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The restaurant interventions for salt reduction in China: a randomized controlled trial

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The restaurant interventions for salt reduction in China: a randomized controlled trial

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ABSTRACT

Introduction Salt intake in China is high, and most of it comes from that added by consumers.

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4 Nevertheless, recent years have seen a rapid increase in the frequency at which people eat out. The
5 aim of this study is to evaluate the effectiveness of interventions designed for salt reduction in
6 restaurants through a randomized controlled trial in China.
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9 **Methods and analysis** As a randomized controlled trial with restaurants as study subjects, we
10 recruited 192 restaurants from 12 counties of 6 provinces in China. After the baseline survey,
11 restaurants were randomly assigned to intervention or control group. Using social cognitive theory,
12 comprehensive intervention activities were designed to encourage salt reduction in all restaurant
13 foods, and at the same time, to encourage consumers to choose lower-salt options when eating out.
14 The interventions will be conducted only in restaurants of the intervention group during the first
15 year. The follow-up assessment will be conducted at the end of the trial. The primary outcome is
16 the change in the average salt content of the 5 best-selling dishes of the restaurant, as measured by
17 laboratory tests. Secondary outcomes include differences in the monthly use of salt and salty
18 condiments between intervention and control restaurants, and the knowledge, attitude and practice
19 (KAP) on salt among restaurant consumers.
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30 **Ethics and dissemination** The study has been reviewed and approved by the Review Board of
31 the National Institute for Nutrition and Health, China CDC, and Queen Mary Research Ethics
32 Committee. Results will be disseminated through presentations, publications and social media.
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36 **Trial registration number** ChiCTR1800019694
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40 **Strengths and limitations of this study**

41 The study will develop an effective and sustainable intervention package for salt reduction in
42 Chinese restaurant settings.
43
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45 Our study covers a wide range of restaurants in China, from 6 provinces and thus representing
46 different cuisines and eating habits.
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49 Due to the commercial nature of restaurants, the implementation of the salt reduction interventions
50 may be challenging, and need strong multisectoral support and cooperation.
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54 **INTRODUCTION**

55 High salt intake is one of the leading dietary risk factors for deaths and disability globally,¹ and was
56 associated with 3 million deaths and 70 million DALYs in adults around the world. In China, high
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4 salt intake attributed to more than 0.5 million cardiometabolic deaths in 2010-12.² The most
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6 common risk of high salt intake is raised blood pressure, which alone accounts for an estimated 10.7
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8 million deaths each year worldwide.³ Statistics from the 2015 China's Report on Nutrition and
9
10 Chronic Diseases revealed that the prevalence of hypertension among the Chinese population aged
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12 18 years and older was 25.2% in 2012,⁴ with the total number of individuals with high blood
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14 pressure reaching 270 million. International experience has proved that reducing population salt
15
16 intake lowered blood pressure and reduced the risk of cardiovascular disease (CVD).^{5 6} Salt
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18 reduction is considered one of the most cost-effective measures to improve public health.⁷ In China,
19
20 people consume significantly more salt than the WHO-recommended level of maximum 5g per day
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22 for adults.^{8 9}

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24 With the rapid urbanization and lifestyle changes in China, eating in restaurants has been becoming
25
26 popular, especially in urban areas. National survey (2010-12) statistics have shown that, 35.5% of
27
28 the Chinese aged 6 years and older have eaten out in the past week. The proportion of people dining
29
30 out was 42.2% and 28.5% in urban and rural areas respectively.⁴ Restaurants are becoming the
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32 second major dining location in China, and this has important impacts on public health and nutrition.
33
34 A pilot study using a one-week salt estimation method in Beijing found that approximately 40% of
35
36 the salt intake was consumed outside the home.¹⁰ Restaurant dishes seem to have a high sodium
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38 content in both developed and developing countries.¹¹⁻¹⁴ A study showed that 46.8% of the dishes
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40 served in Chinese restaurants in Beijing contained more salt than the daily salt intake recommended
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42 by WHO.¹⁴ Sodium content was substantially higher in restaurant foods than in home-made foods.
43
44 ¹⁵⁻¹⁷ Therefore, to help consumers reduce their overall salt intake, it is important to develop an
45
46 effective strategy to reduce the sodium content of restaurant foods.

47
48 To tackle the high salt intake levels in China, Action on Salt China (ASC) was set up in 2017, funded
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50 by the UK National Institute for Health Research (NIHR). ASC aims to implement comprehensive
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52 national salt reduction programs, with the leadership of Queen Mary University of London
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54 (QMUL), the George Institute China (TGI), Chinese Center for Disease Control and Prevention
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56 (China CDC) and other key related organizations.¹⁸ The ASC team developed two national health
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58 campaigns (health education and salt reduction in packaged food) and four randomized controlled
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60 trials (RCTs) to test interventions targeting the major sources of salt intake¹⁹. The RCTs consisted
of (1) an application-based intervention study in schoolchildren and their families (AIS);²⁰ (2) a

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4 home cook-based intervention study (HIS); (3) a comprehensive intervention study (CIS);²¹ and (4)
5 a restaurant-based intervention study (RIS), which is the one reported in the present paper.

6
7 RIS was designed to test the effectiveness and feasibility of a restaurant salt reduction package in 6
8 provinces of China. The key interventions were based on social cognitive theory²² and included:
9
10 (1) building tailored restaurant environments that encourage consumers to order lower-salt or
11 reduced-salt dishes; (2) lower-salt or reduced-salt ordering reminders from the waiters; (3) training
12 cooks in reduced-salt cooking; (4) salt reduction campaigns. As a part of the ASC program, this
13 article reports on the design of the RIS intervention package and its implementation, evaluation, and
14 current status.
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23 **METHODS AND ANALYSIS**

24 **Study setting and sampling method**

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26 To account for geographical, economic and dietary disparities, our study will be carried out in 6
27 provinces of China: Heilongjiang, Hebei, Qinghai, Hunan, Sichuan and Jiangxi. As a RCT study,
28 the RIS baseline survey was conducted in May 2019, and an evaluation survey will be conducted a
29 year later, at the end of the trial. One hundred ninety-two restaurants were selected from 12 counties
30 of the above-mentioned 6 provinces. In each province, two counties of similar socioeconomic level
31 in the provincial capital city were selected. The counties that had participated in other salt-reduction
32 projects were excluded to minimize contamination. To determine the effectiveness of the salt
33 reduction package in restaurants of different sizes, of the 16 Chinese restaurants randomly selected
34 from each county, it was ensured these included 4 large restaurants, 8 medium restaurants and 4
35 small restaurants. The restaurants were then randomly allocated to the intervention or control group
36 after the baseline survey, using the random procedure on electronic data recording platform (EDC).
37 The comprehensive intervention package is designed to both inspire the salt-reduction requirement
38 in consumers and promote the skills of reduced-salt cooking and ordering service in restaurant staff.
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52 **Restaurant inclusion criteria and recruitment**

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54 Firstly, we released an open letter via local Media and cooperated with the Market Regulation
55 Bureau to recruit restaurants which are interested in participating in the program. Then the standard
56 inclusion criteria were used to screen for potential restaurants, including: (1) restaurants mainly
57 offering Chinese cuisine; (2) agreeing to participate in one year of comprehensive salt reduction
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intervention and in at least two assessment surveys; (3) with complete records of salt and other condiments purchase and usage; (4) had been operating normally for more than 1 year and without plan of relocating or closing in the next 2 years; (5) with >50% of the dishes that could be prepared with less salt. Restaurants that were already involved in other salt reduction programs will be excluded. Restaurant size was determined based on surface area or number of seats (table 1). The EDC platform conducted the random selection procedure using the above information of restaurants.

Table 1 Restaurant size classification

Classification	Square meters (m ²)	(or) Number of seats
Large restaurant	>500 and ≤3000	>250 and ≤1000
Medium restaurant	>150 and ≤500	>75 and ≤250
Small restaurant	≤150	≤75

Randomization

After baseline assessment, restaurants were randomly allocated to either the control group or the intervention group (96 restaurants in each group). The randomization was stratified by the size of restaurants and carried out using computer generated random numbers by a statistician who is not involved in the study and is blind to the identity of the restaurants. For the year following the baseline survey, the intervention restaurants will implement a series of intervention activities aiming to reduce salt. Meanwhile, the control restaurants will operate as usual.

Intervention

The objective of RIS is to reduce salt use in restaurants. We aim to achieve not only short-term, but also sustainable long-term effects. Social cognitive theory proposes behavior is influenced by the constant interaction of personal factors (ie. Skills, knowledge) and environmental factors (ie. appropriate modeling for learning, available materials)²². Therefore, we designed the intervention activities based on both the supply (restaurant) and demand (consumer) sides (Figure 1). For the intervention group, the RIS intervention package included the following activities:

Figure 1 The RIS intervention design

(1) Menu labelling:

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4 In the baseline survey, we collected the detailed ingredients composition, including the amount of
5 salt and condiments, of the 50 best-selling dishes of each restaurant. If a restaurant offers fewer than
6 50 dishes, information on all available dishes were collected. In each restaurant, the 10% of the
7 dishes that had the lowest sodium content (according to baseline survey) were labelled “lower salt”
8 on the menu, thus providing clear information to the customers. This menu will be used in the
9 intervention restaurants throughout the trial period (one year).
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15 (2) Training for chef and waiter/waitress:

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17 In close collaboration with culinary experts, we developed a series of training materials, including
18 manual and videos, to guide chefs and waiters/waitresses in encouraging salt reduction services in
19 their routine work. Besides, we organized the service of a professional team to offer face-to-face
20 training for the restaurant staff of each county at least once a year. At least 3 representatives per
21 restaurant were required to attend the training. This training mainly focused on the following
22 aspects: “salt sources in restaurant dishes”, “why reduce salt”, “practical skills in reducing salt for
23 restaurant cooking”, “building a reduced-salt environment in a restaurant” and “service and
24 communication skills”. Local county investigators are responsible to enhance the knowledge and
25 skills among staff in each intervention restaurant by conducting monthly follow-up supervisions.
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34 During the trial, each intervention restaurant is encouraged to reduce salt usage by 10% in all dishes,
35 and greater reductions according to the customers’ request (such as, -30% or -50% salt).
36 Furthermore, at least 3 lower-salt dishes (sodium \leq 100mg/100g) per restaurant should be developed
37 through reformulation to provide customers more lower-salt options. Waiters/waitresses are
38 required to recommend customers the lower-salt dishes, as well as remind them they can choose the
39 reduced-salt option with almost all the other dishes.
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47 (3) Supportive environment for salt reduction in restaurants:

48 Information that refers to salt reduction, salt and health, and available reduced-salt dishes will be
49 shown through videos, posters, brochures, leaflets, and table displays to build restaurant
50 environments that are making it easier for the customers to choose lower-salt options. For example,
51 messages with announcement “-30%/-50% salt options are available for most dishes” will be posted
52 on dining tables. These materials will be displayed at noticeable positions in the intervention
53 restaurants during the trial period.
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(4) Salt reduction campaign:

To create a social environment supportive of salt reduction, local investigators will organize a campaign at least once during the 1-year trial, with the theme of “less salt, healthy eating”, to help raise consumers’ awareness of salt reduction when they eat out. Another important aim is to encourage restaurants to pay more attention to reducing salt and offering lower-salt dishes. To expand the reach of the campaign, news agencies and social media will be encouraged to disseminate the campaign messages. To limit contamination to control group, the salt reduction campaign should only involve the restaurants in intervention group.

A certified medal of “ASC Salt Reducing Restaurant” will be granted to intervention restaurants, according to the standardized requirements. The medal will help motivate restaurants for salt reduction and value their efforts.

Sample size

In the current randomized controlled trial, selected restaurants are the study subjects. Based on the results of a study on Chinese restaurants,²³ we assume a standard deviation (SD) of 1g/100g of dish for the sodium content of Chinese restaurant dishes, and expect that a sample of 192 restaurants will achieve 80% power (with two-sided alpha=0.05) to detect a change of 0.5 g/100g dish for the 5 best-selling dishes in each restaurant, allowing for a 20% dropping rate of restaurants. Therefore, a total of 192 restaurants were recruited into the study.

Outcome measures

The primary outcome is the change in the sodium content of the 5 best-selling dishes from baseline to the end of the trial (Figure 2).

Secondary outcomes include the differences between the intervention and control groups in: (1) monthly use of salt and main salty condiments by the restaurant chefs; (2) salt-related knowledge, attitude and practice (KAP) in restaurant customers.

Figure 2 RIS trial design

Outcome assessments

The primary and secondary outcomes will be assessed before and after the 1-year intervention, in

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4 both intervention and control restaurants.

