 health service resources. The randomization will be carried out using
13 computer generated random number system by an independent statistician
14 who will be blind to the identity of the communities. The randomization
15 will take place after written consents have been obtained and the baseline
16 assessments have completed. Therefore, the participants, and the local
17 investigators who undertake participant recruitment and data collection,
18 will be unaware of the allocation until the point prior to the commencement
19 of the intervention.
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28 **Intervention**

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30 The primary health staff will unite with workers from neighborhood
31 committee and/or local women's federation to carry out the following
32 interventions under the guidance of local CDC. In the intervention group,
33 the salt reduction intervention package will include:
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37 (1) Supportive environment, such as posters, videos and local broadcast, to
38 deliver core messages of salt reduction. We will develop brochures, posters
39 and videos about salt reduction targeting at home cooks. And Posters will
40 be put up both in communities and markets. Videos will be played in the
41 primary health institutions and at the community activities organized by
42 neighborhood committees.
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48 (2) Lectures on salt reduction knowledge and skills. We will develop a set
49 of standard slides to disseminate the knowledge and skills to reduce salt
50 intake for the target population. The key knowledge and skills will include
51 the relationship between salt and health, the source of salt intake, low
52 sodium salt, misunderstanding of salt reduction, how to reduce salt intake
53 during cooking or when eating outside, and how to wisely choose low salt
54 pre-packaged food. These slides will be provided for the local health
55 institutions who participate in this programme. And they will use it to
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4 deliver the lectures every two month.

5 (3) Family 7-day salt intake monitoring activity. The main function of this
6 monitoring activity is to monitor the amount of salt intake per person per
7 day and improve the awareness of salt reduction among target population.
8 This activity will conduct every two months, and once for 7 consecutive
9 days. The local CDC and local primary health institutions will regularly
10 collect the monitoring records. We will develop an applet of
11 WeChat/webpage ahead to type in the records and calculate the average
12 salt intake of each family member, and the results will be fed back to each
13 family.
14

15 (4) Online health education through social media. The national project
16 team will publish the core knowledge of salt reduction through the WeChat
17 public account to conduct health education for the public.
18

19 The salt reduction education described above will not be given to the
20 control group.
21

22 **Sample Size**

23 Based on the School-EduSalt trial²², assuming a standard deviation of 24-
24 hour urinary sodium excretion is 85mmol/day, and intra-class correlation
25 coefficient (ICC) is 0.05, we estimate that a sample size of 1426 individuals
26 (713 home cooks and 713 family members) would provide a power of 80%
27 (with a two-sided alpha=0.05) to detect a difference in mean 24-hour
28 urinary sodium ≥ 20 mmol/day (1g/d salt) between intervention and control
29 group, allowing for a 20% drop-out rate of participants. We aim to recruit
30 1 home cooks and 1 family member per household, and in order to ensure
31 that the number of households in every community remains same, 12
32 households in each community will be selected, resulting in a total of 720
33 households and 1440 individuals. In addition, considering that response
34 rate of 24-hour urine collection is often low²³, we decided to add one more
35 family per community, therefore 1560 individuals (780 home cooks and
36 780 family members) will be recruited into the study for evaluation.
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38 **Data collection**

39 All outcome measurements and assessments will be carried out at baseline
40 and at the end of the trial in exactly the same way in all communities for
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4 all participants, irrespective of their assignment to intervention or control
5 group.
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7 The participants will be carefully instructed on how to accurately collect
8 24-hour urine by trained research staff. On the first day, the participants
9 will be asked to come to the survey location. The researchers will ask the
10 participants to empty bladder and discard the urine. The researchers will
11 record the start time and date of the 24-hour urine collection. They will
12 then give the participants the collection equipment including containers
13 and collection aids. On the second day at the same time, the participants
14 will be asked to bring the urine collection bottles back to the survey
15 location, and they will be asked to pass the last urine into the container.
16 The researchers will record the finish time of the 24-hour urine collection.
17 During the 24-hour urine collection period, the participants will be asked
18 to take spare urine containers with them when they go to work. In case
19 that the participant misses one or more urine voids or spillage occurs, the
20 participant will be asked to do a further 24-hour urine collection. For each
21 participant, the 24-hour urines will be collected on the same days of the
22 week for baseline and follow-up at the end of the trial. We will measure
23 urine volume, sodium, potassium and creatinine. Ion-selective electrode
24 method will be used for sodium and potassium analysis and enzymatic
25 method for creatinine assay. Twenty-four-hour urinary creatinine together
26 with urine volume will be used to determine if the collection is likely to be
27 complete. The biochemist who performs the measurements of urinary
28 electrolytes will not be told to which group the participant is allocated.
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30 In addition to 24-hour urine collection, we will measure BP and heart rate
31 using a validated automatic machine with the appropriate size of cuff.
32 Three readings will be taken in the right arm at 1- to 2-min intervals at
33 sitting position after the participant has had 10-min rest in a quiet room.
34 Body weight, height and waist circumference will also be measured.
35 Survey on KAP related to salt will be completed via questionnaire.
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37 The RCT Data will be collected through a specially designed mobile
38 device-based electronic data capture system (mEDC) by well-trained field
39 investigators. The RCT Data includes information on demographics,
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3 social-economic information, KAP, measurement of height, weight, waist
4 circumference, BP, heart rate, 24-hour urine volume and electrolytes, as
5 well as information about intervention.
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9 And in order to ensure the quality of intervention, quality control will be
10 set in every step of the trial using the electronic system.
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12 **Statistical methods**

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14 The difference of 24-hour sodium excretion as well as the secondary
15 outcomes between the two groups will be compared using linear mixed
16 models with participants nested within family units and families nested
17 within community/village units. We will include group (intervention,
18 control), time (baseline, end of trial), and time×group interaction, with the
19 time×group interaction term indicating different change by group from
20 baseline to the end of the trial. To account for missing data on continuous
21 outcomes, we will use the likelihood based random effects model that uses
22 all available data and provides valid estimates of the intervention effects
23 when data are missing at random. We will adjust for the stratification
24 variables at randomization and potential confounding variables. We will
25 also carry out various sensitivity analyses to examine the robustness of the
26 conclusions of the primary analysis.
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30 SAS 9.4 will be used for the analyses. Results will be reported as mean,
31 SD, SE, and 95% confidence interval when appropriate. All analyses were
32 two sided, and $P<0.05$ was considered significant.
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35 **Project timelines**

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37 Recruitment of communities and participants started in October 2018.
38 Baseline assessments were carried out between October and December
39 2018. As the intervention duration is 1 year, the final follow-up
40 assessments will be carried out between October and December 2019.
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42 **Expected outcome and potential impact**

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44 The study will provide a feasible and effective approach to achieving a
45 sustainable reduction in salt intake by covering home cooks. The offline
46 intervention methods combined with the online intervention are
47 particularly advantageous over the traditional methods. In addition, the
48 results should therefore be generally applicable to the whole Chinese
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4 population. If the programme is implemented and sustained across China,
5 it will reduce population salt intake and thereby prevent hundreds of
6 thousands of strokes, heart attacks and heart failure each year, and lead to
7 major cost-savings to individuals, their families and the health service.
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10 Although our study will be carried out in China, the programme of home
11 cook intervention to reduce salt could potentially be adopted by many other
12 countries where most of the salt in the diet is added by the consumers,
13 which will have great public health implications.
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19 **ETHICS AND DISSEMINATION**

20 **Ethics**

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22 The study has been reviewed and approved by the Queen Mary Research
23 Ethics Committee (QMERC2018/13) and Institutional Review Board of
24 Chinese Center for Disease Control and Prevention (No.201801).
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28 Written consent will be obtained from all participants in the research
29 according to well-established practices. Every participant has the right to
30 withdraw from the study at any time.
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34 There are no substantive ethical issues associated with the conduct of our
35 research project. The collection of the urine samples constitutes
36 inconvenience but no risk to the individuals involved. A modest reduction
37 in salt intake has no risk to the participants.
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41 During this study, if a participant is found to have high BP, we will
42 recommend him/her to see a doctor and, if he/she agrees, we will help make
43 an appointment with a doctor in a local hospital.
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46 **Dissemination**

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48 The findings of this study will be disseminated through conference
49 presentations, peer-reviewed publications and the general media.
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52 **Acknowledgments**

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54 The authors would like to thank the local CDC and primary health staff
55 who shared their opinion on the development of the intervention
56 programme.
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Contributors

Xiaochang Zhang and Xiao Hu contributed to the work equally. Jixiang Ma, Puhong Zhang, Xiaochang Zhang, Yuan Li and Fengjun He conceived the project and designed the study. Xiaochang Zhang, Xiao Hu, Yuan Li and Rong Luo designed the intervention tools. All authors contributed to the development of the intervention and evaluation. Xiaochang Zhang and Xiao Hu wrote the first draft of the manuscript. Jixiang Ma, Fengjun He, Puhong Zhang and Yuan Li revised the draft. All authors contributed to the refinement of the study protocol and approved the final manuscript.

