CONSORT-EHEALTH (V 1.6.1) - Submission/Publication Form

The CONSORT-EHEALTH checklist is intended for authors of randomized trials evaluating web-based and Internet-based applications/interventions, including mobile interventions, electronic games (incl multiplayer games), social media, certain telehealth applications, and other interactive and/or networked electronic applications. Some of the items (e.g. all subitems under item 5 - description of the intervention) may also be applicable for other study designs.

The goal of the CONSORT EHEALTH checklist and guideline is to be

- a) a guide for reporting for authors of RCTs,
- b) to form a basis for appraisal of an ehealth trial (in terms of validity)

CONSORT-EHEALTH items/subitems are MANDATORY reporting items for studies published in the Journal of Medical Internet Research and other journals / scientific societies endorsing the checklist.

Items numbered 1., 2., 3., 4a., 4b etc are original CONSORT or CONSORT-NPT (non-pharmacologic treatment) items.

Items with Roman numerals (i., ii, iii, iv etc.) are CONSORT-EHEALTH extensions/clarifications.

As the CONSORT-EHEALTH checklist is still considered in a formative stage, we would ask that you also RATE ON A SCALE OF 1-5 how important/useful you feel each item is FOR THE PURPOSE OF THE CHECKLIST and reporting guideline (optional).

Mandatory reporting items are marked with a red *.

In the textboxes, either copy & paste the relevant sections from your manuscript into this form - please include any quotes from your manuscript in QUOTATION MARKS, or answer directly by providing additional information not in the manuscript, or elaborating on why the item was not relevant for this study.

YOUR ANSWERS WILL BE PUBLISHED AS A SUPPLEMENTARY FILE TO YOUR PUBLICATION IN JMIR AND ARE CONSIDERED PART OF YOUR PUBLICATION (IF ACCEPTED). Please fill in these questions diligently. Information will not be copyedited, so please use proper spelling and grammar, use correct capitalization, and avoid abbreviations.

DO NOT FORGET TO SAVE AS PDF _AND_ CLICK THE SUBMIT BUTTON SO YOUR ANSWERS ARE IN OUR DATABASE !!!

Citation Suggestion (if you append the pdf as Appendix we suggest to cite this paper in the caption):

Eysenbach G, CONSORT-EHEALTH Group

CONSORT-EHEALTH: Improving and Standardizing Evaluation Reports of Web-based and Mobile Health Interventions

J Med Internet Res 2011;13(4):e126

URL: http://www.jmir.org/2011/4/e126/



doi: 10.2196/jmir.1923 PMID: 22209829

* Required

Your name *

First Last

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Primary Affiliation (short), City, Country *

University of Toronto, Toronto, Canada

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Your e-mail address *

abc@gmail.com

lixinhua@chinacdc.cn

Title of your manuscript *

Provide the (draft) title of your manuscript.

Action on Salt China (ASC): rationale and design

Name of your App/Software/Intervention *

If there is a short and a long/alternate name, write the short name first and add the long name in brackets.

ASC (Action on Salt China); Note: it is a comple

Evaluated Version (if any) e.g. "V1", "Release 2017-03-01", "Version 2.0.27913"
AppSalt: V1.2.3; KnowSalt: V1.2; FoodSwitch ((
Language(s) * What language is the intervention/app in? If multiple languages are available, separate by comma (e.g. "English, French")
Chinese
URL of your Intervention Website or App e.g. a direct link to the mobile app on app in appstore (itunes, Google Play), or URL of the website. If the intervention is a DVD or hardware, you can also link to an Amazon page.
https://www.actionsaltchina.com/
URL of an image/screenshot (optional)
Your answer
Accessibility * Can an enduser access the intervention presently?
access is free and open
access only for special usergroups, not open
access is open to everyone, but requires payment/subscription/in-app purchases
app/intervention no longer accessible
Other: AppSalt is accessible only for participants in intervention group; Knowsalt is of

Primary Medical Inc	cation/Disease	/Condition *
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e.g. "Stress", "Diabetes", or define the target group in brackets after the condition, e.g. "Autism (Parents of children with)", "Alzheimers (Informal Caregivers of)"

Hypertention (the public)

Primary Outcomes measured in trial *

comma-separated list of primary outcomes reported in the trial

Salt reduction evaluated by 24-h urinary sodiur

Secondary/other outcomes

Are there any other outcomes the intervention is expected to affect?

Process evaluation, changes in knowledge, attitude and practice (KAP) on salt intake, and economic evaluation

Recommended "Dose" *

What do the instructions for users say on how often the app should be used?