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6 For the primary outcome, we will collect the whole portion of the 5 best-selling dishes of each
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8 restaurant at baseline and follow-up assessment, to test their sodium content using laboratory flame
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10 atomic absorption spectrometry method. Although it would be possible to estimate the sodium
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12 content of a dish by asking the chefs what ingredients and condiments they have used, this would
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14 rely on the chefs' memory. By using laboratory tests, we ensure the accurate assessment of the
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16 sodium content of the dishes. The dishes chosen for laboratory test should be top-selling firstly, and
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18 then involve different types according to the ingredients (ie. animal food based dishes, mixed food
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20 dishes, and vegetable food based dishes). The local researchers will go to each restaurant and buy
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22 the 5 best-selling dishes anonymously in order to avoid introducing bias. The whole dishes,
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24 including sauce and soup when appropriate, will be weighed and photographed. Once cooled off,
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26 they will be transferred to a sampling bag. The samples are stored at -20°C in refrigerator until
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28 transferred to the laboratory. Theoretically, for each restaurant, the same dishes bought at a similar
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30 date of the year should be assessed at baseline and follow-up assessment. However, if the dishes
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32 collected at baseline are no longer sold at the follow-up assessment, comparable dishes with similar
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34 ingredients and cooking method could be chosen as alternatives.

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36 For the secondary outcomes, questionnaires will be administered by trained local investigators
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38 through a mobile EDC app developed for RIS. Compared to traditional data collection methods, the
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40 mobile EDC has advantages in terms of process and quality control, as demonstrated in clinical trial
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42 study ²⁴. There are two questionnaires in the survey, including restaurant assessment and consumer
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44 survey. The questions related to the restaurant assessment consist of: (1) basic information about
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46 the restaurant; (2) salt reduction environment and services in restaurant; (3) monthly salt and salty
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48 condiments usage; (4) attitude and challenges related to reducing salt in restaurant; (5) dishes (≤ 50
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50 dishes/restaurant) recipe (all ingredients and condiments used, and in what quantity) and cooking
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52 method. The restaurant-related questions will be asked to the owners/managers who directly manage
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54 the restaurant, and the recipes will be collected by face-to-face interview with chefs who are familiar
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56 with preparing those dishes. To assist chefs in remembering accurately the amount of ingredients
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58 used in the dishes, the investigators will show them the weighed amount using a usual spoon or
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60 other measuring instruments used in their restaurants.

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4 For the consumer survey, we will randomly select 20 customers (10 males and 10 females) in all
5 intervention and control restaurants, before and after the trial, to assess the changes and differences
6 of knowledge, attitudes, and behaviours related to salt reduction.
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9 **Data collection, management and analysis**

10 **Data collection**

11
12 We use the specially designed mobile EDC to collect assessments data during the RIS program, as
13 well as monthly supervision records in the 1-year comprehensive intervention. The local CDCs are
14 responsible for data collection. The structure of data collection system consists of 192 restaurants.
15
16 The local researchers log in the system, input the assessment data and supervision records in each
17 restaurant page. The assessment data includes: (1) information on restaurants' salt reduction-related
18 environment, service, attitude, challenges, and monthly salt usage, as well as some sales data; (2)
19 information on recipe, cooking method, and laboratory sodium content; (3) information on customer
20 knowledge, attitude, and behaviors related to salt reduction. Supervision records include
21 information on the process of intervention activities, and any reason for not carrying them out, as
22 well as photos that could inform on the intervention status.
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33 **Data management**

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35 The mobile EDC used in the RIS program was developed by the Beijing University of Aeronautics
36 and Astronautics. The security of data management was demonstrated in another publication under
37 the same ASC project ²⁰. To guarantee the integrity and authenticity of data collection, local
38 researchers were given different level of authority according to their roles. For example, the local
39 investigators are responsible for inputting survey and supervision data, but could not delete the
40 records they added. The inspectors have authority to check the data accuracy, delete mistaken
41 records, start and close discussion about doubtful data, but cannot add new records. The person in
42 charge at county, provincial and national levels, can view the data of all restaurants under their
43 management, but could not make any changes. All modifications will be stored in the EDC system.
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52 **Statistical analysis**

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54 The effect of the intervention package for restaurants on the outcomes will be determined using
55 linear mixed models, including group (intervention, group), time (baseline, follow-up), and
56 interaction of group*time, with adjustments for potential confounding variables. We will consider
57 sensitivity analyses to examine the robustness of the conclusion of the primary analysis. Results
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4 will be described as mean, SD, standard error (SE), and 95% confidence interval when appropriate.
5
6 SAS 9.4 will be used for the data cleaning and statistical analyses. All analyses will be two sided,
7
8 and $P < 0.05$ will be considered significant.

9 10 **Economic and process evaluation**

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12 Economic evaluation will be conducted from the health sector perspective to compare the
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14 comprehensive intervention package for restaurant on salt reduction versus business as usual, and it
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16 will include two dimensions: a trial-based economic evaluation, and a modelled economic
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18 evaluation of long-term costs and outcomes. Intervention costs will include the direct costs of
19
20 running the program, excluding any research and development costs. We will consider restaurant
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22 dishes consumption at the population level to examine the economic evaluation. Therefore, the trial-
23
24 based economic evaluation will be assessed in terms of incremental cost per unit salt reduction in
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26 restaurant dishes and systolic blood pressure (BP). The conversion of sodium in restaurant dishes to
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28 daily sodium intake for the population, and its relationship with systolic BP, will be based on the
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30 scientific literature and other population trials under the ASC project. The modelled economic
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32 evaluation will examine the cost, survival, health states (including death and CVD events) to
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34 estimate incremental cost per life year saved and cost per quality-adjusted life year gained. The
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36 transition probabilities across health states and costs attached to different health states, and the long-
37
38 term effects of reduction in sodium intake will be based on literature data. Sensitivity analyses will
39
40 be used to estimate uncertainty about the primary findings associated with various key parameters.
41
42 The process evaluation will help us assess the fidelity and adoption of key components of
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44 intervention (frequency, coverage and satisfaction), and understand the barriers and facilitators of
45
46 the intervention. The evaluation will be conducted using mixed-methods during and at the end of
47
48 the trial, from monthly supervision records, structured process evaluation form, and in-depth
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50 interviews with restaurant staff and customers. Designed forms, including sales form of lower-salt
51
52 labeling dishes, recipe information form of reduced-salt dishes, and consumer feedback cards will
53
54 be collected at three time points during the intervention period, in order to monitor the acceptance
55
56 and the effect of the RIS intervention.

56 57 **Project status and timelines**

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59 The recruitment of restaurants started in April 2019. Baseline assessments were conducted between
60
May and June 2019. One hundred ninety-two restaurants from 12 counties completed the baseline

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3 survey, with data from 976 laboratory-tested dishes, 8145 recipes, and 3840 customers.
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5 Theoretically, the follow-up assessment will be conducted in the middle 2020, after 12 months
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7 intervention. Due to nation-wide epidemic of novel coronavirus disease (COVID-19) in China,
8
9 restaurants have been closed for several months, since late January 2020. We will evaluate the
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11 influence of the epidemic on restaurants, especially for the intervention group, and decide on
12
13 whether to postpone the follow-up assessment and other issues.
14

15 **Expected outcome and potential impact**

16
17 Unlike the standardized menus found in western fast food chains, Chinese dishes vary considerably
18
19 by areas, restaurants, and chefs, even for dishes with the same name. Few studies exist on the sodium
20
21 content of restaurant dishes in China.^{14 25} The current study covers a wide range of restaurants in 6
22
23 provinces, could provide the evidence on the sodium level and sources in Chinese restaurants, which
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25 is helpful to develop the specific intervention measures. The study will explore a feasible, effective
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27 and sustainable approach to achieve salt reduction for Chinese restaurants. With an increasing
28
29 proportion of people eating out, restaurant dishes contribute much more sodium than decades before
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31 and induce more health risks. Compared with salt reduction initiatives in individuals, communities
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33 or schools, those conducted in restaurants face more challenges. With this study, we will identify
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35 barriers and motivations for implementation, as well as solutions suitable to Chinese restaurants to
36
37 reduce salt, and based on these findings, we will be able to draw important public health
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39 implications.
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41 **Patient and public involvement**

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43 Using information on the current situation of Chinese restaurants, inclusion criteria were determined
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45 before the recruitment. An open letter was disseminated via local media, introducing the RIS project
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47 and calling for participation publicly. Local CDC investigators, with support from the
48
49 Administration for Market Regulation, make various mobilization efforts to help restaurant owners
50
51 understand the purpose of the project and the information to be collected in the investigation. With
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53 the consent of selected restaurants, we will conduct assessment surveys and implement the
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55 intervention. At the end of the study, we will disseminate the results to the restaurants, and discuss
56
57 with related stakeholders how to translate the research findings into practice and develop a public
58
59 health strategy.
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ETHICS AND DISSEMINATION

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4 According to the results of ethics review by the Review Board of the National Institute for Nutrition
5 and Health, China CDC, and Queen Mary Research Ethics Committee, written informed consent
6 from restaurants is exempted from the RIS project. However, the investigators should fully inform
7 the selected restaurants of the purpose and activities of the project, strive for understanding and
8 cooperation, and keep the information confidential. The restaurants will be free to discontinue their
9 participation at any time without reasons.

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14
15 The findings of this research will be disseminated through conference presentations, peer-reviewed
16 publications, press release and social media.

17 18 19 **Author affiliations**

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22 Beijing, China

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48
49
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51 study design and implementation. WD, JZ, HW, YL, PZ, FJH, XZ, HX, YG, LY, XC and WY
52 facilitates restaurant and public involvement and were responsible for setting up the study in each
53 site. All authors contributed to the development of intervention and evaluation. WD wrote the first
54 draft of the manuscript, and JZ, HW, YL, PZ, FJH, MT, GAM and RL revised the draft. All authors
55 contributed to the refinement of the study protocol and approved the final manuscript.

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13 **Disclaimer** The findings of this study will be disseminated through discussions or presentations at
14 conferences, peer-reviewed publications and general media.
15
16

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20 Blood Pressure UK (BPUK), chairman of CASH and chairman of WASH and does not receive any
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22 charitable organizations. All other authors have no competing interests to declare.
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29 **Patient consent for publication** Not required.
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31 **Ethics approval** The study has been reviewed and approved by the Review Board of the National
32 Institute for Nutrition and Health, China CDC (20180314), and Queen Mary Research Ethics
33 Committee (QMERC2018/14).
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51 Figure 1 The RIS intervention design

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54 Figure 2 RIS trial design
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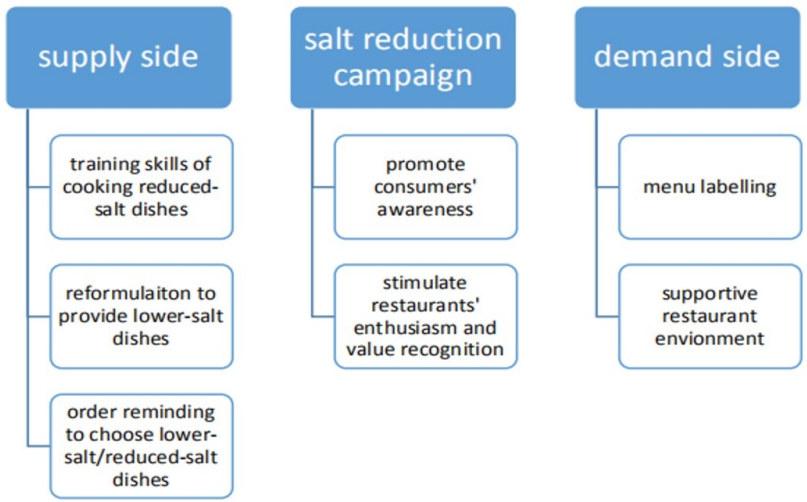


Figure 1 The RIS intervention design

338x190mm (96 x 96 DPI)

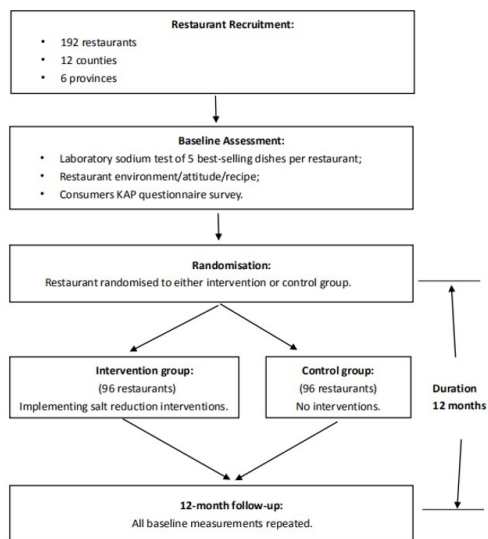


Figure 2 RIS trial design

338x190mm (96 x 96 DPI)



SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents*

Section/item	Item No	Description
Administrative information		
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym <input checked="" type="checkbox"/>
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry <input checked="" type="checkbox"/>
	2b	All items from the World Health Organization Trial Registration Data Set <input checked="" type="checkbox"/>
Protocol version	3	Date and version identifier <input checked="" type="checkbox"/>
Funding	4	Sources and types of financial, material, and other support <input checked="" type="checkbox"/>
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors <input checked="" type="checkbox"/>
	5b	Name and contact information for the trial sponsor <input checked="" type="checkbox"/>
	5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities <input checked="" type="checkbox"/>
	5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee) <input checked="" type="checkbox"/>
Introduction		
Background and rationale	6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention <input checked="" type="checkbox"/>
	6b	Explanation for choice of comparators <input checked="" type="checkbox"/>
Objectives	7	Specific objectives or hypotheses <input checked="" type="checkbox"/>
Trial design	8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory) <input checked="" type="checkbox"/>

Methods: Participants, interventions, and outcomes

Study setting	9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained <input checked="" type="checkbox"/>
Eligibility criteria	10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists) <input checked="" type="checkbox"/>
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered <input checked="" type="checkbox"/>
	11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease) <input checked="" type="checkbox"/>
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests) <input checked="" type="checkbox"/>
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial <input checked="" type="checkbox"/>
Outcomes	12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended <input checked="" type="checkbox"/>
Participant timeline	13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure) <input checked="" type="checkbox"/>
Sample size	14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations <input checked="" type="checkbox"/>
Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size <input checked="" type="checkbox"/>

Methods: Assignment of interventions (for controlled trials)

Allocation:

Sequence generation	16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions <input checked="" type="checkbox"/>
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2	Allocation	16b	Mechanism of implementing the allocation sequence (eg, central
3	concealment		telephone; sequentially numbered, opaque, sealed envelopes),
4	mechanism		describing any steps to conceal the sequence until interventions are
5			assigned <input checked="" type="checkbox"/>
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7	Implementation	16c	Who will generate the allocation sequence, who will enrol participants,
8			and who will assign participants to interventions <input checked="" type="checkbox"/>
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10	Blinding	17a	Who will be blinded after assignment to interventions (eg, trial
11	(masking)		participants, care providers, outcome assessors, data analysts), and
12			how <input checked="" type="checkbox"/>
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14		17b	If blinded, circumstances under which unblinding is permissible, and
15			procedure for revealing a participant's allocated intervention during
16			the trial <input checked="" type="checkbox"/>
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Methods: Data collection, management, and analysis

21	Data collection	18a	Plans for assessment and collection of outcome, baseline, and other
22	methods		trial data, including any related processes to promote data quality (eg,
23			duplicate measurements, training of assessors) and a description of
24			study instruments (eg, questionnaires, laboratory tests) along with
25			their reliability and validity, if known. Reference to where data
26			collection forms can be found, if not in the protocol <input checked="" type="checkbox"/>
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28		18b	Plans to promote participant retention and complete follow-up,
29			including list of any outcome data to be collected for participants who
30			discontinue or deviate from intervention protocols <input checked="" type="checkbox"/>
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32	Data	19	Plans for data entry, coding, security, and storage, including any
33	management		related processes to promote data quality (eg, double data entry;
34			range checks for data values). Reference to where details of data
35			management procedures can be found, if not in the protocol <input checked="" type="checkbox"/>
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37	Statistical	20a	Statistical methods for analysing primary and secondary outcomes.
38	methods		Reference to where other details of the statistical analysis plan can be
39			found, if not in the protocol <input checked="" type="checkbox"/>
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41		20b	Methods for any additional analyses (eg, subgroup and adjusted
42			analyses) <input checked="" type="checkbox"/>
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44		20c	Definition of analysis population relating to protocol non-adherence
45			(eg, as randomised analysis), and any statistical methods to handle
46			missing data (eg, multiple imputation) <input checked="" type="checkbox"/>
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Methods: Monitoring

52	Data monitoring	21a	Composition of data monitoring committee (DMC); summary of its role
53			and reporting structure; statement of whether it is independent from
54			the sponsor and competing interests; and reference to where further
55			details about its charter can be found, if not in the protocol.
56			Alternatively, an explanation of why a DMC is not needed <input checked="" type="checkbox"/>
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1		21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial <input checked="" type="checkbox"/>
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6	Harms	22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct <input checked="" type="checkbox"/>
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11	Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor <input checked="" type="checkbox"/>
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Ethics and dissemination

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17	Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval <input checked="" type="checkbox"/>
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21	Protocol amendments	25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators) <input checked="" type="checkbox"/>
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26	Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32) <input checked="" type="checkbox"/>
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30		26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable <input checked="" type="checkbox"/>
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33	Confidentiality	27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial <input checked="" type="checkbox"/>
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37	Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site <input checked="" type="checkbox"/>
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41	Access to data	29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators <input checked="" type="checkbox"/>
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45	Ancillary and post-trial care	30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation <input checked="" type="checkbox"/>
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48	Dissemination policy	31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions <input checked="" type="checkbox"/>
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54		31b	Authorship eligibility guidelines and any intended use of professional writers <input checked="" type="checkbox"/>
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57		31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code <input checked="" type="checkbox"/>
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Appendices

Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates
Biological specimens	33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable

*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items. Amendments to the protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT Group under the Creative Commons "[Attribution-NonCommercial-NoDerivs 3.0 Unported](#)" license.

For peer review only

BMJ Open

The restaurant interventions for salt reduction in China: a randomized controlled trial

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The restaurant interventions for salt reduction in China: a randomized controlled trial

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ABSTRACT

Introduction Salt intake in China is high, and most of it comes from that added by consumers.

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4 Nevertheless, recent years have seen a rapid increase in the frequency at which people eat out. The
5 aim of this study is to evaluate the effectiveness of interventions designed for salt reduction in
6 restaurants through a randomized controlled trial in China.
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9 **Methods and analysis** As a randomized controlled trial with restaurants as study subjects, we
10 recruited 192 restaurants from 12 counties of 6 provinces in China. After the baseline survey,
11 restaurants were randomly assigned to intervention or control group. Using social cognitive theory,
12 comprehensive intervention activities were designed to encourage salt reduction in all restaurant
13 foods, and at the same time, to encourage consumers to choose lower-salt options when eating out.
14 The interventions will be conducted only in restaurants of the intervention group during the first
15 year. The follow-up assessment will be conducted at the end of the trial. The primary outcome is
16 the change in the average salt content of the 5 best-selling dishes of the restaurant, as measured by
17 laboratory tests. Secondary outcomes include differences in the monthly use of salt and salty
18 condiments between intervention and control restaurants, and the knowledge, attitude and practice
19 (KAP) on salt among restaurant consumers.
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30 **Ethics and dissemination** The study was reviewed and approved by the Review Board of the
31 National Institute for Nutrition and Health, China CDC, and Queen Mary Research Ethics
32 Committee. Results will be disseminated through presentations, publications and social media.
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36 **Trial registration number** ChiCTR1800019694
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40 **Strengths and limitations of this study**

41 The study develops an effective and sustainable intervention package for salt reduction in Chinese
42 restaurant settings.
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45 Our study covers a wide range of restaurants in China, from 6 provinces and thus representing
46 different cuisines and eating habits.
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49 Due to the commercial nature of restaurants, the implementation of the salt reduction interventions
50 may be challenging, and need strong multisector support and cooperation.
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55 **INTRODUCTION**

56 High salt intake is one of the leading dietary risk factors for deaths and disability globally¹ and
57 associated with 3 million deaths and 70 million DALYs in adults around the world. In China, high
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4 salt intake attributed to more than 0.5 million cardiometabolic deaths in 2010-12.² The most
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6 common risk of high salt intake is raised blood pressure, which alone accounted for an estimated
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8 10.7 million deaths each year worldwide.³ Statistics from the 2015 China's Report on Nutrition and
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10 Chronic Diseases revealed that the prevalence of hypertension among the Chinese population aged
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12 18 years and older was 25.2% in 2012,⁴ with the total number of individuals with high blood
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14 pressure reaching 270 million. International experience had proved that reducing population salt
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16 intake lowered blood pressure and reduced the risk of cardiovascular disease (CVD).^{5 6} Salt
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18 reduction is considered one of the most cost-effective measures to improve public health.⁷ In China,
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20 the average salt intake was 12-14g salt per day, which was more than double the WHO-
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22 recommended maximum level of 5g salt per day for adults.^{8 9}

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24 With the rapid urbanization and lifestyle changes in China, eating in restaurants has been becoming
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26 popular, especially in urban areas. National survey (2010-12) statistics showed that, 35.5% of the
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28 Chinese aged 6 years and older had eaten out in the past week. The proportion of people dining out
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30 was 42.2% and 28.5% in urban and rural areas respectively.⁴ Restaurants became the second major
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32 dining location after home-cooking in China, and this had important impacts on public health and
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34 nutrition. A pilot study using a one-week salt estimation method in Beijing found that approximately
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36 40% of the salt intake was consumed outside the home.¹⁰ Restaurant dishes seemed to have a high
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38 sodium content in both developed and developing countries.¹¹⁻¹⁴ A study showed that 46.8% of the
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40 dishes served in Chinese restaurants in Beijing contained more salt than the daily salt intake
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42 recommended by WHO.¹⁴ Sodium content was substantially higher in restaurant foods than in
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44 home-made foods.¹⁵⁻¹⁷ Therefore, to help consumers reduce their overall salt intake, it is important
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46 to develop an effective strategy to reduce the sodium content of restaurant foods.

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48 To tackle the high salt intake levels in China, Action on Salt China (ASC) was set up in 2017, funded
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50 by the UK National Institute for Health Research (NIHR). ASC aimed to implement comprehensive
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52 national salt reduction programs, with the leadership of Queen Mary University of London
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54 (QMUL), the George Institute China (TGI), Chinese Center for Disease Control and Prevention
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56 (China CDC) and other key related organizations.¹⁸ The ASC team developed two national health
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58 campaigns (health education and salt reduction in packaged food) and four randomized controlled
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60 trials (RCTs) to test interventions targeting the major sources of salt intake¹⁹. The RCTs consisted
of (1) an application-based intervention study in schoolchildren and their families (AIS);²⁰ (2) a

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4 home cook-based intervention study (HIS); (3) a comprehensive intervention study (CIS);²¹ and (4)
5 a restaurant-based intervention study (RIS), which is the one reported in the present paper.

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7 The objective of RIS was to reduce salt use by at least 0.5g per 100g in restaurant dishes. To achieve
8 the goal, we developed a restaurant salt reduction package, the feasibility and effectiveness of which
9 are being tested by RIS. The key interventions were based on social cognitive theory²² and included:
10 (1) building tailored restaurant environments that encourage consumers to order lower-salt or
11 reduced-salt dishes; (2) lower-salt or reduced-salt ordering reminders from the waiters; (3) training
12 cooks in reduced-salt cooking; (4) salt reduction campaigns. As a part of the ASC program, this
13 article reports on the design of the RIS intervention package and its implementation, evaluation, and
14 current status.
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25 **METHODS AND ANALYSIS**

26 **Study setting and sampling method**

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28 To account for geographical, economic and dietary disparities, our study was carried out in 6
29 provinces of China, which were consistent with other RCTs of ASC, covering north (Heilongjiang,
30 Hebei, Qinghai) and south (Hunan, Sichuan and Jiangxi) China. As a RCT, the RIS baseline survey,
31 which included the assessment of laboratory sodium level of 5 best-selling dishes, restaurant
32 environment and attitude on salt reduction, detailed recipe information, and consumers' knowledge,
33 attitude and practice (KAP) on salt reduction in each restaurant, was conducted in May 2019, and
34 an evaluation survey with the same assessments will be conducted after 1-year follow-up, at the end
35 of the trial. 192 restaurants were selected from 12 counties of the above-mentioned 6 provinces. In
36 each province, 2 counties of similar socioeconomic level in the provincial capital city were selected.
37 The counties that had participated in other salt-reduction projects were excluded to minimize
38 contamination. To determine the effectiveness of the salt reduction package in restaurants of
39 different sizes, of the 16 Chinese restaurants selected from each county, it was ensured these
40 included 4 large restaurants, 8 medium restaurants and 4 small restaurants. The restaurants in each
41 county were then randomly allocated to the intervention or control group after the baseline survey,
42 using the random procedure on electronic data recording platform (EDC). The comprehensive
43 intervention package was designed to both inspire the consumers to demand for lower salt dishes
44 and promote the skills of reduced-salt cooking and ordering service in restaurant staff.
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Restaurant inclusion criteria and recruitment

Firstly, we released an open letter via local Media and cooperated with the Market Regulation Bureau to recruit restaurants which were interested in participating in the program. Then the standard inclusion criteria were used to screen for potential restaurants, including: (1) restaurants mainly offering Chinese cuisine; (2) agreeing to participate in 1 year of comprehensive salt reduction intervention and in at least two assessment surveys (baseline and follow-up surveys); (3) with complete records of salt and other condiments purchase and usage; (4) had been operating normally for more than 1 year and without plan of relocating or closing in the next 2 years; (5) with >50% of the dishes that could be prepared with less salt. Restaurants that were already involved in other salt reduction programs will be excluded. Restaurant size was determined based on surface area or number of seats (table 1). Finally, 16 restaurants in each country were selected according to the above inclusion and exclusion criteria, including 4 large-size, 8 medium-size and 4 small-size restaurants.