Funding

The study is being funded, in full, by the National Institute of Health Research (NIHR) using Official Development Assistance funding (16/136/77). The views expressed in this publication are those of the authors and not necessarily those of the NIHR or the Department of Health and Social Care.

Competing interests

FJH is a member of Consensus Action on Salt & Health (CASH) and World Action on Salt & Health (WASH). Both CASH and WASH are nonprofit charitable organizations, and FJH does not receive any financial support from CASH or WASH. GAM is Chairman of Blood Pressure UK (BPUK), Chairman of CASH, WASH, and Action on Sugar. BPUK, CASH, WASH and Action on Sugar are nonprofit charitable organizations. GAM does not receive any financial support from any of these organizations. Other authors have no disclosures to report.

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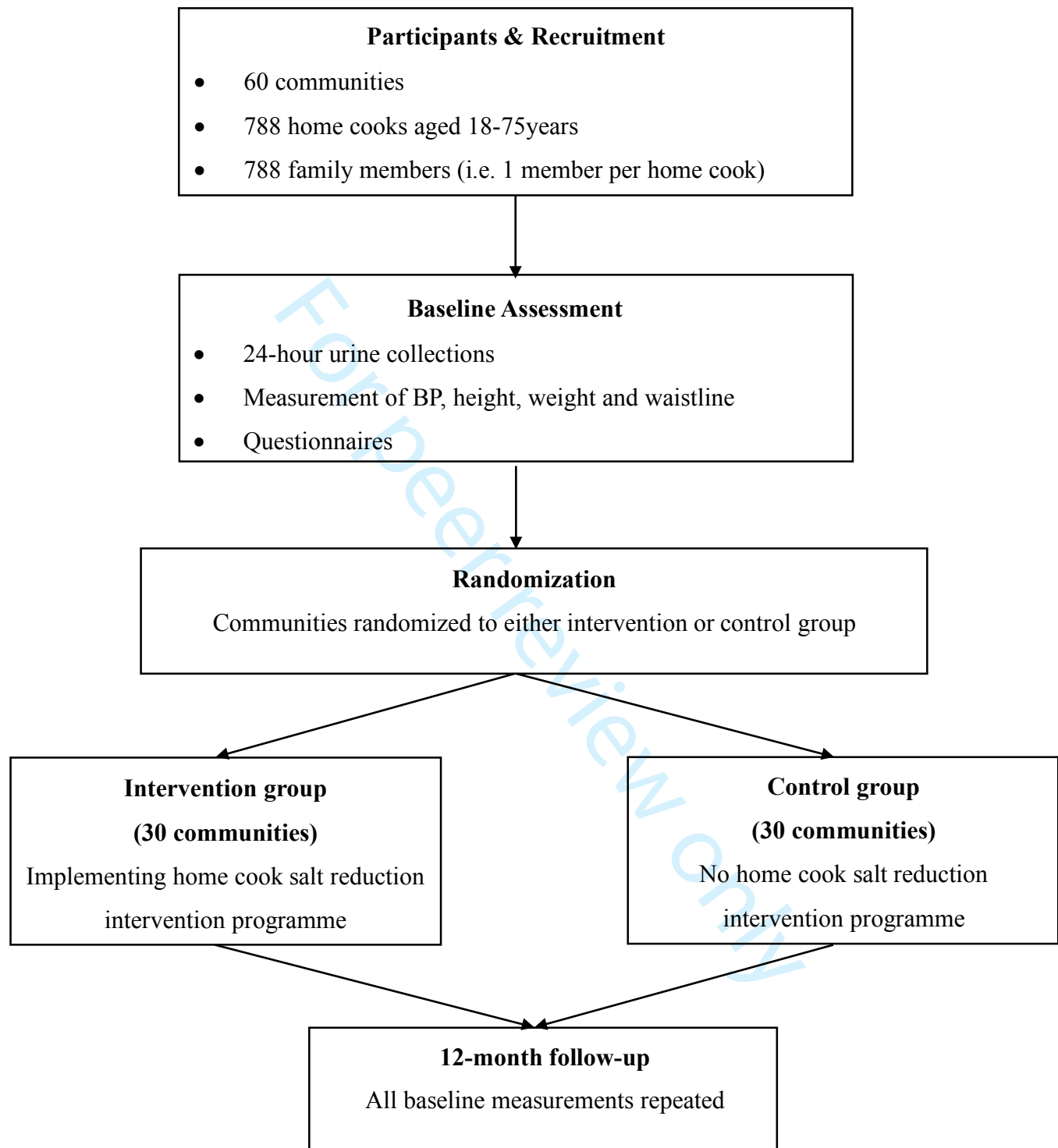


Figure 1. Home cook intervention trial design

BMJ Open

Protocol for a cluster randomized controlled trial of home cook intervention to reduce salt intake in China

Journal:	<i>BMJ Open</i>
Manuscript ID	bmjopen-2019-033842.R1
Article Type:	Protocol
Date Submitted by the Author:	08-Jan-2020
Complete List of Authors:	Zhang, Xiaochang; Chinese Center for Disease Control and Prevention Hu, Xiao; Beijing Center for Diseases Prevention and Control, Ma, Jixiang; Chinese Center for Disease Control and Prevention Zhang, Puhong ; The George Institute at Peking University Health Science Center, Diabetes Program Li, Yuan; The George Institute for Global Health, Peking University Health Science Centre Luo, Rong; The George Institute for Global Health at Peking University Health Science Center, He, Feng; Queen Mary University of London, Wolfson Institute of Preventive Medicine MacGregor, Graham; Queen Mary University of London, Wolfson Institute of Preventive Medicine Wang, Jinglei; Chinese Center for Disease Control and Prevention Yin, Zhaoxue; Chinese Center for Disease Control and Prevention
Primary Subject Heading:	Public health
Secondary Subject Heading:	Epidemiology
Keywords:	Protocols & guidelines < HEALTH SERVICES ADMINISTRATION & MANAGEMENT, PUBLIC HEALTH, Salt reduction

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Protocol for a cluster randomized controlled trial of home cook intervention to reduce salt intake in China

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ABSTRACT

Introduction Salt intake in China is twice the upper limit recommended by the World Health Organization (WHO), and nearly 80% of salt is added during cooking. This study will develop a package of salt reduction interventions targeting home cooks and evaluate its effectiveness and feasibility for scale-up.