- Approximately Daily
- Approximately Weekly
- Approximately Monthly
- Approximately Yearly
- as needed"
- Other: Biweekly for AppSalt, Quarterly for KnowSalt, As needed for FoodSwitch

Approx. Percentage of Users (starters) still using the app as recommended after 3 months *
unknown / not evaluated
0-10%
O 11-20%
21-30%
31-40%
41-50%
51-60%
61-70%
71%-80%
81-90%
91-100%
Other:
Overall, was the app/intervention effective? *
yes: all primary outcomes were significantly better in intervention group vs control
partly: SOME primary outcomes were significantly better in intervention group vs control
on statistically significant difference between control and intervention
outcomes potentially harmful: control was significantly better than intervention in one or more
inconclusive: more research is needed
Other: Still in the progress of evaluation. We can only give an estimation after the stage

Article Preparation Status/Stage * At which stage in your article preparation are you currently (at the time you fill in this form)	
onot submitted yet - in early draft status	
onot submitted yet - in late draft status, just before submission	
submitted to a journal but not reviewed yet	
submitted to a journal and after receiving initial reviewer comments	
submitted to a journal and accepted, but not published yet	
O published	
Other:	
Journal *	
Journal * If you already know where you will submit this paper (or if it is already submitted), please provide the journal name (if it is not JMIR, provide the journal name under "other")	
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If you already know where you will submit this paper (or if it is already submitted), please provide the journal name (if it is not JMIR, provide the journal name under "other") Onot submitted yet / unclear where I will submit this Journal of Medical Internet Research (JMIR)	
If you already know where you will submit this paper (or if it is already submitted), please provide the journal name (if it is not JMIR, provide the journal name under "other") Onot submitted yet / unclear where I will submit this Journal of Medical Internet Research (JMIR) JMIR mHealth and UHealth	
If you already know where you will submit this paper (or if it is already submitted), please provide the journal name (if it is not JMIR, provide the journal name under "other") Onot submitted yet / unclear where I will submit this Journal of Medical Internet Research (JMIR) JMIR mHealth and UHealth JMIR Serious Games	
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If you already know where you will submit this paper (or if it is already submitted), please provide the journal name (if it is not JMIR, provide the journal name under "other") Onot submitted yet / unclear where I will submit this Journal of Medical Internet Research (JMIR) JMIR mHealth and UHealth JMIR Serious Games JMIR Mental Health JMIR Public Health JMIR Formative Research	

Is this a full powered effectiveness trial or a pilot/feasibility trial? *
O Pilot/feasibility
Fully powered
Manuscript tracking number *
If this is a JMIR submission, please provide the manuscript tracking number under "other" (The ms tracking number can be found in the submission acknowledgement email, or when you login as author in JMIR. If the paper is already published in JMIR, then the ms tracking number is the four-digit number at the end of the DOI, to be found at the bottom of each published article in JMIR)
on ms number (yet) / not (yet) submitted to / published in JMIR
Other: JMU ms# 16994
TITLE AND ABSTRACT
TITLE AND ABSTRACT 1a) TITLE: Identification as a randomized trial in the title
1a) TITLE: Identification as a randomized trial in the title
 1a) TITLE: Identification as a randomized trial in the title 1a) Does your paper address CONSORT item 1a? * I.e does the title contain the phrase "Randomized Controlled Trial"? (if not, explain the reason under
 1a) TITLE: Identification as a randomized trial in the title 1a) Does your paper address CONSORT item 1a? * I.e does the title contain the phrase "Randomized Controlled Trial"? (if not, explain the reason under "other")

1a-i) Identify the mode of delivery in the title

Identify the mode of delivery. Preferably use "web-based" and/or "mobile" and/or "electronic game" in the title. Avoid ambiguous terms like "online", "virtual", "interactive". Use "Internet-based" only if Intervention includes non-web-based Internet components (e.g. email), use "computer-based" or "electronic" only if offline products are used. Use "virtual" only in the context of "virtual reality" (3-D worlds). Use "online" only in the context of "online support groups". Complement or substitute product names with broader terms for the class of products (such as "mobile" or "smart phone" instead of "iphone"), especially if the application runs on different platforms.

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Does your paper address subitem 1a-i? *

Copy and paste relevant sections from manuscript title (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

Not applicable due to the paper is outlining the overall design of ASC which is composed of several intervention packages, each of which contains electronic tools and other interventions such as training, broad education, professional/peer support, et al.

1a-ii) Non-web-based components or important co-interventions in title

Mention non-web-based components or important co-interventions in title, if any (e.g., "with telephone support").