Table 1 Restaurant size classification

Classification	Square meters (m ²)	(or) Number of seats
Large restaurant	>500 and ≤3000	>250 and ≤1000
Medium restaurant	>150 and ≤500	>75 and ≤250
Small restaurant	≤150	≤75

Randomization

After baseline assessment, restaurants were randomly allocated to either the control group or the intervention group (96 restaurants in each group). The randomization was stratified by the size of restaurants and carried out using computer generated random numbers by a statistician who was not involved in the study and blind to the identity of the restaurants. Following the baseline survey, the restaurants allocated to the intervention group implemented a series of salt reduction activities. Meanwhile, the control restaurants operated as usual.

Intervention

The objective of RIS was to reduce salt use in restaurants. We aimed to achieve not only short-term, but also sustainable long-term effects. Social cognitive theory proposes behavior was influenced by

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4 the constant interaction of personal factors (ie. skills, knowledge) and environmental factors (ie.
5 appropriate modeling for learning, available materials)²². Therefore, we designed the intervention
6 activities based on both the supply (restaurant) and demand (consumer) sides (Figure 1). For the
7 intervention group, the RIS intervention package included the following activities:
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13 Figure 1 The RIS intervention design
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15 (1) Menu labelling:

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17 In the baseline survey, we collected the detailed ingredients composition, including the amount of
18 salt and condiments, of the 50 best-selling dishes of each restaurant. If a restaurant offers fewer than
19 50 dishes, information on all available dishes were collected. In each restaurant, the 10% of the
20 dishes that had the lowest sodium content (according to baseline survey) were labelled “lower salt”
21 on the menu, thus providing clear information to the customers. This menu will be used in the
22 intervention restaurants throughout the 1- year trial period.
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29 (2) Training for chef and waiter/waitress:

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31 In close collaboration with culinary experts, we developed a series of training materials, including
32 manual and videos, to guide chefs and waiters/waitresses in encouraging salt reduction services in
33 their routine work. Besides, we organized the service of a professional team to offer face-to-face
34 training for the restaurant staff of each county at least once a year. At least 3 representatives per
35 restaurant were required to attend the training. This training mainly focused on the following
36 aspects: “salt sources in restaurant dishes”, “why reduce salt”, “practical skills in reducing salt for
37 restaurant cooking”, “building a reduced-salt environment in a restaurant” and “service and
38 communication skills”. Local county investigators were responsible to enhance the knowledge and
39 skills among staff in each intervention restaurant by conducting monthly follow-up supervisions.
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48 During the trial, each intervention restaurant was encouraged to reduce salt usage by 10% in all
49 dishes, and greater reductions according to the customers’ request (such as, -30% or -50% salt).
50 Furthermore, at least 3 lower-salt dishes (sodium \leq 100mg/100g) per restaurant should be developed
51 through reformulation to provide customers more options of lower-salt dishes. Waiters/waitresses
52 were required to recommend customers the lower-salt dishes, as well as remind them they can
53 choose the reduced-salt option with almost all the other dishes.
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60 (3) Supportive environment for salt reduction in restaurants:

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4 Information that refers to salt reduction, salt and health, and available reduced-salt dishes were
5 shown through videos, posters, brochures, leaflets, and table displays to build restaurant
6 environments that makes it easier for the customers to choose lower-salt options. For example,
7 messages with announcement “-30%/-50% salt options were available for most dishes” will be
8 posted on dining tables. These materials should be displayed at noticeable positions in the
9 intervention restaurants during the trial period.

15 (4) Salt reduction campaign:

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17 To create a social environment supportive of salt reduction, local investigators were encouraged to
18 organize a campaign at least once during the 1-year trial, with the theme of “less salt, healthy
19 eating”, to help raise consumers’ awareness of salt reduction when they eat out. Another import aim
20 was to encourage restaurants to pay more attention to reducing salt and offering lower-salt dishes.
21 To expand the reach of the campaign, news agencies and social media were used to disseminate the
22 campaign messages. To limit contamination to control group, the salt reduction campaign should
23 only involve the restaurants in intervention group.

24
25 Certified medals of “ASC Salt Reducing Restaurant” were granted to intervention restaurants,
26 according to the standardized requirements. The medal will help motivate restaurants for salt
27 reduction and value their efforts.

38 **Sample size**

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40 In the current randomized controlled trial, selected restaurants were the study subjects. Based on the
41 results of a study on Chinese restaurants,²³ we assumed a standard deviation (SD) of 1g/100g of
42 dish for the sodium content of Chinese restaurant dishes, and expected that a sample of 192
43 restaurants would achieve 80% power (with two-sided $\alpha=0.05$) to detect a change in salt content
44 by 0.5 g/100g dish for the 5 best-selling dishes in each restaurant, allowing for a 20% dropping rate
45 of restaurants. Therefore, a total of 192 restaurants were recruited into the study.

54 **Outcome measures**

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56 The primary outcome was the differences between the intervention and control groups in the change
57 of the sodium content of the 5 best-selling dishes from baseline to the end of the trial (Figure 2).

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59 Secondary outcomes included the differences between the intervention and control groups in: (1)
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4 monthly use of salt and main salty condiments by the restaurant chefs; (2) salt-related knowledge,
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6 attitude and practice (KAP) in restaurant customers.
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10 Figure 2 RIS trial design
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13 **Outcome assessments**

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15 The primary and secondary outcomes should be assessed before and after the 1-year intervention,
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17 in both intervention and control restaurants.
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19 For the primary outcome, we collected the whole portion of the 5 best-selling dishes of each
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21 restaurant at baseline and follow-up, to test their sodium content using laboratory flame atomic
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23 absorption spectrometry method. Although it would be possible to estimate the sodium content of a
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25 dish by asking the chefs what ingredients and condiments they have used, this would rely on the
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27 chefs' memory. By using laboratory tests, we ensured the accurate assessment of the sodium content
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29 of the dishes. The dishes chosen for laboratory test should be top-selling firstly, and then involve
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31 different types according to the ingredients (ie. animal food based dishes, mixed food dishes, and
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33 vegetable food based dishes). The local researchers went to each restaurant and bought the 5 best-
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35 selling dishes anonymously in order to avoid introducing bias. The whole dishes, including sauce
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37 and soup when appropriate, were weighed and photographed. Once cooled off, they were transferred
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39 to a sampling bag. The samples were stored at -20°C freezer until transferred to the laboratory.
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41 Theoretically, for each restaurant, the same dishes bought at a similar date of the year should be
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43 assessed at baseline and follow-up assessment. However, if the dishes collected at baseline are no
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45 longer sold at the follow-up assessment, comparable dishes with similar ingredients and cooking
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47 method could be chosen as alternatives.
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49 For the secondary outcomes, questionnaires were administered by trained local investigators
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51 through a mobile EDC app developed for RIS. Compared to traditional data collection methods, the
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53 mobile EDC had advantages in terms of process and quality control, as demonstrated in a previous
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55 clinical trial²⁴. There were two questionnaires in the survey, including restaurant assessment and
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57 consumer survey. The questions related to the restaurant assessment consisted of: (1) basic
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59 information about the restaurant; (2) salt reduction environment and services in restaurant; (3)
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4 monthly salt and salty condiments usage; (4) attitude and challenges related to reducing salt in
5 restaurant; (5) dishes (≤ 50 dishes/restaurant) recipe (all ingredients and condiments used, and in
6 what quantity) and cooking method. The restaurant-related questions were asked to the
7 owners/managers who directly manage the restaurant, and the recipes were collected by face-to-
8 face interview with chefs who were familiar with preparing those dishes. To assist chefs in
9 remembering accurately the amount of ingredients used in the dishes, the investigators could show
10 them the weighed amount using a usual spoon or other measuring instruments used in their
11 restaurants.
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15 For the consumer survey, we randomly selected 20 customers (10 males and 10 females) in all
16 intervention and control restaurants, before and after the trial, to assess the changes and differences
17 of knowledge, attitudes, and behaviours related to salt reduction.
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19 **Data collection, management and analysis**

20 **Data collection**

21 We used the specially designed mobile EDC to collect assessments data during the RIS program, as
22 well as monthly supervision records in the 1-year comprehensive intervention. The local CDCs were
23 responsible for data collection. The structure of data collection system consisted of 192 restaurants.
24 The local researchers logged in the system, input the assessment data and supervision records in
25 each restaurant page. The assessment data included: (1) information on restaurants' salt reduction-
26 related environment, service, attitude, challenges, and monthly salt usage, as well as some sales
27 data; (2) information on recipe, cooking method, and laboratory sodium content; (3) information on
28 customer knowledge, attitude, and behaviors related to salt reduction. To collect the primary
29 indicator-laboratory measured sodium contents of the best-selling dishes, the local investigators
30 went to each restaurant and buy the 5 best-selling dishes anonymously, then put them totally into
31 the sampling bags, weighed the amount, stored at -20°C in refrigerator, and finally transferred to
32 the designated laboratory for sodium test. Monthly supervision records included information on the
33 process of intervention activities, and any reason for not carrying them out, as well as photos that
34 could inform on the intervention status.
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36 **Data management**

37 The mobile EDC used in the RIS program was developed by the Beijing University of Aeronautics
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4 and Astronautics. The security of data management was demonstrated in another publication under
5 the same ASC project ²⁰. To ensure the data validation and detection of keying errors, the EDC
6 system set rules of logic jump for associated questions, and abnormal values recognition. To
7 guarantee the integrity and authenticity of data collection, local researchers were given different
8 level of authority according to their roles. For example, the local investigators were responsible for
9 inputting survey and supervision data, but could not delete the records they added. The inspectors
10 had authority to check the data accuracy, delete mistaken records, start and close discussion about
11 doubtful data, but cannot add new records. The person in charge at county, provincial and national
12 levels, could view the data of all restaurants under their management, but could not make any
13 changes. All modifications were clearly recorded in the EDC system.
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23 **Statistical analysis**

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25 The effect of the intervention package for restaurants on the primary or secondary outcomes will be
26 determined using linear mixed models, including group (intervention, control), time (baseline,
27 follow-up), and interaction of group*time, with adjustments for potential confounding variables,
28 such as restaurant size, cooking method and dish category, etc. We will consider sensitivity analyses
29 to examine the robustness of the conclusion of the primary analysis. Results will be described as
30 mean, SD, standard error (SE), and 95% confidence interval where appropriate. SAS 9.4 will be
31 used for the data cleaning and statistical analyses. All analyses will be two sided, and $P < 0.05$ will
32 be considered significant.
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40 **Economic and process evaluation**

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42 Economic evaluation will be conducted from the health sector perspective to compare the
43 comprehensive intervention package for restaurant on salt reduction versus business as usual, and it
44 will include two dimensions: a trial-based economic evaluation, and a modelled economic
45 evaluation of long-term costs and outcomes. Intervention costs will include the direct costs of
46 running the program, excluding any research and development costs. We will consider restaurant
47 dishes consumption at the population level for the economic evaluation. Therefore, the trial-based
48 economic evaluation will be assessed in terms of incremental cost per unit salt reduction in
49 restaurant dishes and systolic blood pressure (BP). The conversion of sodium in restaurant dishes to
50 daily sodium intake for the population, and its relationship with systolic BP, will be based on the
51 scientific literature and other population trials under the ASC project. The modelled economic
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4 evaluation will examine the cost, survival, health states (including death and CVD events) to
5 estimate incremental cost per life year saved and cost per quality-adjusted life year gained. The
6 transition probabilities across health states and costs attached to different health states, and the long-
7 term effects of reduction in sodium intake will be based on literature data. Sensitivity analyses will
8 be used to estimate uncertainty about the primary findings associated with various key parameters.
9
10 The process evaluation will help us assess the fidelity and adoption of key components of
11 intervention (frequency, coverage and satisfaction), and understand the barriers and facilitators of
12 the intervention. The evaluation will be conducted using mixed-methods during and at the end of
13 the trial, from monthly supervision records, structured process evaluation form, and in-depth
14 interviews with restaurant staff and customers. Designed forms, including sales form of lower-salt
15 labeling dishes, recipe information form of reduced-salt dishes, and consumer feedback cards will
16 be collected at three time points during the intervention period, in order to monitor the acceptance
17 and the effect of the RIS intervention.
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29 **Project status and timelines**

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31 The recruitment of restaurants started in April 2019. Baseline survey was conducted between May
32 and June 2019. 192 restaurants from 12 counties completed the assessments, with data of 976
33 laboratory-tested dishes, 8145 recipes, and 3840 customers. Theoretically, the follow-up survey will
34 be conducted in the middle 2020, after 12 months' intervention. Due to the pandemic of novel
35 coronavirus disease (COVID-19) in early 2020, restaurants were temporarily closed in all the
36 provinces of China. According to the feedback from the 12 counties, all of restaurants in our study
37 were closed from late January to early April.
38 We will evaluate influences of the COVID-19 pandemic on restaurants, especially on those in the
39 intervention group, and decide on whether to postpone the follow-up assessment and other issues.
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48 **Expected outcome and potential impact**

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50 Unlike the standardized menus found in western fast food chains, Chinese dishes vary considerably
51 by areas, restaurants, and chefs, even for dishes with the same name. Few studies existed on the
52 sodium content of restaurant dishes in China.^{14 25} The current study covered a wide range of
53 restaurants in 6 provinces, could provide the evidence on the sodium level and sources in Chinese
54 restaurants, which will be very helpful to develop the specific intervention measures. The study
55 aimed to explore a feasible, effective and sustainable approach to achieve salt reduction for Chinese
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4 restaurants. With an increasing proportion of people eating out, restaurant dishes contributed much
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6 more sodium than decades before and induced more health risks. Compared with salt reduction
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8 initiatives in individuals, communities or schools, those conducted in restaurants may face more
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10 challenges. With this study, we will identify barriers and facilitators for implementation, as well as
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12 solutions suitable to Chinese restaurants to reduce salt. Based on these findings, we will be able to
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14 draw important public health implications.