Methods and analysis A cluster randomized controlled trial (cRCT)

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4 design is adopted in this study, which will be conducted in six provinces
5 covering northern, central and southern China. For each province, 10
6 communities/villages (clusters) with 13 families (one cook and one adult
7 family member) will be selected in each cluster for evaluation. In total, 780
8 home cooks and 780 adult family members will be recruited. The home
9 cooks in the intervention group will be provided with the intervention
10 package, including community-based standardized offline and online
11 health education and salt intake monitoring. The duration of the
12 intervention will be one year. The primary outcome is the difference
13 between the intervention and control group in change in salt intake as
14 measured by 24-hour urinary sodium from baseline to the end of the trial.
15 The secondary outcome is the difference between the two groups in the
16 change in salt-related KAP and blood pressure.
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31 **Ethics and dissemination** The study has been approved by The Queen
32 Mary Research Ethics Committee (QMERC2018/13) and Institutional
33 Review Board of the Chinese Center for Disease Control and Prevention
34 (No.201801). The study findings will be disseminated widely through
35 conference presentations and peer-reviewed publications and the general
36 media.
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44 **Trial registration number** ChiCTR1800016804.
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50 **Strengths and limitations of this study**

- 51 • A new approach will be developed to achieve long-term, sustainable
52 progressive lower salt intake.
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- 54 • A 7-day salt surveillance method will be applied to estimate the salt intake
55 of every member of the family to motivate the target population to reduce
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4 salt intake.

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7 • The study covers a wide range of the population through the inclusion of
8 home cooks and their family members from diverse areas, including
9 northern, central and southern China.
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13 • The results should be generally applicable to the whole Chinese population.
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16 • The study will be carried out in China only; however, the method could
17 potentially be adopted by many other developing countries where most of
18 the salt in the diet is added by consumers.
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26 INTRODUCTION

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29 Excess dietary salt consumption is an important risk factor for high blood
30 pressure, stroke, cardiovascular disease and other adverse health
31 outcomes¹⁻³. As a result, in 2003 the WHO and the United Nations Food
32 and Agriculture Organization (FAO) issued a joint report calling for a
33 reduction in salt intake in the population to less than 5 g per day (<2,000
34 mg sodium)⁴. It has been estimated that the mean salt consumption in 181
35 of 187 countries exceeded the daily intake of salt recommended by the
36 WHO in 2010, and 51 of these countries reported mean intakes greater than
37 double the recommended amount⁵. In April 2019, the *Lancet* published the
38 latest series of studies on the global burden of disease⁶, which found that 3
39 million deaths were attributable to a high-salt diet in 2017.
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52 Salt reduction is highly cost-effective worldwide⁷⁻⁸. It has been estimated
53 that a regulatory intervention to reduce salt intake by 3 g per day would
54 save 194,000 to 392,000 quality-adjusted life-years and \$10 to \$24 billion
55 in health care costs every year in the USA⁹. At the United Nations General
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4 Assembly in 2011, the WHO identified population salt reduction as a
5 priority intervention for ameliorating the global burden of non-
6 communicable diseases (NCDs)⁴. In 2013, the WHO member states agreed
7 on a global target of a 30% relative reduction salt intake in the population
8 to be achieved by 2025¹⁰. Many developed countries have introduced
9 programmes that seek to reduce population-level salt intake, including the
10 UK, Finland, Japan, the US and Canada¹¹.
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18 In China, the current salt intake situation is not satisfactory. High salt
19 intake is the third leading risk factor contributing to death and DALYs¹².
20 A cohort of 16,869 Chinese adults aged 20–60 years over the period of
21 1991–2009 indicated that salt intake remains at high levels, double those
22 of World Health Organization recommendations¹³. A study used two
23 methods (24-hour urine collection and 24-hour dietary recall) to measure
24 salt intake in rural China, and the results showed that mean 24-hour urinary
25 sodium excretion was 13 g and 24-hour dietary salt intake was 10 g¹⁴. In
26 2012, a report examining Chinese residents' chronic diseases and nutrition
27 using a dietary survey showed that the average daily salt intake for Chinese
28 adults was 10.5g¹⁵.
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42 In contrast to Western countries, in China, most dietary salt comes from
43 salt and high-salt condiments that are added during cooking. A survey
44 involving nine provinces of China showed that in 2006 the main sources
45 of dietary sodium were from salt in home cooking (71.5%) followed by
46 soy sauce (8.3%)¹⁶.
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52 The Chinese government has been making great efforts in salt intake
53 surveillance and salt reduction interventions. The Shandong-MOH Action
54 on Salt and Hypertension (SMASH) project¹⁷ and Healthy Lifestyle for All
55 initiative¹⁸ are two representative interventions. Culturally tailored salt
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4 reduction interventions have been applied in various groups and sites,
5 including the distribution of salt restriction spoons and the encouragement
6 of people to use the minimum amount of salt to reduce the amount of salt
7 added during cooking¹⁹. However, the effect of such interventions must be
8 evaluated in a more rigorous way²⁰.
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14 Since cooking salt is the largest source of salt intake in China, home cooks,
15 who are responsible for purchasing food and preparing meals for their
16 families, should be given special attention during intervention activities. In
17 Japan, cooking classes for housewives effectively reduced salt intake from
18 9.57 g/d to 8.95 g/d after a two-month intervention²¹. In China, studies
19 specifically focusing on salt reduction among housewives are scarce, and
20 the type of interventions that are effective for family salt reduction remain
21 unclear. Hence, this study will be undertaken among home cooks in six
22 provinces of China to explore the feasibility of reducing salt intake by
23 means of community-based intervention, which, if proven successful, will
24 be applied on a broader scale.
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37 **Study objectives**

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40 The primary objective is to increase salt awareness in home cooks and to
41 reduce the amount of salt used during cooking, thus helping the population
42 reduce salt intake by at least 1 g/day. The specific objectives include the
43 following: (1) to develop a package of salt reduction interventions through
44 home cooks that are applicable to community families and (2) to evaluate
45 the effectiveness of the intervention package by carrying out a cluster
46 randomized trial with an intervention duration of 12 months.
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58 **METHODS AND ANALYSIS**

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Overall Study design

Using a cluster RCT design, 60 communities will be selected from 6 provinces. A baseline survey will be carried out before randomization among 1560 participants recruited from the 60 communities. The communities will be allocated randomly to the intervention or control group. Information on salt-related KAP, blood pressure and 24-h urinary sodium will be collected. The intervention group will receive the salt reduction intervention for 1 year. (Figure 1)

Study Setting

Considering the geographical location, economic level and dietary habits, our study will be undertaken in selected counties from six provinces in Qinghai, Hebei, Heilongjiang, Sichuan, Jiangxi and Hunan. The interventions will be targeted to all home cooks and their family members in the selected communities.

Outcomes

The primary outcome is the difference between the intervention and control group in the change in 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 in salt-related KAP and blood pressure.

Study Population

Selection of communities

A county/district will be selected from each province, and ten communities will be selected from each county/district. For the selection of communities, we will take into consideration the geographical area, urbanization, size of

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4 the populations, age structure of the populations, economic status, and
5 health service resources, among others, to ensure all the communities have
6 similar characteristics. The selected communities should have local
7 workers to carry out the intervention activities from the primary health
8 service supported by the neighbourhood committee (women's federation
9 workers). Communities involved in other salt reduction projects should be
10 excluded.
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18 ***Selection of participants***

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21 Participants will be randomly selected according to age and sex. Inclusion
22 criteria for participants include the following: (1) age of 18-75 years; (2)
23 two family members from each family, one of whom is the major cook and
24 the other of whom is another adult family member (better to be of different
25 gender, spouse is preferred); (3) consumption of homemade meals at least
26 4 days per week by both of the family members; and (4) residence in the
27 community for more than 6 months and no relocation plans in the next 24
28 months. The exclusion criteria include the following: (1) women who are
29 pregnant or lactating; (2) individuals currently participating in any other
30 clinical trial; and (3) individuals who cannot or refuse to collect 24-hour
31 urine.
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45 **Randomization**

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47 Sixty communities (clusters) will be randomly assigned (1:1) to either the
48 intervention or the control group. Randomization will be stratified by the
49 geographical area (urban or rural), size of the population, economic status,
50 and health service resources. Randomization will be carried out using a
51 computer-generated random number system by an independent statistician
52 who will be blinded to the identity of the communities. The randomization
53 will be implemented after receiving written consent and completing the
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4 baseline assessments. Therefore, the participants and the local
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6 investigators who undertake participant recruitment and data collection
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8 will be unaware of the allocation until commencement of the intervention.
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10 **Intervention**

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13 The intervention group will receive the salt reduction intervention package
14 developed in this study, while the control group will not receive any of the
15 interventions. The primary health staff will collaborate with workers from
16 the neighbourhood committee and/or local women's federation to carry out
17 the following interventions under the guidance of the local CDC. The salt
18 reduction intervention package will include the following.
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26 (1) A supportive environment, such as posters, brochures, videos and local
27 broadcasts, to deliver core messages regarding salt reduction. We will
28 develop brochures, posters, videos and audio materials about salt reduction
29 targeting home cooks. Additionally, posters will be put up in communities
30 and markets. Videos will be played in primary health institutions and at
31 community activities organized by neighbourhood committees.
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40 (2) Lectures on salt reduction knowledge and skills. We will develop a set
41 of standard slides to disseminate knowledge and skills to reduce salt intake
42 for the target population. In the intervention communities, these slides will
43 be provided for the local health institutions. They will organize and deliver
44 lectures to the participants, especially the home cooks, once every two
45 months. A total of 6 training lectures will be delivered in 12 months. The
46 brief contents of the six courses will include salt-related health outcomes,
47 sources of salt intake, low-sodium salt, misunderstandings of salt reduction,
48 how to reduce salt intake during cooking or when eating outside the home,
49 and how to wisely choose low-salt pre-packaged food.
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4 (3) A 7-day salt intake monitoring activity. This method will be used to
5 estimate the amount of salt intake for every member of the family and
6 improve the awareness of salt reduction among the target population.
7 Participants will record the frequency of dining out, consumption of
8 processed foods and amount of salt added during cooking. The added salt
9 will be assessed by weighing salt, soy sauce and other primary salty
10 condiments on the first and last day of the evaluation period²². Additionally,
11 the local CDCs and primary health institutions will help participants with
12 the results estimated by this method and remind the families about their
13 salt intake in relation to the set targets and highlight further action plans.

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18 (4) Online health education. The national project team will publish core
19 knowledge on salt reduction through the WeChat public account to conduct
20 health education for the public.
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25 **Sample Size**

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34 Based on the School-EduSalt trial²³, assuming a standard deviation of 24-
35 hour urinary sodium excretion of 85 mmol/day and an intra-class
36 correlation coefficient (ICC) of 0.05, we estimated that a sample size of
37 1426 individuals (713 home cooks and 713 family members) would
38 provide a power of 80% (with a two-sided alpha=0.05) to detect a
39 difference in mean 24-hour urinary sodium ≥ 20 mmol/day (1 g/d salt)
40 between the intervention and control group, allowing for a 20% drop-out
41 rate of participants. We aim to recruit 1 home cook and 1 family member
42 per household to ensure that the number of households in every community
43 remains the same. We will select 12 households in each community,
44 resulting in a total of 720 households and 1440 individuals. In addition,
45 considering that the response rate of 24-hour urine collection is often low²⁴,
46 we have decided to add one more family per community, resulting in the
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4 recruitment of 1560 individuals (780 home cooks and 780 family members)
5 into the study for evaluation.
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8 **Data collection**

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11 All outcome measurements and assessments will be carried out at baseline
12 and at the end of the trial in exactly the same way in all communities for
13 all participants, irrespective of their assignment to the intervention or
14 control group.
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20 The participants will be carefully instructed on how to accurately collect
21 24-hour urine by trained research staff. On the first day, the participants
22 will be asked to visit the survey location. The researchers will ask the
23 participants to empty their bladders and discard the urine. The researchers
24 will record the start time and date of the 24-hour urine collection. They will
25 then supply the participants with collection equipment including containers
26 and collection aids. At the same time, on the second day, the participants
27 will be asked to bring the urine collection bottles back to the survey
28 location and to pass the last urine into the container. The researchers will
29 record the finish time of the 24-hour urine collection. During the 24-hour
30 urine collection period, the participants will be asked to take spare urine
31 containers with them to work. In case the participant misses one or more
32 urine voids or spillage occurs, the participant will be asked to perform an
33 additional 24-hour urine collection. For each participant, the 24-hour urine
34 will be collected on the same days of the week for the baseline visit and
35 follow-up visit at the end of the trial. We will measure urine volume,
36 sodium, potassium and creatinine. An ion-selective electrode method will
37 be used for sodium and potassium analysis and an enzymatic method for
38 the creatinine assay. The 24-hour urinary creatinine together with the urine
39 volume will be used to determine if the collection is likely to be complete.
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4 The biochemist who performs the measurements of urinary electrolytes
5 will be unaware of the group to which the participant is allocated.
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9 In addition to 24-hour urine collection, we will measure BP and heart rate
10 using a validated automatic machine with the appropriate cuff size. Three
11 readings will be taken for the right arm at 1 to 2-min intervals in a sitting
12 position after the participant has rested for 10 min in a quiet room. Body
13 weight, height and waist circumference will also be measured. A survey on
14 KAP related to salt will be completed via questionnaire.
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21 The RCT data will be collected through a specially designed mobile
22 device-based electronic data capture system (mEDC) by well-trained field
23 investigators. The RCT data include information on demographics, social-
24 economic information, KAP, measurements of height, weight, waist
25 circumference, BP, heart rate, 24-hour urine volume and electrolytes, as
26 well as information about the intervention.
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34 Additionally, to ensure the quality of the intervention, quality control will
35 be established at every step of the trial using the electronic system.
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39 **Data collection**

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

Statistical methods

The difference in 24-hour sodium excretion as well as the secondary outcomes between the two groups will be compared using linear mixed models with participants nested within family units and families nested within community/village units. We will include group (intervention, control), time (baseline, end of trial), and time×group interactions, with the time×group interaction term indicating different changes by group from baseline to the end of the trial. To account for missing data on continuous outcomes, we will use the likelihood-based random effects model that uses all available data and provides valid estimates of the intervention effects when data are missing at random. We will adjust for the stratification variables at randomization and potential confounding variables. We will also carry out various sensitivity analyses to examine the robustness of the conclusions of the primary analysis.

SAS 9.4 will be used for the analyses. The results will be reported as the mean, SD, SE, and 95% confidence interval when appropriate. All analyses will be two-sided, and $P < 0.05$ will be considered significant.

Project timelines

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

Expected outcome and potential impact

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4 The study will provide a feasible and effective approach to achieving a
5 sustainable reduction in salt intake by targeting home cooks. The offline
6 intervention methods combined with the online intervention are
7 particularly advantageous over traditional methods. Therefore, the results
8 should be generally applicable to the whole Chinese population. If the
9 programme is implemented and sustained across China, it will reduce
10 population salt intake and thereby prevent hundreds of thousands of strokes,
11 heart attacks and heart failure each year, leading to major cost-savings to
12 individuals, their families and health services.
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23 Although our study will be conducted in China, the home cook intervention
24 programme to reduce salt could potentially be adopted by many other
25 countries where most of the salt in the diet is added by consumers, which
26 will have great public health implications.
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31 **Patient and Public Involvement**

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34 No patient involved.
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40 **ETHICS AND DISSEMINATION**

41 **Ethics**

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46 The study has been reviewed and approved by the Queen Mary Research
47 Ethics Committee (QMERC2018/13) and the Institutional Review Board
48 of the Chinese Center for Disease Control and Prevention (No.201801).
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53 Written consent will be obtained from all participants in the research
54 according to well-established practices. Every participant has the right to
55 withdraw from the study at any time.
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60 There are no substantive ethical issues associated with the conduct of our