15 **Patient and public involvement**

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17 Using information on the current situation of Chinese restaurants, inclusion criteria were determined
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19 before the recruitment. An open letter was disseminated via local media, introducing the RIS project
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21 and calling for participation publicly. Local CDC investigators, with support from the
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23 Administration for Market Regulation, made various mobilization efforts to help restaurant owners
24
25 understand the purpose of the project and the information to be collected in the investigation. With
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27 the consent of selected restaurants, we conducted assessment surveys and implemented the
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29 intervention. At the end of the study, we will disseminate the results to the restaurants, and discuss
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31 with related stakeholders how to translate the research findings into practice and develop a public
32
33 health strategy.

34 **ETHICS AND DISSEMINATION**

35
36 According to the results of ethics review by the Review Board of the National Institute for Nutrition
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38 and Health, China CDC, and Queen Mary Research Ethics Committee, written informed consent
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40 from restaurants and consumers were exempted from the RIS project. However, the investigators
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42 should fully inform the selected restaurants and consumers of the purpose and activities of the
43
44 project, strive for understanding and cooperation, and keep the information confidential. The
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46 restaurants and consumers will be free to discontinue their participation at any time without giving
47
48 any reasons.

49
50 The findings of this research will be disseminated through conference presentations, peer-reviewed
51
52 publications, press release and social media.

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57
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59
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Patient consent for publication Not required.

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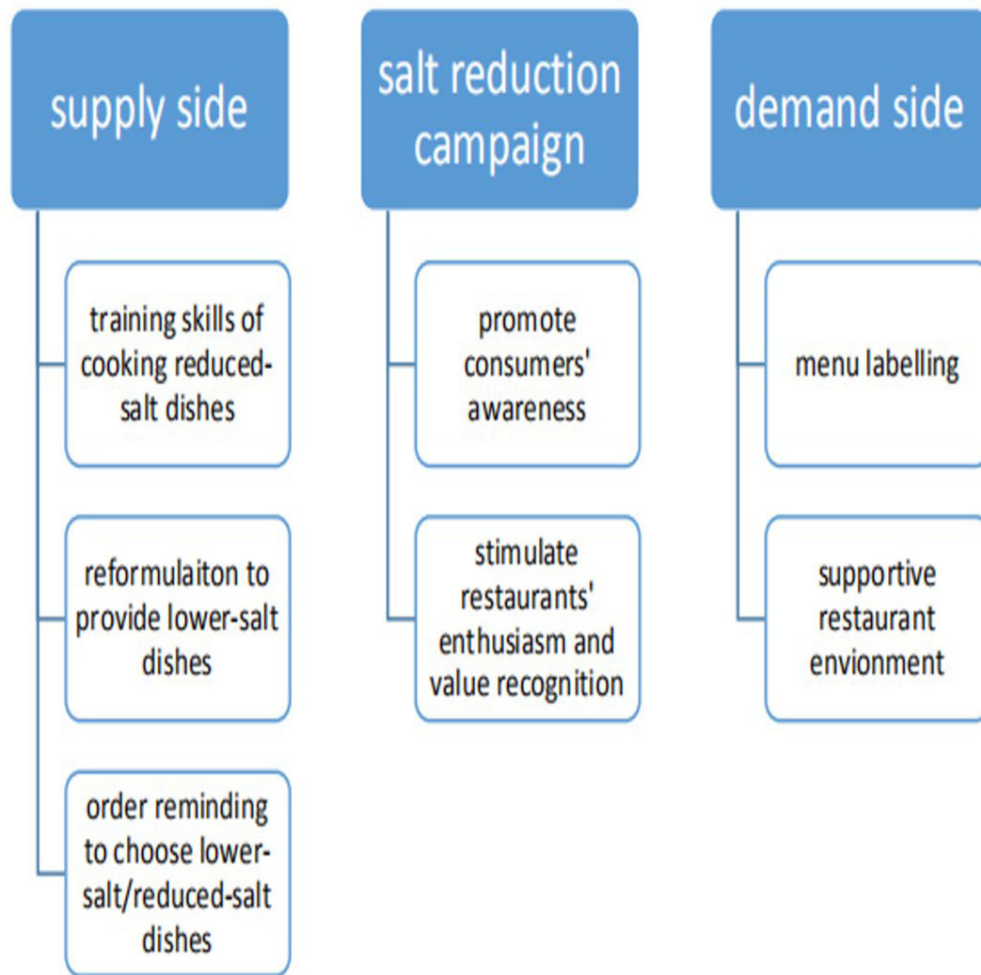
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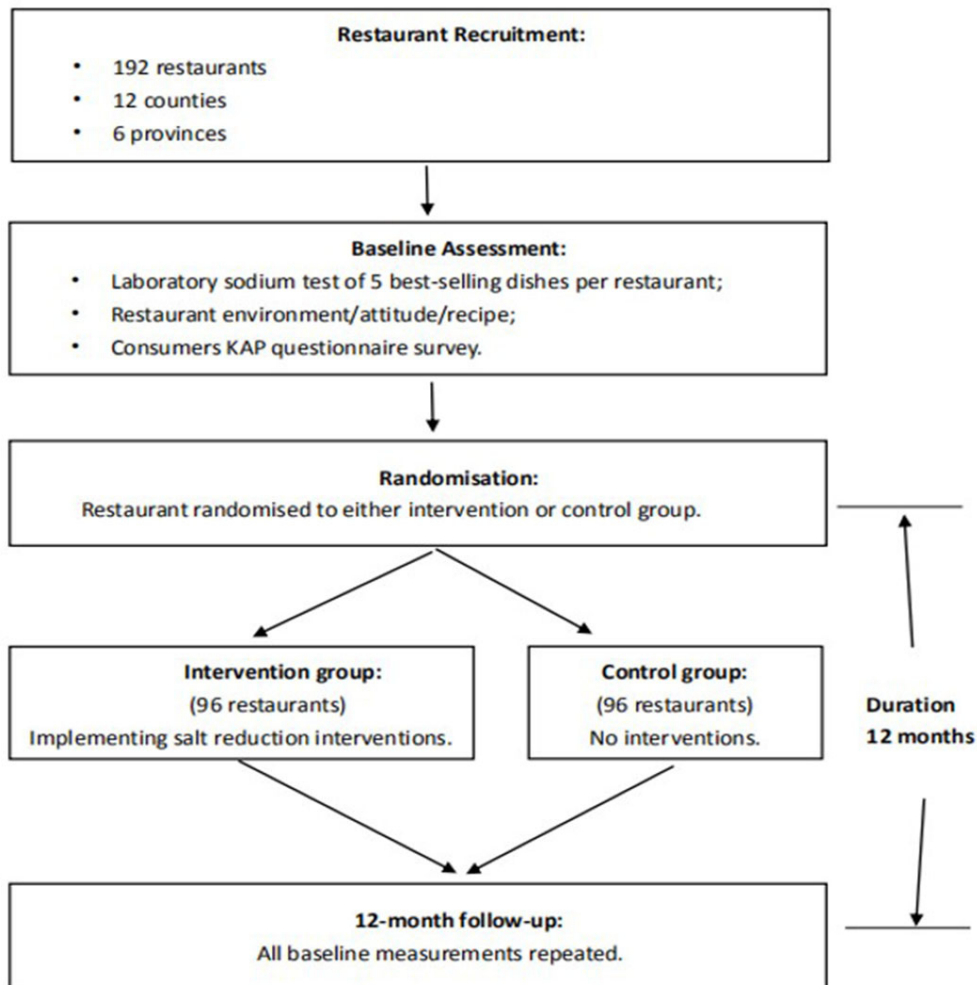
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28 Figure 1. The RIS intervention design

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30 Figure 2. RIS trial design
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SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents*

Section/item	Item No	Description
Administrative information		
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym <input checked="" type="checkbox"/>
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry <input checked="" type="checkbox"/>
	2b	All items from the World Health Organization Trial Registration Data Set <input checked="" type="checkbox"/>
Protocol version	3	Date and version identifier <input checked="" type="checkbox"/>
Funding	4	Sources and types of financial, material, and other support <input checked="" type="checkbox"/>
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors <input checked="" type="checkbox"/>
	5b	Name and contact information for the trial sponsor <input checked="" type="checkbox"/>
	5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities <input checked="" type="checkbox"/>
	5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee) <input checked="" type="checkbox"/>
Introduction		
Background and rationale	6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention <input checked="" type="checkbox"/>
	6b	Explanation for choice of comparators <input checked="" type="checkbox"/>
Objectives	7	Specific objectives or hypotheses <input checked="" type="checkbox"/>
Trial design	8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory) <input checked="" type="checkbox"/>

Methods: Participants, interventions, and outcomes

Study setting	9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained <input checked="" type="checkbox"/>
Eligibility criteria	10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists) <input checked="" type="checkbox"/>
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered <input checked="" type="checkbox"/>
	11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease) <input checked="" type="checkbox"/>
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests) <input checked="" type="checkbox"/>
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial <input checked="" type="checkbox"/>
Outcomes	12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended <input checked="" type="checkbox"/>
Participant timeline	13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure) <input checked="" type="checkbox"/>
Sample size	14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations <input checked="" type="checkbox"/>
Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size <input checked="" type="checkbox"/>

Methods: Assignment of interventions (for controlled trials)

Allocation:

Sequence generation	16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions <input checked="" type="checkbox"/>
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Allocation concealment mechanism	16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned <input checked="" type="checkbox"/>
Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions <input checked="" type="checkbox"/>
Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how <input checked="" type="checkbox"/>
	17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial <input checked="" type="checkbox"/>

Methods: Data collection, management, and analysis

Data collection methods	18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol <input checked="" type="checkbox"/>
	18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols <input checked="" type="checkbox"/>
Data management	19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol <input checked="" type="checkbox"/>
Statistical methods	20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol <input checked="" type="checkbox"/>
	20b	Methods for any additional analyses (eg, subgroup and adjusted analyses) <input checked="" type="checkbox"/>
	20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation) <input checked="" type="checkbox"/>

Methods: Monitoring

Data monitoring	21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed <input checked="" type="checkbox"/>
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1		21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial <input checked="" type="checkbox"/>
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6	Harms	22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct <input checked="" type="checkbox"/>
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11	Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor <input checked="" type="checkbox"/>
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Ethics and dissemination

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17	Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval <input checked="" type="checkbox"/>
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21	Protocol amendments	25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators) <input checked="" type="checkbox"/>
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26	Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32) <input checked="" type="checkbox"/>
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30		26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable <input checked="" type="checkbox"/>
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33	Confidentiality	27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial <input checked="" type="checkbox"/>
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37	Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site <input checked="" type="checkbox"/>
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41	Access to data	29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators <input checked="" type="checkbox"/>
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45	Ancillary and post-trial care	30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation <input checked="" type="checkbox"/>
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48	Dissemination policy	31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions <input checked="" type="checkbox"/>
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54		31b	Authorship eligibility guidelines and any intended use of professional writers <input checked="" type="checkbox"/>
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57		31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code <input checked="" type="checkbox"/>
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Appendices

Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates
Biological specimens	33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable

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For peer review only

BMJ Open

The restaurant interventions for salt reduction in China: protocol for a randomized controlled trial

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Keywords:	EPIDEMIOLOGY, Health policy < HEALTH SERVICES ADMINISTRATION & MANAGEMENT, NUTRITION & DIETETICS, PUBLIC HEALTH, Protocols & guidelines < HEALTH SERVICES ADMINISTRATION & MANAGEMENT

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3 **The restaurant interventions for salt reduction in China: protocol for a randomized**
4 **controlled trial**
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13 **Word count:** 3711.