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4 research project. The collection of urine samples constitutes inconvenience
5 but no risk to the individuals involved. A modest reduction in salt intake
6 has no risk to the participants.
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10 During this study, if a participant is found to have high BP, we will
11 recommend that he/she sees a doctor, and if he/she agrees, we will help
12 make an appointment with a doctor in a local hospital.
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16 17 **Dissemination**

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19 The findings of this study will be disseminated through conference
20 presentations, peer-reviewed publications and the general media.
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28 29 **Acknowledgements**

30
31 The authors would like to thank the local CDC and primary health staff
32 who shared their opinions regarding the development of the intervention
33 programme.
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40 41 **Contributors**

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43 Xiaochang Zhang and Xiao Hu contributed to this work equally. Jixiang
44 Ma, Puhong Zhang, Xiaochang Zhang, Yuan Li, Fengjun He, and Graham
45 A MacGregor conceived the project and designed the study. Xiaochang
46 Zhang, Xiao Hu, Yuan Li and Rong Luo designed the intervention tools.
47 All authors contributed to the development of the intervention and
48 evaluation. Xiaochang Zhang and Xiao Hu wrote the first draft of the
49 manuscript. Jixiang Ma, Fengjun He, Puhong Zhang, Yuan Li, Graham A
50 MacGregor, Jinglei Wang, and Zhaoxue Yin revised the manuscript draft.
51 All authors contributed to the refinement of the study protocol and
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4 approved the final manuscript.
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9 **Funding**

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11
12 The study is being funded in full by the National Institute of Health
13 Research (NIHR) using Official Development Assistance funding
14 (16/136/77). The views expressed in this publication are those of the
15 authors and not necessarily those of the NIHR or the Department of Health
16 and Social Care.
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26 **Competing interests**

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29 FJH is a member of Consensus Action on Salt & Health (CASH) and
30 World Action on Salt & Health (WASH). Both CASH and WASH are
31 nonprofit charitable organizations, and FJH has not received any financial
32 support from CASH or WASH. GAM is Chairman of Blood Pressure UK
33 (BPUK), Chairman of CASH, WASH, and Action on Sugar. BPUK,
34 CASH, WASH and Action on Sugar are nonprofit charitable organizations.
35 GAM has not received receive any financial support from any of these
36 organizations. The other authors have no disclosures to report.
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56 Figure Legends

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4 **Figure1.** Home cook intervention trial design.
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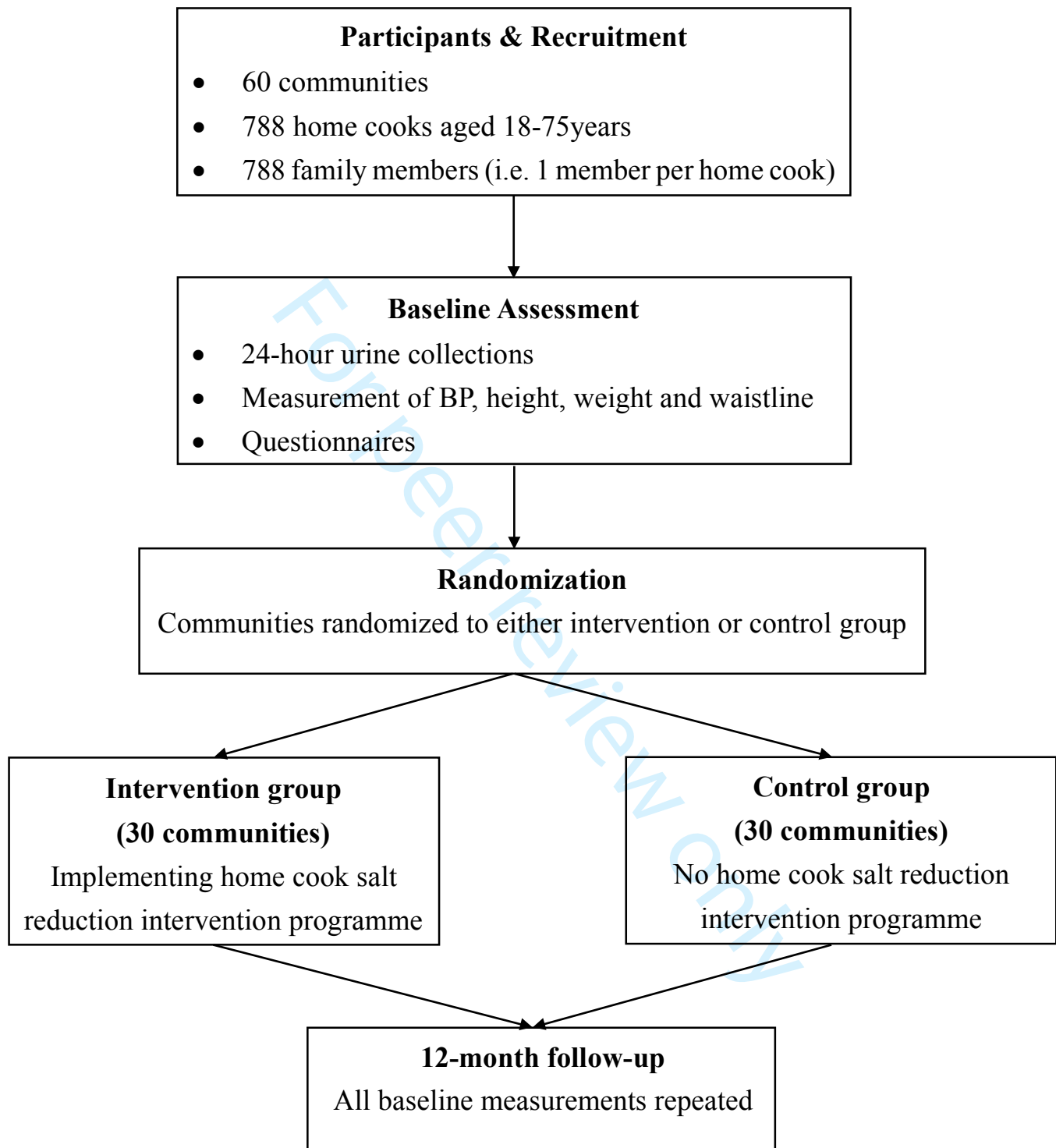


Figure 1 Home cook intervention trial design.

BMJ Open

Protocol for a cluster randomized controlled trial of home cook intervention to reduce salt intake in China

Journal:	<i>BMJ Open</i>
Manuscript ID	bmjopen-2019-033842.R2
Article Type:	Protocol
Date Submitted by the Author:	14-Feb-2020
Complete List of Authors:	Zhang, Xiaochang; Chinese Center for Disease Control and Prevention Hu, Xiao; Beijing Center for Diseases Prevention and Control, Ma, Jixiang; Chinese Center for Disease Control and Prevention Zhang, Puhong ; The George Institute at Peking University Health Science Center, Diabetes Program Li, Yuan; The George Institute for Global Health, Peking University Health Science Centre Luo, Rong; The George Institute for Global Health at Peking University Health Science Center, He, Feng; Queen Mary University of London, Wolfson Institute of Preventive Medicine MacGregor, Graham; Queen Mary University of London, Wolfson Institute of Preventive Medicine Wang, Jinglei; Chinese Center for Disease Control and Prevention Yin, Zhaoxue; Chinese Center for Disease Control and Prevention
Primary Subject Heading:	Public health
Secondary Subject Heading:	Epidemiology
Keywords:	Protocols & guidelines < HEALTH SERVICES ADMINISTRATION & MANAGEMENT, PUBLIC HEALTH, Salt reduction

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Protocol for a cluster randomized controlled trial of home cook intervention to reduce salt intake in China

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ABSTRACT

Introduction Salt intake in China is twice the upper limit recommended by the World Health Organization (WHO), and nearly 80% of salt is added during cooking. This study will develop a package of salt reduction interventions targeting home cooks and evaluate its effectiveness and feasibility for scale-up.