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18 **ABSTRACT**

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21 **Introduction** Salt intake in China is high, and most of it comes from that added by consumers.
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23 Nevertheless, recent years have seen a rapid increase in the frequency at which people eat out. The
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25 aim of this study is to evaluate the effectiveness of interventions designed for salt reduction in
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27 restaurants through a randomized controlled trial in China.

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30 **Methods and analysis** As a randomized controlled trial with restaurants as study subjects, we
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32 recruited 192 restaurants from 12 counties of 6 provinces in China. After the baseline survey,
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34 restaurants were randomly assigned to intervention or control group. Using social cognitive theory,
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36 comprehensive intervention activities were designed to encourage salt reduction in all restaurant
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38 foods, and at the same time, to encourage consumers to choose lower-salt options when eating out.
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40 The interventions will be conducted only in restaurants of the intervention group during the first
41
42 year. The follow-up assessment will be conducted at the end of the trial. The primary outcome is
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44 the change in the average salt content of the 5 best-selling dishes of the restaurant, as measured by
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46 laboratory tests. Secondary outcomes include differences in the monthly use of salt and salty
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48 condiments between intervention and control restaurants, and the knowledge, attitude and practice
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50 (KAP) on salt among restaurant consumers.

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52 **Ethics and dissemination** The study was reviewed and approved by the Review Board of the
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54 National Institute for Nutrition and Health, China CDC, and Queen Mary Research Ethics
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56 Committee. Results will be disseminated through presentations, publications and social media.

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58 **Trial registration number** ChiCTR1800019694

Strengths and limitations of this study

The study develops an effective and sustainable intervention package for salt reduction in Chinese restaurant settings.

Our study covers a wide range of restaurants in China, from 6 provinces and thus representing different cuisines and eating habits.

Due to the commercial nature of restaurants, the implementation of the salt reduction interventions may be challenging, and need strong multisector support and cooperation.

INTRODUCTION

High salt intake is one of the leading dietary risk factors for deaths and disability globally¹ and associated with 3 million deaths and 70 million DALYs in adults around the world. In China, high salt intake attributed to more than 0.5 million cardiometabolic deaths in 2010-12.² The most common risk of high salt intake is raised blood pressure, which alone accounted for an estimated 10.7 million deaths each year worldwide.³ Statistics from the 2015 China's Report on Nutrition and Chronic Diseases revealed that the prevalence of hypertension among the Chinese population aged 18 years and older was 25.2% in 2012,⁴ with the total number of individuals with high blood pressure reaching 270 million. International experience had proved that reducing population salt intake lowered blood pressure and reduced the risk of cardiovascular disease (CVD).^{5 6} Salt reduction is considered one of the most cost-effective measures to improve public health.⁷ In China, the average salt intake was 12-14g salt per day, which was more than double the WHO-recommended maximum level of 5g salt per day for adults.^{8 9}

With the rapid urbanization and lifestyle changes in China, eating in restaurants has been becoming popular, especially in urban areas. National survey (2010-12) statistics showed that, 35.5% of the Chinese aged 6 years and older had eaten out in the past week. The proportion of people dining out was 42.2% and 28.5% in urban and rural areas respectively.⁴ Restaurants became the second major dining location after home-cooking in China, and this had important impacts on public health and

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4 nutrition. A pilot study using a one-week salt estimation method in Beijing found that approximately
5 40% of the salt intake was consumed outside the home.¹⁰ Restaurant dishes seemed to have a high
6 sodium content in both developed and developing countries.¹¹⁻¹⁴ A study showed that 46.8% of the
7 dishes served in Chinese restaurants in Beijing contained more salt than the daily salt intake
8 recommended by WHO.¹⁴ Sodium content was substantially higher in restaurant foods than in
9 home-made foods.¹⁵⁻¹⁷ Therefore, to help consumers reduce their overall salt intake, it is important
10 to develop an effective strategy to reduce the sodium content of restaurant foods.
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18 To tackle the high salt intake levels in China, Action on Salt China (ASC) was set up in 2017, funded
19 by the UK National Institute for Health Research (NIHR). ASC aimed to implement comprehensive
20 national salt reduction programs, with the leadership of Queen Mary University of London
21 (QMUL), the George Institute China (TGI), Chinese Center for Disease Control and Prevention
22 (China CDC) and other key related organizations.¹⁸ The ASC team developed two national health
23 campaigns (health education and salt reduction in packaged food) and four randomized controlled
24 trials (RCTs) to test interventions targeting the major sources of salt intake¹⁹. The RCTs consisted
25 of (1) an application-based intervention study in schoolchildren and their families (AIS);²⁰ (2) a
26 home cook-based intervention study (HIS); (3) a comprehensive intervention study (CIS);²¹ and (4)
27 a restaurant-based intervention study (RIS), which is the one reported in the present paper.
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38 The objective of RIS was to reduce salt use by at least 0.5g per 100g in restaurant dishes. To achieve
39 the goal, we developed a restaurant salt reduction package, the feasibility and effectiveness of which
40 are being tested by RIS. The key interventions were based on social cognitive theory²² and included:
41 (1) building tailored restaurant environments that encourage consumers to order lower-salt or
42 reduced-salt dishes; (2) lower-salt or reduced-salt ordering reminders from the waiters; (3) training
43 cooks in reduced-salt cooking; (4) salt reduction campaigns. As a part of the ASC program, this
44 article reports on the design of the RIS intervention package and its implementation, evaluation, and
45 current status.
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57 **METHODS AND ANALYSIS**

58 **Study setting and sampling method**

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4 To account for geographical, economic and dietary disparities, our study was carried out in 6
5 provinces of China, which were consistent with other RCTs of ASC, covering north (Heilongjiang,
6 Hebei, Qinghai) and south (Hunan, Sichuan and Jiangxi) China. As a RCT, the RIS baseline survey,
7 which included the assessment of laboratory sodium level of 5 best-selling dishes, restaurant
8 environment and attitude on salt reduction, detailed recipe information, and consumers' knowledge,
9 attitude and practice (KAP) on salt reduction in each restaurant, was conducted in May 2019, and
10 an evaluation survey with the same assessments will be conducted after 1-year follow-up, at the end
11 of the trial. 192 restaurants were selected from 12 counties of the above-mentioned 6 provinces. In
12 each province, 2 counties of similar socioeconomic level in the provincial capital city were selected.
13 The counties that had participated in other salt-reduction projects were excluded to minimize
14 contamination. To determine the effectiveness of the salt reduction package in restaurants of
15 different sizes, of the 16 Chinese restaurants selected from each county, it was ensured these
16 included 4 large restaurants, 8 medium restaurants and 4 small restaurants. The restaurants in each
17 county were then randomly allocated to the intervention or control group after the baseline survey,
18 using the random procedure on electronic data recording platform (EDC). The comprehensive
19 intervention package was designed to both inspire the consumers to demand for lower salt dishes
20 and promote the skills of reduced-salt cooking and ordering service in restaurant staff.

21 **Restaurant inclusion criteria and recruitment**

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23 Firstly, we released an open letter via local Media and cooperated with the Market Regulation
24 Bureau to recruit restaurants which were interested in participating in the program. Then the
25 standard inclusion criteria were used to screen for potential restaurants, including: (1) restaurants
26 mainly offering Chinese cuisine; (2) agreeing to participate in 1 year of comprehensive salt
27 reduction intervention and in at least two assessment surveys (baseline and follow-up surveys); (3)
28 with complete records of salt and other condiments purchase and usage; (4) had been operating
29 normally for more than 1 year and without plan of relocating or closing in the next 2 years; (5) with
30 >50% of the dishes that could be prepared with less salt. Restaurants that were already involved in
31 other salt reduction programs will be excluded. Restaurant size was determined based on surface
32 area or number of seats (table 1). Finally, 16 restaurants in each country were selected according to
33 the above inclusion and exclusion criteria, including 4 large-size, 8 medium-size and 4 small-size
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6 Table 1 Restaurant size classification

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8 Classification	9 Square meters (m ²)	10 (or) Number of seats
11 Large restaurant	12 >500 and ≤3000	13 >250 and ≤1000
14 Medium restaurant	15 >150 and ≤500	16 >75 and ≤250
17 Small restaurant	18 ≤150	19 ≤75

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22 **Randomization**

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24 After baseline assessment, restaurants were randomly allocated to either the control group or the
25 intervention group (96 restaurants in each group). The randomization was stratified by the size of
26 restaurants and carried out using computer generated random numbers by a statistician who was not
27 involved in the study and blind to the identity of the restaurants. Following the baseline survey, the
28 restaurants allocated to the intervention group implemented a series of salt reduction activities.
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30 Meanwhile, the control restaurants operated as usual.
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40 **Intervention**

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42 The objective of RIS was to reduce salt use in restaurants. We aimed to achieve not only short-term,
43 but also sustainable long-term effects. Social cognitive theory proposes behavior was influenced by
44 the constant interaction of personal factors (ie. skills, knowledge) and environmental factors (ie.
45 appropriate modeling for learning, available materials)²². Therefore, we designed the intervention
46 activities based on both the supply (restaurant) and demand (consumer) sides (Figure 1). For the
47 intervention group, the RIS intervention package included the following activities:
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58 Figure 1 The RIS intervention design

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60 (1) Menu labelling:

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4 In the baseline survey, we collected the detailed ingredients composition, including the amount of
5 salt and condiments, of the 50 best-selling dishes of each restaurant. If a restaurant offers fewer than
6 50 dishes, information on all available dishes were collected. In each restaurant, the 10% of the
7 dishes that had the lowest sodium content (according to baseline survey) were labelled “lower salt”
8 on the menu, thus providing clear information to the customers. This menu will be used in the
9 intervention restaurants throughout the 1- year trial period.
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16 (2) Training for chef and waiter/waitress:
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18 In close collaboration with culinary experts, we developed a series of training materials, including
19 manual and videos, to guide chefs and waiters/waitresses in encouraging salt reduction services in
20 their routine work. Besides, we organized the service of a professional team to offer face-to-face
21 training for the restaurant staff of each county at least once a year. At least 3 representatives per
22 restaurant were required to attend the training. This training mainly focused on the following
23 aspects: “salt sources in restaurant dishes”, “why reduce salt”, “practical skills in reducing salt for
24 restaurant cooking”, “building a reduced-salt environment in a restaurant” and “service and
25 communication skills”. Local county investigators were responsible to enhance the knowledge and
26 skills among staff in each intervention restaurant by conducting monthly follow-up supervisions.
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37 During the trial, each intervention restaurant was encouraged to reduce salt usage by 10% in all
38 dishes, and greater reductions according to the customers’ request (such as, -30% or -50% salt).
39 Furthermore, at least 3 lower-salt dishes (sodium \leq 100mg/100g) per restaurant should be developed
40 through reformulation to provide customers more options of lower-salt dishes. Waiters/waitresses
41 were required to recommend customers the lower-salt dishes, as well as remind them they can
42 choose the reduced-salt option with almost all the other dishes.
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49 (3) Supportive environment for salt reduction in restaurants:
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51 Information that refers to salt reduction, salt and health, and available reduced-salt dishes were
52 shown through videos, posters, brochures, leaflets, and table displays to build restaurant
53 environments that makes it easier for the customers to choose lower-salt options. For example,
54 messages with announcement “-30%/-50% salt options were available for most dishes” will be
55 posted on dining tables. These materials should be displayed at noticeable positions in the
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4 intervention restaurants during the trial period.

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6 (4) Salt reduction campaign:

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9 To create a social environment supportive of salt reduction, local investigators were encouraged to
10 organize a campaign at least once during the 1-year trial, with the theme of “less salt, healthy
11 eating”, to help raise consumers’ awareness of salt reduction when they eat out. Another import aim
12 was to encourage restaurants to pay more attention to reducing salt and offering lower-salt dishes.
13 To expand the reach of the campaign, news agencies and social media were used to disseminate the
14 campaign messages. To limit contamination to control group, the salt reduction campaign should
15 only involve the restaurants in intervention group.
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23 Certified medals of “ASC Salt Reducing Restaurant” were granted to intervention restaurants,
24 according to the standardized requirements. The medal will help motivate restaurants for salt
25 reduction and value their efforts.
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33 **Sample size**

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35 In the current randomized controlled trial, selected restaurants were the study subjects. Based on the
36 results of a study on Chinese restaurants,²³ we assumed a standard deviation (SD) of 1g/100g of
37 dish for the sodium content of Chinese restaurant dishes, and expected that a sample of 192
38 restaurants would achieve 80% power (with two-sided alpha=0.05) to detect a change in salt content
39 by 0.5 g/100g dish for the 5 best-selling dishes in each restaurant, allowing for a 20% dropping rate
40 of restaurants. Therefore, a total of 192 restaurants were recruited into the study.
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50 **Outcome measures**

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52 (1) Effectiveness outcomes:

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55 The primary outcome was the differences between the intervention and control groups in the change
56 of the sodium content of the 5 best-selling dishes from baseline to the end of the trial (Figure 2).
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59 Secondary outcomes included the differences between the intervention and control groups in: (1)
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4 monthly use of salt and main salty condiments by the restaurant chefs; (2) salt-related knowledge,
5 attitude and practice (KAP) in restaurant customers.
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11 Figure 2 RIS trial design
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13 (2) Feasibility outcomes:
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16 The feasibility outcomes included two dimensions: 1) the cost-benefit values, and 2) the fidelity and
17 adoption of the interventions (frequency, coverage and satisfaction), as well as the barriers and
18 facilitators of conducting the interventions.
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21 22 **Outcome assessments** 23

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25 (1) Effectiveness outcome assessments:
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28 The primary and secondary effectiveness outcomes should be assessed before and after the 1-year
29 intervention, in both intervention and control restaurants.
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32 For the primary outcome, we collected the whole portion of the 5 best-selling dishes of each
33 restaurant at baseline and follow-up, to test their sodium content using laboratory flame atomic
34 absorption spectrometry method. Although it would be possible to estimate the sodium content of a
35 dish by asking the chefs what ingredients and condiments they have used, this would rely on the
36 chefs' memory. By using laboratory tests, we ensured the accurate assessment of the sodium content
37 of the dishes. The dishes chosen for laboratory test should be top-selling firstly, and then involve
38 different types according to the ingredients (ie. animal food based dishes, mixed food dishes, and
39 vegetable food based dishes). The local researchers went to each restaurant and bought the 5 best-
40 selling dishes anonymously in order to avoid introducing bias. The whole dishes, including sauce
41 and soup when appropriate, were weighed and photographed. Once cooled off, they were transferred
42 to a sampling bag. The samples were stored at -20°C freezers until transferred to the laboratory.
43
44 Theoretically, for each restaurant, the same dishes bought at a similar date of the year should be
45 assessed at baseline and follow-up assessment. However, if the dishes collected at baseline are no
46 longer sold at the follow-up assessment, comparable dishes with similar ingredients and cooking
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4 method could be chosen as alternatives.
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6 For the secondary outcomes, questionnaires were administered by trained local investigators
7 through a mobile EDC app developed for RIS. Compared to traditional data collection methods, the
8 mobile EDC had advantages in terms of process and quality control, as demonstrated in a previous
9 clinical trial²⁴. There were two questionnaires in the survey, including restaurant assessment and
10 consumer survey. The questions related to the restaurant assessment consisted of: (1) basic
11 information about the restaurant; (2) salt reduction environment and services in restaurant; (3)
12 monthly salt and salty condiments usage; (4) attitude and challenges related to reducing salt in
13 restaurant; (5) dishes (≤ 50 dishes/restaurant) recipe (all ingredients and condiments used, and in
14 what quantity) and cooking method. The restaurant-related questions were asked to the
15 owners/managers who directly manage the restaurant, and the recipes were collected by face-to-
16 face interview with chefs who were familiar with preparing those dishes. To assist chefs in
17 remembering accurately the amount of ingredients used in the dishes, the investigators could show
18 them the weighed amount using a usual spoon or other measuring instruments used in their
19 restaurants.
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34 For the consumer survey, we randomly selected 20 customers (10 males and 10 females) in all
35 intervention and control restaurants, before and after the trial, to assess the changes and differences
36 of knowledge, attitudes, and behaviours related to salt reduction.
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40 (2) Feasibility outcome assessments: 41

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43 Economic evaluation will be conducted from the health sector perspective to compare the
44 comprehensive intervention package for restaurant on salt reduction versus business as usual, and it
45 will include two dimensions: a trial-based economic evaluation, and a modelled economic
46 evaluation of long-term costs and outcomes. Intervention costs will include the direct costs of
47 running the program, excluding any research and development costs. We will consider restaurant
48 dishes consumption at the population level for the economic evaluation. Therefore, the trial-based
49 economic evaluation will be assessed in terms of incremental cost per unit salt reduction in
50 restaurant dishes and systolic blood pressure (BP). The conversion of sodium in restaurant dishes to
51 daily sodium intake for the population, and its relationship with systolic BP, will be based on the
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4 scientific literature and other population trials under the ASC project. The modelled economic
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6 evaluation will examine the cost, survival, health states (including death and CVD events) to
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8 estimate incremental cost per life year saved and cost per quality-adjusted life year gained. The
9
10 transition probabilities across health states and costs attached to different health states, and the long-
11
12 term effects of reduction in sodium intake will be based on literature data. Sensitivity analyses will
13
14 be used to estimate uncertainty about the primary findings associated with various key
15
16 parameters. The process evaluation will help us assess the fidelity and adoption of key components
17
18 of intervention (frequency, coverage and satisfaction), and understand the barriers and facilitators
19
20 of the intervention. The evaluation will be conducted using mixed-methods during and at the end of
21
22 the trial, from monthly supervision records, structured process evaluation form, and in-depth
23
24 interviews with restaurant staff and customers. Designed forms, including sales form of lower-salt
25
26 labeling dishes, recipe information form of reduced-salt dishes, and consumer feedback cards will
27
28 be collected at three time points during the intervention period, in order to monitor the acceptance
29
30 and the effect of the RIS intervention.

31 **Data collection, management and analysis**

32 **Data collection**

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35 We used the specially designed mobile EDC to collect assessments data during the RIS program, as
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37 well as monthly supervision records in the 1-year comprehensive intervention. The local CDCs were
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39 responsible for data collection. The structure of data collection system consisted of 192 restaurants.
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41 The local researchers logged in the system, input the assessment data and supervision records in
42
43 each restaurant page. The assessment data included: (1) information on restaurants' salt reduction-
44
45 related environment, service, attitude, challenges, and monthly salt usage, as well as some sales
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47 data; (2) information on recipe, cooking method, and laboratory sodium content; (3) information on
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49 customer knowledge, attitude, and behaviors related to salt reduction. To collect the primary
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51 indicator-laboratory measured sodium contents of the best-selling dishes, the local investigators
52
53 went to each restaurant and buy the 5 best-selling dishes anonymously, then put them totally into
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55 the sampling bags, weighed the amount, stored at -20°C in refrigerator, and finally transferred to
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57 the designated laboratory for sodium test. Monthly supervision records included information on the
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4 process of intervention activities, and any reason for not carrying them out, as well as photos that
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6 could inform on the intervention status.
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8 **Data management**

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10 The mobile EDC used in the RIS program was developed by the Beijing University of Aeronautics
11 and Astronautics. The security of data management was demonstrated in another publication under
12 the same ASC project²⁰. To ensure the data validation and detection of keying errors, the EDC
13 system set rules of logic jump for associated questions, and abnormal values recognition. To
14 guarantee the integrity and authenticity of data collection, local researchers were given different
15 level of authority according to their roles. For example, the local investigators were responsible for
16 inputting survey and supervision data, but could not delete the records they added. The inspectors
17 had authority to check the data accuracy, delete mistaken records, start and close discussion about
18 doubtful data, but cannot add new records. The person in charge at county, provincial and national
19 levels, could view the data of all restaurants under their management, but could not make any
20 changes. All modifications were clearly recorded in the EDC system.
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33 **Statistical analysis**

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35 The effect of the intervention package for restaurants on the primary or secondary outcomes will be
36 determined using linear mixed models. The differential change by groups from baseline to the end
37 of follow-up will be indicated by including group (intervention, control), time (baseline, follow-up),
38 and the interaction of group*time, with adjustments for potential confounding variables (area,
39 restaurant size, cooking method and dish category). We will consider sensitivity analyses to examine
40 the robustness of the conclusion of the primary analysis. Results will be described as mean, SD,
41 standard error (SE), and 95% confidence interval where appropriate. SAS 9.4 will be used for the
42 data cleaning and statistical analyses. All analyses will be two sided, and $P < 0.05$ will be considered
43 significant.
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56 **Project status and timelines**

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58 The recruitment of restaurants started in April 2019. Baseline survey was conducted between May
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4 and June 2019. 192 restaurants from 12 counties completed the assessments, with data of 976
5 laboratory-tested dishes, 8145 recipes, and 3840 customers. Theoretically, the follow-up survey will
6 be conducted in the middle 2020, after 12 months' intervention. Due to the pandemic of novel
7 coronavirus disease (COVID-19) in early 2020, restaurants were temporarily closed in all the
8 provinces of China. According to the feedback from the 12 counties, all of restaurants in our study
9 were closed from late January to early April.
10 We will evaluate influences of the COVID-19 pandemic on restaurants, especially on those in the
11 intervention group, and decide on whether to postpone the follow-up assessment and other issues.
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20 **Expected outcome and potential impact**

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22 Unlike the standardized menus found in western fast food chains, Chinese dishes vary considerably
23 by areas, restaurants, and chefs, even for dishes with the same name. Few studies existed on the
24 sodium content of restaurant dishes in China.^{14 25} The current study covered a wide range of
25 restaurants in 6 provinces, could provide the evidence on the sodium level and sources in Chinese
26 restaurants, which will be very helpful to develop the specific intervention measures. The study
27 aimed to explore a feasible, effective and sustainable approach to achieve salt reduction for Chinese
28 restaurants. With an increasing proportion of people eating out, restaurant dishes contributed much
29 more sodium than decades before and induced more health risks. Compared with salt reduction
30 initiatives in individuals, communities or schools, those conducted in restaurants may face more
31 challenges. With this study, we will identify barriers and facilitators for implementation, as well as
32 solutions suitable to Chinese restaurants to reduce salt. Based on these findings, we will be able to
33 draw important public health implications.
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47 **Patient and public involvement**

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49 Using information on the current situation of Chinese restaurants, inclusion criteria were determined
50 before the recruitment. An open letter was disseminated via local media, introducing the RIS project
51 and calling for participation publicly. Local CDC investigators, with support from the
52 Administration for Market Regulation, made various mobilization efforts to help restaurant owners
53 understand the purpose of the project and the information to be collected in the investigation. With
54 the consent of selected restaurants, we conducted assessment surveys and implemented the
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4 intervention. At the end of the study, we will disseminate the results to the restaurants, and discuss
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6 with related stakeholders how to translate the research findings into practice and develop a public
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8 health strategy.
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10 **ETHICS AND DISSEMINATION**

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12 According to the results of ethics review by the Review Board of the National Institute for Nutrition
13
14 and Health, China CDC, and Queen Mary Research Ethics Committee, written informed consent
15
16 from restaurants and consumers were exempted from the RIS project. However, the investigators
17
18 should fully inform the selected restaurants and consumers of the purpose and activities of the
19
20 project, strive for understanding and cooperation, and keep the information confidential. The
21
22 restaurants and consumers will be free to discontinue their participation at any time without giving
23
24 any reasons.
25

26
27 The findings of this research will be disseminated through conference presentations, peer-reviewed
28
29 publications, press release and social media.
30

31 **Author affiliations**

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33
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35
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37

38
39 ²The George Institute for Global Health at Peking University Health Science Center, Beijing, China
40

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47

48
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52 ⁵Qinghai Provincial Center for Disease Control and Prevention, Xining, China
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55 ⁶Hebei Provincial Center for Disease Control and Prevention, Shijiazhuang, China
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58 ⁷Hunan Provincial Center for Disease Control and Prevention, Changsha, China
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⁸Sichuan Provincial Center for Disease Control and Prevention, Chengdu, China

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4 ⁹Jiangxi Provincial Center for Disease Control and Prevention, Nanchang, China
5

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7
8 consumers, local administration for market regulation, experts of Sichuan Tourism University for
9
10 their opinions on the development of the intervention program.
11

12
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14
15 study design and implementation. WD, JZ, HW, YL, PZ, FJH, XZ, ZX, YG, LY, XC and WY
16
17 facilitates restaurant and public involvement and were responsible for setting up the study in each
18
19 site. All authors contributed to the development of intervention and evaluation. WD wrote the first
20
21 draft of the manuscript, and JZ, HW, YL, PZ, FJH, MT, GAM and RL revised the draft. All authors
22
23 contributed to the refinement of the study protocol and approved the final manuscript.
24

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28
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30
31 those of the author(s) and not necessarily those of the NIHR or the Department of Health and Social
32
33 Care.
34

35 **Disclaimer** The findings of this study will be disseminated through discussions or presentations at
36
37 conferences, peer-reviewed publications and general media.
38