Methods and analysis A cluster randomized controlled trial (cRCT) design is adopted in this study, which will be conducted in six provinces covering northern, central and southern China. For each province, 10 communities/villages (clusters) with 13 families (one cook and one adult family member) will be selected in each cluster for evaluation. In total, 780 home cooks and 780 adult family members will be recruited. The home cooks in the intervention group will be provided with the intervention package, including community-based standardized offline and online health education and salt intake monitoring. The duration of the intervention will be one year. The primary outcome is the difference between the intervention and control group in change in salt intake as

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4 measured by 24-hour urinary sodium from baseline to the end of the trial.
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6 The secondary outcome is the difference between the two groups in the
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8 change in salt-related knowledge, attitude and practice (KAP) and blood
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10 pressure.

11 **Ethics and dissemination** The study has been approved by The Queen
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13 Mary Research Ethics Committee (QMERC2018/13) and Institutional
14
15 Review Board of the Chinese Center for Disease Control and Prevention
16
17 (No.201801). The study findings will be disseminated widely through
18
19 conference presentations and peer-reviewed publications and the general
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21 media.

22 **Trial registration number** ChiCTR1800016804.
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25 **Strengths and limitations of this study**

- 26 • A new approach will be developed to achieve long-term, sustainable
27
28 progressive lower salt intake.
- 29 • A 7-day salt surveillance method will be applied to estimate the salt intake
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31 of every member of the family to motivate the target population to reduce
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33 salt intake.
- 34 • The study covers a wide range of the population through the inclusion of
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36 home cooks and their family members from diverse areas, including
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38 northern, central and southern China.
- 39 • The study will be carried out in China only; however, the method could
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41 potentially be adopted by many other developing countries where most of
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43 the salt in the diet is added by consumers.
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48 **INTRODUCTION**

49 Excess dietary salt consumption is an important risk factor for high blood
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51 pressure, stroke, cardiovascular disease and other adverse health
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53 outcomes¹⁻³. As a result, in 2003 the WHO and the United Nations Food
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55 and Agriculture Organization (FAO) issued a joint report calling for a
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57 reduction in salt intake in the population to less than 5 g per day (<2,000
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59 mg sodium)⁴. It has been estimated that the mean salt consumption in 181
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of 187 countries exceeded the daily intake of salt recommended by the

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4 WHO in 2010, and 51 of these countries reported mean intakes greater than
5 double the recommended amount⁵. In April 2019, the *Lancet* published the
6 latest series of studies on the global burden of disease⁶, which found that 3
7 million deaths were attributable to a high-salt diet in 2017.
8

9
10 Salt reduction is highly cost-effective worldwide⁷⁻⁸. It has been estimated
11 that a regulatory intervention to reduce salt intake by 3 g per day would
12 save 194,000 to 392,000 quality-adjusted life-years and \$10 to \$24 billion
13 in health care costs every year in the USA⁹. At the United Nations General
14 Assembly in 2011, the WHO identified population salt reduction as a
15 priority intervention for ameliorating the global burden of non-
16 communicable diseases (NCDs)⁴. In 2013, the WHO member states agreed
17 on a global target of a 30% relative reduction salt intake in the population
18 to be achieved by 2025¹⁰. Many developed countries have introduced
19 programmes that seek to reduce population-level salt intake, including the
20 UK, Finland, Japan, the US and Canada¹¹.
21

22
23 In China, the current salt intake situation is not satisfactory. High salt
24 intake is the third leading risk factor contributing to death and DALYs¹².
25 A cohort of 16,869 Chinese adults aged 20–60 years over the period of
26 1991–2009 indicated that salt intake remains at high levels, double those
27 of World Health Organization recommendations¹³. A study used two
28 methods (24-hour urine collection and 24-hour dietary recall) to measure
29 salt intake in rural China, and the results showed that mean 24-hour urinary
30 sodium excretion was 13 g and 24-hour dietary salt intake was 10 g¹⁴. In
31 2012, a report examining Chinese residents' chronic diseases and nutrition
32 using a dietary survey showed that the average daily salt intake for Chinese
33 adults was 10.5g¹⁵.
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35
36 In contrast to Western countries, in China, most dietary salt comes from
37 salt and high-salt condiments that are added during cooking. A survey
38 involving nine provinces of China showed that in 2006 the main sources
39 of dietary sodium were from salt in home cooking (71.5%) followed by
40 soy sauce (8.3%)¹⁶.
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43 The Chinese government has been making great efforts in salt intake
44 surveillance and salt reduction interventions. The Shandong-MOH Action
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4 on Salt and Hypertension (SMASH) project¹⁷ and Healthy Lifestyle for All
5 initiative¹⁸ are two representative interventions. Culturally tailored salt
6 reduction interventions have been applied in various groups and sites,
7 including the distribution of salt restriction spoons and the encouragement
8 of people to use the minimum amount of salt to reduce the amount of salt
9 added during cooking¹⁹. However, the effect of such interventions must be
10 evaluated in a more rigorous way²⁰.

11
12 Since cooking salt is the largest source of salt intake in China, home cooks,
13 who are responsible for purchasing food and preparing meals for their
14 families, should be given special attention during intervention activities. In
15 Japan, cooking classes for housewives effectively reduced salt intake from
16 9.57 g/d to 8.95 g/d after a two-month intervention²¹. In China, studies
17 specifically focusing on salt reduction among housewives are scarce, and
18 the type of interventions that are effective for family salt reduction remain
19 unclear. Hence, this study will be undertaken among home cooks in six
20 provinces of China to explore the feasibility of reducing salt intake by
21 means of community-based intervention, which, if proven successful, will
22 be applied on a broader scale.

23 **Study objectives**

24 The primary objective is to increase salt awareness in home cooks and to
25 reduce the amount of salt used during cooking, thus helping the population
26 reduce salt intake by at least 1 g/day. The specific objectives include the
27 following: (1) to develop a package of salt reduction interventions through
28 home cooks that are applicable to community families and (2) to evaluate
29 the effectiveness of the intervention package by carrying out a cluster
30 randomized trial with an intervention duration of 12 months.

31 **METHODS AND ANALYSIS**

32 **Overall Study design**

33 Using a cluster RCT design, 60 communities will be selected from 6
34 provinces. A baseline survey will be carried out before randomization
35 among 1560 participants recruited from the 60 communities. The
36 communities will be allocated randomly to the intervention or control
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4 group. Information on salt-related KAP, blood pressure and 24-h urinary
5 sodium will be collected. The intervention group will receive the salt
6 reduction intervention for 1 year. (Figure 1)
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8 9 **Study Setting**

10 Considering the geographical location, economic level and dietary habits,
11 our study will be undertaken in selected counties from six provinces in
12 Qinghai, Hebei, Heilongjiang, Sichuan, Jiangxi and Hunan. The
13 interventions will be targeted to all home cooks and their family members
14 in the selected communities.
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19 **Outcomes**

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21 The primary outcome is the difference between the intervention and control
22 group in the change in salt intake as measured by 24-hour urinary sodium
23 from baseline to the end of the trial.
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26 The secondary outcome is the difference between the two groups in the
27 change in salt-related KAP and blood pressure.
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30 **Study Population**

31 *Selection of communities*

32
33 A county/district will be selected from each province, and ten communities
34 will be selected from each county/district. For the selection of communities,
35 we will take into consideration the geographical area, urbanization, size of
36 the populations, age structure of the populations, economic status, and
37 health service resources, among others, to ensure all the communities have
38 similar characteristics. The selected communities should have local
39 workers to carry out the intervention activities from the primary health
40 service supported by the neighbourhood committee (women's federation
41 workers). Communities involved in other salt reduction projects should be
42 excluded.
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50 *Selection of participants*

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52 Participants will be randomly selected according to age and sex. Inclusion
53 criteria for participants include the following: (1) age of 18-75 years; (2)
54 two family members from each family, one of whom is the major cook and
55 the other of whom is another adult family member (better to be of different
56 gender, spouse is preferred); (3) consumption of homemade meals at least
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4 4 days per week by both of the family members; and (4) residence in the
5 community for more than 6 months and no relocation plans in the next 24
6 months. The exclusion criteria include the following: (1) women who are
7 pregnant or lactating; (2) individuals currently participating in any other
8 clinical trial; and (3) individuals who cannot or refuse to collect 24-hour
9 urine.
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14 **Randomization**

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16 Sixty communities (clusters) will be randomly assigned (1:1) to either the
17 intervention or the control group. Randomization will be stratified by the
18 geographical area (urban or rural), size of the population, economic status,
19 and health service resources. Randomization will be carried out using a
20 computer-generated random number system by an independent statistician
21 who will be blinded to the identity of the communities. The randomization
22 will be implemented after receiving written consent and completing the
23 baseline assessments. Therefore, the participants and the local
24 investigators who undertake participant recruitment and data collection
25 will be unaware of the allocation until commencement of the intervention.
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34 **Intervention**

35 The intervention group will receive the salt reduction intervention package
36 developed in this study, while the control group will not receive any of the
37 interventions. The primary health staff will collaborate with workers from
38 the neighbourhood committee and/or local women's federation to carry out
39 the following interventions under the guidance of the local CDC. The salt
40 reduction intervention package will include the following.
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46 (1) A supportive environment, such as posters, brochures, videos and local
47 broadcasts, to deliver core messages regarding salt reduction. We will
48 develop brochures, posters, videos and audio materials about salt reduction
49 targeting home cooks. Additionally, posters will be put up in communities
50 and markets. Videos will be played in primary health institutions and at
51 community activities organized by neighbourhood committees.
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56 (2) Lectures on salt reduction knowledge and skills. We will develop a set
57 of standard slides to disseminate knowledge and skills to reduce salt intake
58 for the target population. In the intervention communities, these slides will
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4 be provided for the local health institutions. They will organize and deliver
5 lectures to the participants, especially the home cooks, once every two
6 months. A total of 6 training lectures will be delivered in 12 months. The
7 brief contents of the six courses will include salt-related health outcomes,
8 sources of salt intake, low-sodium salt, misunderstandings of salt reduction,
9 how to reduce salt intake during cooking or when eating outside the home,
10 and how to wisely choose low-salt pre-packaged food.
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16 (3) A 7-day salt intake monitoring activity. This method will be used to
17 estimate the amount of salt intake for every member of the family and
18 improve the awareness of salt reduction among the target population.
19 Participants will record the frequency of dining out, consumption of
20 processed foods and amount of salt added during cooking. The added salt
21 will be assessed by weighing salt, soy sauce and other primary salty
22 condiments on the first and last day of the evaluation period²². Additionally,
23 the local CDCs and primary health institutions will help participants with
24 the results estimated by this method and remind the families about their
25 salt intake in relation to the set targets and highlight further action plans.
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33 (4) Online health education. The national project team will publish core
34 knowledge on salt reduction through the WeChat public account to conduct
35 health education for the public.
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39 **Sample Size**

40 Based on the School-EduSalt trial²³, assuming a standard deviation of 24-
41 hour urinary sodium excretion of 85 mmol/day and an intra-class
42 correlation coefficient (ICC) of 0.05, we estimated that a sample size of
43 1426 individuals (713 home cooks and 713 family members) would
44 provide a power of 80% (with a two-sided alpha=0.05) to detect a
45 difference in mean 24-hour urinary sodium ≥ 20 mmol/day (1 g/d salt)
46 between the intervention and control group, allowing for a 20% drop-out
47 rate of participants. We aim to recruit 1 home cook and 1 family member
48 per household to ensure that the number of households in every community
49 remains the same. We will select 12 households in each community,
50 resulting in a total of 720 households and 1440 individuals. In addition,
51 considering that the response rate of 24-hour urine collection is often low²⁴,
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4 we have decided to add one more family per community, resulting in the
5 recruitment of 1560 individuals (780 home cooks and 780 family members)
6 into the study for evaluation.
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9 **Data collection**

10 All outcome measurements and assessments will be carried out at baseline
11 and at the end of the trial in exactly the same way in all communities for
12 all participants, irrespective of their assignment to the intervention or
13 control group.
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17 The participants will be carefully instructed on how to accurately collect
18 24-hour urine by trained research staff. On the first day, the participants
19 will be asked to visit the survey location. The researchers will ask the
20 participants to empty their bladders and discard the urine. The researchers
21 will record the start time and date of the 24-hour urine collection. They will
22 then supply the participants with collection equipment including containers
23 and collection aids. At the same time, on the second day, the participants
24 will be asked to bring the urine collection bottles back to the survey
25 location and to pass the last urine into the container. The researchers will
26 record the finish time of the 24-hour urine collection. During the 24-hour
27 urine collection period, the participants will be asked to take spare urine
28 containers with them to work. In case the participant misses one or more
29 urine voids or spillage occurs, the participant will be asked to perform an
30 additional 24-hour urine collection. For each participant, the 24-hour urine
31 will be collected on the same days of the week for the baseline visit and
32 follow-up visit at the end of the trial. We will measure urine volume,
33 sodium, potassium and creatinine. An ion-selective electrode method will
34 be used for sodium and potassium analysis and an enzymatic method for
35 the creatinine assay. The 24-hour urinary creatinine together with the urine
36 volume will be used to determine if the collection is likely to be complete.
37 The biochemist who performs the measurements of urinary electrolytes
38 will be unaware of the group to which the participant is allocated.
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40 In addition to 24-hour urine collection, we will measure BP and heart rate
41 using a validated automatic machine with the appropriate cuff size. Three
42 readings will be taken for the right arm at 1 to 2-min intervals in a sitting
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4 position after the participant has rested for 10 min in a quiet room. Body
5 weight, height and waist circumference will also be measured. A survey on
6 KAP related to salt will be completed via questionnaire.
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9 The RCT data will be collected through a specially designed mobile
10 device-based electronic data capture system (mEDC) by well-trained field
11 investigators. The RCT data include information on demographics, social-
12 economic information, KAP, measurements of height, weight, waist
13 circumference, BP, heart rate, 24-hour urine volume and electrolytes, as
14 well as information about the intervention.
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19 Additionally, to ensure the quality of the intervention, quality control will
20 be established at every step of the trial using the electronic system.
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23 **Data management**

24 All cleaned and locked datasets together with the study design,
25 questionnaire, code list and definition of database and variables will be
26 stored with a unique ID number attached but no personal identifiers, in the
27 China CDC, following an established standard operating procedure for
28 data security. To guarantee the data security, the mobile app developer
29 must follow the 'Mobile Application Information Service Regulation'
30 issued by the Cyberspace Administration of China in 2016. Although
31 personal data are accessible to the app developer, the disclosure of such
32 information is prohibited. In addition to the development and maintenance
33 of a mEDC, an information technology team will also provide the data
34 management service during the study to guarantee the safety, integrity and
35 proper use of the data collected through the mEDC.
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46 **Statistical methods**

47 The difference in 24-hour sodium excretion as well as the secondary
48 outcomes between the two groups will be compared using linear mixed
49 models with participants nested within family units and families nested
50 within community/village units. We will include group (intervention,
51 control), time (baseline, end of trial), and time×group interactions, with the
52 time×group interaction term indicating different changes by group from
53 baseline to the end of the trial. To account for missing data on continuous
54 outcomes, we will use the likelihood-based random effects model that uses
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4 all available data and provides valid estimates of the intervention effects
5 when data are missing at random. We will adjust for the stratification
6 variables at randomization and potential confounding variables. We will
7 also carry out various sensitivity analyses to examine the robustness of the
8 conclusions of the primary analysis.
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12 SAS 9.4 will be used for the analyses. The results will be reported as the
13 mean, SD, SE, and 95% confidence interval when appropriate. All analyses
14 will be two-sided, and $P < 0.05$ will be considered significant.
15