39
40 **Competing interests** FJH is a member of the Consensus Action on Salt & Health (CASH), a non-
41
42 profit charitable organization, and its international branch World Action on Salt & Health (WASH).
43
44 FJH does not receive any financial support from CASH or WASH. GAM is the chairman of Blood
45
46 Pressure UK (BPUK), chairman of CASH and chairman of WASH and does not receive any
47
48 financial support from any of these organizations. BPUK, CASH and WASH are non-profit
49
50 charitable organizations. All other authors have no competing interests to declare.
51

52 **Patient consent for publication** Not required.
53

54
55 **Ethics approval** The study has been reviewed and approved by the Review Board of the National
56
57 Institute for Nutrition and Health, China CDC (20180314), and Queen Mary Research Ethics
58
59 Committee (QMERC2018/14).
60

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4 **Provenance and peer review** Not mentioned; externally peer reviewed.
5

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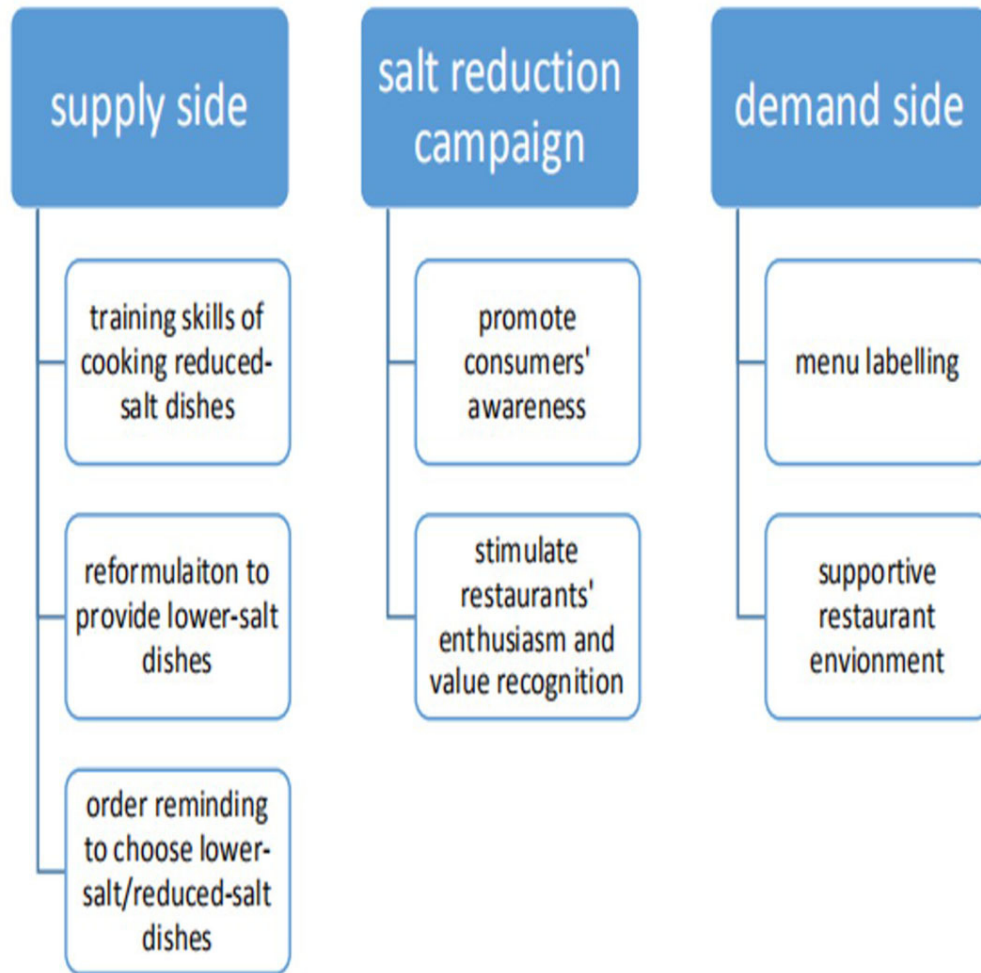
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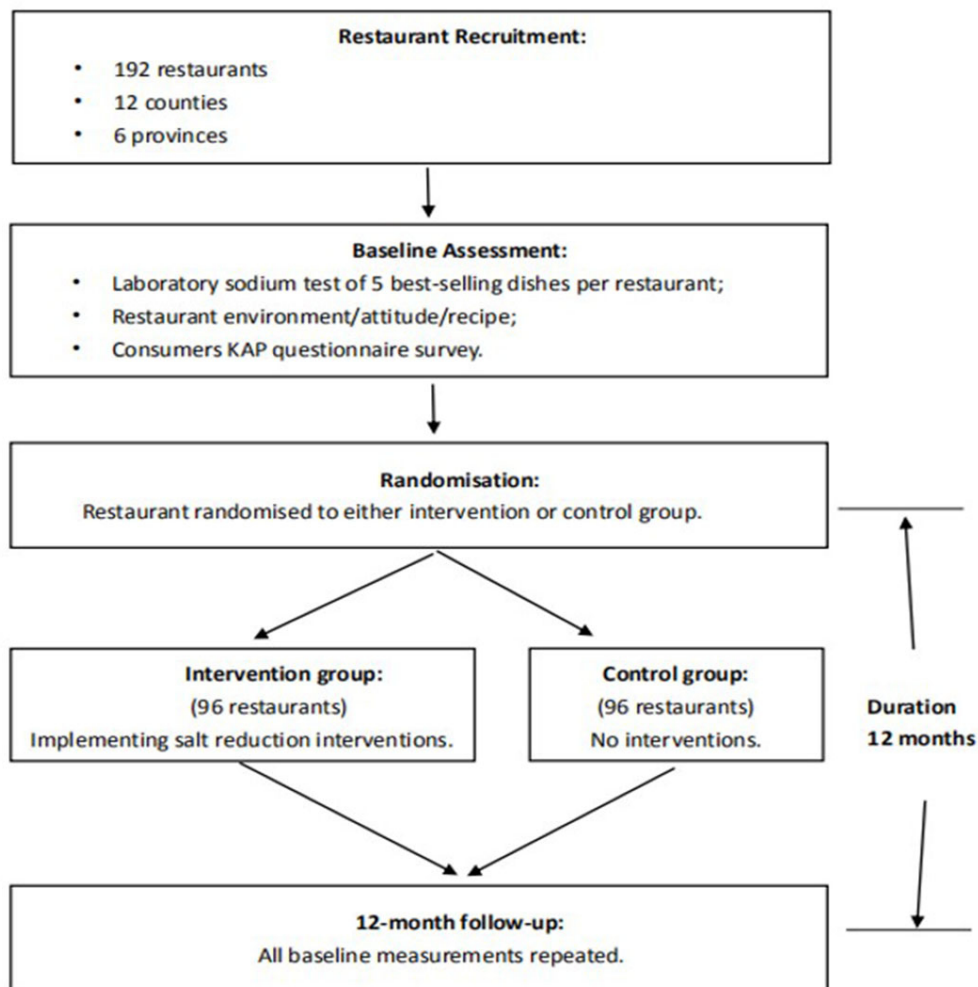
41 Figure 1. The RIS intervention design
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45 Figure 2. RIS trial design
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The RIS intervention design

90x90mm (300 x 300 DPI)



RIS trial design

90x90mm (300 x 300 DPI)



SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents*

Section/item	Item No	Description
Administrative information		
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym <input checked="" type="checkbox"/>
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry <input checked="" type="checkbox"/>
	2b	All items from the World Health Organization Trial Registration Data Set <input checked="" type="checkbox"/>
Protocol version	3	Date and version identifier <input checked="" type="checkbox"/>
Funding	4	Sources and types of financial, material, and other support <input checked="" type="checkbox"/>
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors <input checked="" type="checkbox"/>
	5b	Name and contact information for the trial sponsor <input checked="" type="checkbox"/>
	5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities <input checked="" type="checkbox"/>
	5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee) <input checked="" type="checkbox"/>
Introduction		
Background and rationale	6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention <input checked="" type="checkbox"/>
	6b	Explanation for choice of comparators <input checked="" type="checkbox"/>
Objectives	7	Specific objectives or hypotheses <input checked="" type="checkbox"/>
Trial design	8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory) <input checked="" type="checkbox"/>

Methods: Participants, interventions, and outcomes

Study setting	9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained <input checked="" type="checkbox"/>
Eligibility criteria	10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists) <input checked="" type="checkbox"/>
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered <input checked="" type="checkbox"/>
	11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease) <input checked="" type="checkbox"/>
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests) <input checked="" type="checkbox"/>
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial <input checked="" type="checkbox"/>
Outcomes	12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended <input checked="" type="checkbox"/>
Participant timeline	13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure) <input checked="" type="checkbox"/>
Sample size	14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations <input checked="" type="checkbox"/>
Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size <input checked="" type="checkbox"/>

Methods: Assignment of interventions (for controlled trials)

Allocation:

Sequence generation	16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions <input checked="" type="checkbox"/>
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1			
2	Allocation	16b	Mechanism of implementing the allocation sequence (eg, central
3	concealment		telephone; sequentially numbered, opaque, sealed envelopes),
4	mechanism		describing any steps to conceal the sequence until interventions are
5			assigned <input checked="" type="checkbox"/>
6			
7	Implementation	16c	Who will generate the allocation sequence, who will enrol participants,
8			and who will assign participants to interventions <input checked="" type="checkbox"/>
9			
10	Blinding	17a	Who will be blinded after assignment to interventions (eg, trial
11	(masking)		participants, care providers, outcome assessors, data analysts), and
12			how <input checked="" type="checkbox"/>
13			
14		17b	If blinded, circumstances under which unblinding is permissible, and
15			procedure for revealing a participant's allocated intervention during
16			the trial <input checked="" type="checkbox"/>
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Methods: Data collection, management, and analysis

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21	Data collection	18a	Plans for assessment and collection of outcome, baseline, and other
22	methods		trial data, including any related processes to promote data quality (eg,
23			duplicate measurements, training of assessors) and a description of
24			study instruments (eg, questionnaires, laboratory tests) along with
25			their reliability and validity, if known. Reference to where data
26			collection forms can be found, if not in the protocol <input checked="" type="checkbox"/>
27			
28		18b	Plans to promote participant retention and complete follow-up,
29			including list of any outcome data to be collected for participants who
30			discontinue or deviate from intervention protocols <input checked="" type="checkbox"/>
31			
32	Data	19	Plans for data entry, coding, security, and storage, including any
33	management		related processes to promote data quality (eg, double data entry;
34			range checks for data values). Reference to where details of data
35			management procedures can be found, if not in the protocol <input checked="" type="checkbox"/>
36			
37	Statistical	20a	Statistical methods for analysing primary and secondary outcomes.
38	methods		Reference to where other details of the statistical analysis plan can be
39			found, if not in the protocol <input checked="" type="checkbox"/>
40			
41		20b	Methods for any additional analyses (eg, subgroup and adjusted
42			analyses) <input checked="" type="checkbox"/>
43			
44		20c	Definition of analysis population relating to protocol non-adherence
45			(eg, as randomised analysis), and any statistical methods to handle
46			missing data (eg, multiple imputation) <input checked="" type="checkbox"/>
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Methods: Monitoring

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53	Data monitoring	21a	Composition of data monitoring committee (DMC); summary of its role
54			and reporting structure; statement of whether it is independent from
55			the sponsor and competing interests; and reference to where further
56			details about its charter can be found, if not in the protocol.
57			Alternatively, an explanation of why a DMC is not needed <input checked="" type="checkbox"/>
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1		21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial <input checked="" type="checkbox"/>
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6	Harms	22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct <input checked="" type="checkbox"/>
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11	Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor <input checked="" type="checkbox"/>
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Ethics and dissemination

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17	Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval <input checked="" type="checkbox"/>
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20			
21	Protocol amendments	25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators) <input checked="" type="checkbox"/>
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26	Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32) <input checked="" type="checkbox"/>
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30		26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable <input checked="" type="checkbox"/>
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33	Confidentiality	27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial <input checked="" type="checkbox"/>
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37	Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site <input checked="" type="checkbox"/>
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41	Access to data	29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators <input checked="" type="checkbox"/>
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45	Ancillary and post-trial care	30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation <input checked="" type="checkbox"/>
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47			
48	Dissemination policy	31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions <input checked="" type="checkbox"/>
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54		31b	Authorship eligibility guidelines and any intended use of professional writers <input checked="" type="checkbox"/>
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57		31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code <input checked="" type="checkbox"/>
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Appendices

Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates
Biological specimens	33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable

*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items. Amendments to the protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT Group under the Creative Commons "[Attribution-NonCommercial-NoDerivs 3.0 Unported](#)" license.

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