16 17 **Project timelines**

18
19 Recruitment of communities and participants was started in October 2018.
20 Baseline assessments were carried out between October and December
21 2018. As the intervention duration is 1 year, the final follow-up
22 assessments will be carried out between October and December 2019.
23

24 25 **Expected outcome and potential impact**

26
27 The study will provide a feasible and effective approach to achieving a
28 sustainable reduction in salt intake by targeting home cooks. The offline
29 intervention methods combined with the online intervention are
30 particularly advantageous over traditional methods. Therefore, the results
31 should be generally applicable to the whole Chinese population. If the
32 programme is implemented and sustained across China, it will reduce
33 population salt intake and thereby prevent hundreds of thousands of strokes,
34 heart attacks and heart failure each year, leading to major cost-savings to
35 individuals, their families and health services.
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37
38 Although our study will be conducted in China, the home cook intervention
39 programme to reduce salt could potentially be adopted by many other
40 countries where most of the salt in the diet is added by consumers, which
41 will have great public health implications.
42

43 44 **Patient and Public Involvement**

45
46 No patient involved.
47

48 49 **ETHICS AND DISSEMINATION**

50 51 **Ethics**

52
53 The study has been reviewed and approved by the Queen Mary Research
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Ethics Committee (QMERC2018/13) and the Institutional Review Board of the Chinese Center for Disease Control and Prevention (No.201801).

Written consent will be obtained from all participants in the research according to well-established practices. Every participant has the right to withdraw from the study at any time.

There are no substantive ethical issues associated with the conduct of our research project. The collection of urine samples constitutes inconvenience but no risk to the individuals involved. A modest reduction in salt intake has no risk to the participants.

During this study, if a participant is found to have high BP, we will recommend that he/she sees a doctor, and if he/she agrees, we will help make an appointment with a doctor in a local hospital.

Dissemination

The findings of this study will be disseminated through conference presentations, peer-reviewed publications and the general media.

Acknowledgements

The authors would like to thank the local CDC and primary health staff who shared their opinions regarding the development of the intervention programme.

Contributors

Xiaochang Zhang and Xiao Hu contributed to this work equally. Jixiang Ma, Puhong Zhang, Xiaochang Zhang, Yuan Li, Fengjun He, and Graham A MacGregor conceived the project and designed the study. Xiaochang Zhang, Xiao Hu, Yuan Li and Rong Luo designed the intervention tools. All authors contributed to the development of the intervention and evaluation. Xiaochang Zhang and Xiao Hu wrote the first draft of the manuscript. Jixiang Ma, Fengjun He, Puhong Zhang, Yuan Li, Graham A MacGregor, Jinglei Wang, and Zhaoxue Yin revised the manuscript draft. All authors contributed to the refinement of the study protocol and approved the final manuscript.

Funding

The study is being funded in full by the National Institute of Health Research (NIHR) using Official Development Assistance funding (16/136/77). The views expressed in this publication are those of the authors and not necessarily those of the NIHR or the Department of Health and Social Care.

Competing interests

FJH is a member of Consensus Action on Salt & Health (CASH) and World Action on Salt & Health (WASH). Both CASH and WASH are nonprofit charitable organizations, and FJH has not received any financial support from CASH or WASH. GAM is Chairman of Blood Pressure UK (BPUK), Chairman of CASH, WASH, and Action on Sugar. BPUK, CASH, WASH and Action on Sugar are nonprofit charitable organizations. GAM has not received receive any financial support from any of these organizations. The other authors have no disclosures to report.

Data sharing

The de-identified participant-level data, research forms and statistical code generated and/or analysed during this study are not publicly available due to confidentiality requirements but are available from the corresponding author on reasonable request after April 1st, 2022. Also, any data cross-border transfer must obtain official approval for relevant governmental authorities. Any data/dataset sharing with other parties will be recorded and formulated in written contractual agreements.

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10 **Figure Legends**

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14 **Figure1.** Home cook intervention trial design.
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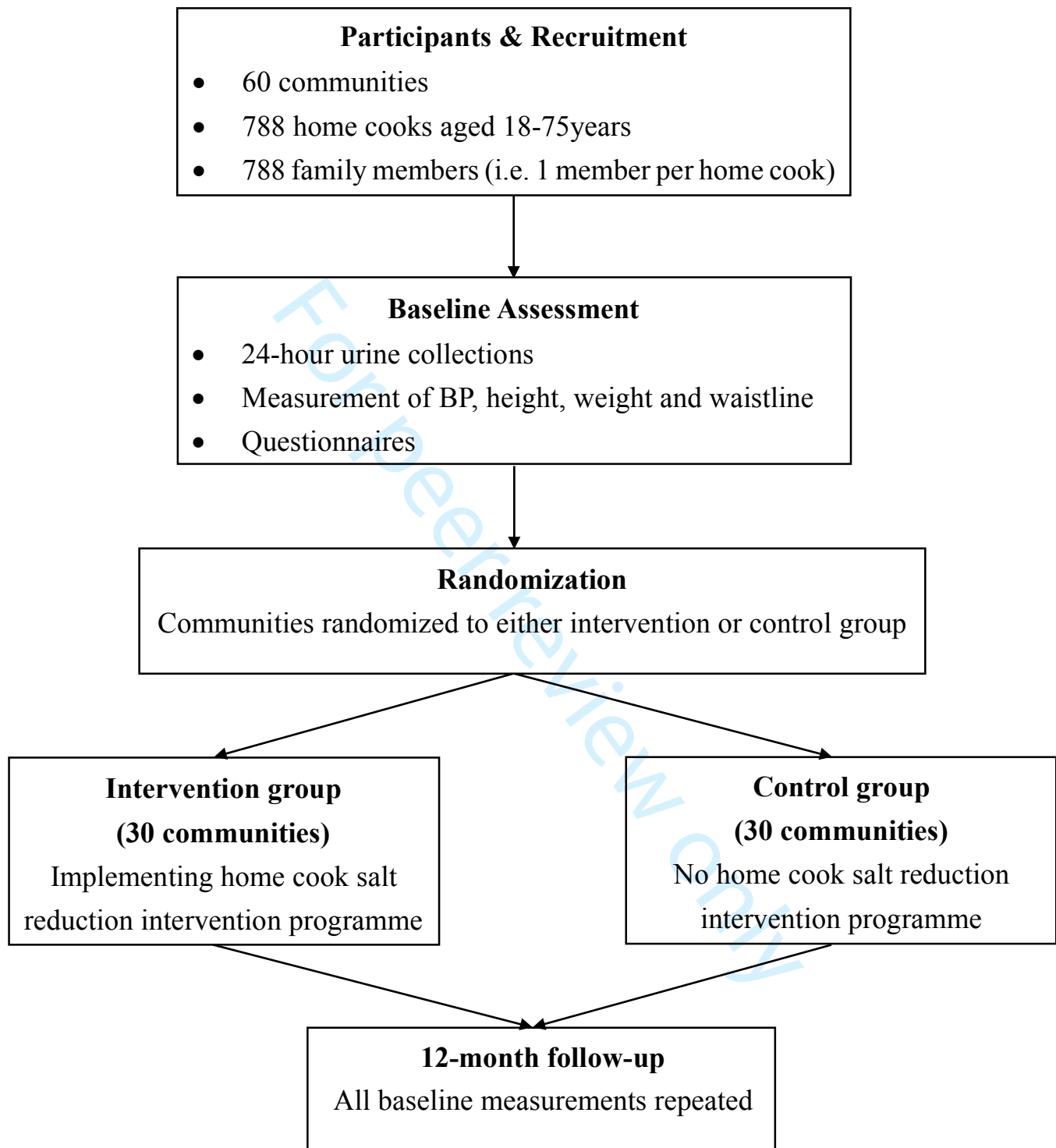


Figure 1 Home cook intervention trial design.