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Does your paper address subitem 1a-ii?

Copy and paste relevant sections from manuscript title (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

No. As mentioned above, this is an overall design paper for an action which contains 6 parallel programmes

1a-iii)	Primary	condition	or target	aroup	in the	title
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Mention primary condition or target group in the title, if any (e.g., "for children with Type I Diabetes") Example: A Web-based and Mobile Intervention with Telephone Support for Children with Type I Diabetes: Randomized Controlled Trial

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Does your paper address subitem 1a-iii? *

Copy and paste relevant sections from manuscript title (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

"Action on Salt China"

1b) ABSTRACT: Structured summary of trial design, methods, results, and conclusions

NPT extension: Description of experimental treatment, comparator, care providers, centers, and blinding status.

1b-i) Key features/functionalities/components of the intervention and comparator in the METHODS section of the ABSTRACT

Mention key features/functionalities/components of the intervention and comparator in the abstract. If possible, also mention theories and principles used for designing the site. Keep in mind the needs of systematic reviewers and indexers by including important synonyms. (Note: Only report in the abstract what the main paper is reporting. If this information is missing from the main body of text, consider adding it)

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Does your paper address subitem 1b-i? *

Copy and paste relevant sections from the manuscript abstract (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

"ASC consists of six programmes working in synergy to increase salt awareness and to reduce the amount of salt used during cooking at home and in restaurants, as well as in processed foods."

1b-ii) Level of human involvement in the METHODS section of the ABSTRACT

Clarify the level of human involvement in the abstract, e.g., use phrases like "fully automated" vs. "therapist/nurse/care provider/physician-assisted" (mention number and expertise of providers involved, if any). (Note: Only report in the abstract what the main paper is reporting. If this information is missing from the main body of text, consider adding it)

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Does your paper address subitem 1b-ii?

Copy and paste relevant sections from the manuscript abstract (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

"In AIS, HIS and CIS, the primary outcome of salt reduction will be evaluated by 24-h urinary sodium excretion in more than 6030 participants, including 5436 adults and 594 students around 9 years old. In RIS, the salt reduction in restaurant-provided dishes will be measured by laboratory food analysis of the five best-selling dishes from each of the 192 restaurants."

1b-iii) Open vs. closed, web-based (self-assessment) vs. face-to-face assessments in the METHODS section of the ABSTRACT

Mention how participants were recruited (online vs. offline), e.g., from an open access website or from a clinic or a closed online user group (closed usergroup trial), and clarify if this was a purely web-based trial, or there were face-to-face components (as part of the intervention or for assessment). Clearly say if outcomes were self-assessed through questionnaires (as common in web-based trials). Note: In traditional offline trials, an open trial (open-label trial) is a type of clinical trial in which both the researchers and participants know which treatment is being administered. To avoid confusion, use "blinded" or "unblinded" to indicated the level of blinding instead of "open", as "open" in web-based trials usually refers to "open access" (i.e. participants can self-enrol). (Note: Only report in the abstract what the main paper is reporting. If this information is missing from the main body of text, consider adding it)

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Does your paper address subitem 1b-iii?

Copy and paste relevant sections from the manuscript abstract (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

"four open label cluster randomised controlled trials". "In AIS, HIS and CIS, the primary outcome of salt reduction will be evaluated by 24-h urinary sodium excretion in more than 6030 participants, including 5436 adults and 594 students around 9 years old. In RIS, the salt reduction in restaurant-provided dishes will be measured by laboratory food analysis of the five best-selling dishes from each of the 192 restaurants."

1b-iv) RESULTS section in abstract must contain use data

Report number of participants enrolled/assessed in each group, the use/uptake of the intervention (e.g., attrition/adherence metrics, use over time, number of logins etc.), in addition to primary/secondary outcomes. (Note: Only report in the abstract what the main paper is reporting. If this information is missing from the main body of text, consider adding it)

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Does your paper address subitem 1b-iv?

Copy and paste relevant sections from the manuscript abstract (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

Key data (primary outcomes and second outcomes) were mentioned: "In AIS, HIS and CIS, the primary outcome of salt reduction will be evaluated by 24-h urinary sodium excretion in more than 6030 participants, including 5436 adults and 594 students around 9 years old. In RIS, the salt reduction in restaurant-provided dishes will be measured by laboratory food analysis of the five best-selling dishes from each of the 192 restaurants." "Secondary outcomes will consist of process evaluation, changes in knowledge, attitude and practice (KAP) on salt intake, and economic evaluation." The data collection will be summarised in separate protocol of each RCT.

1b-v) CONCLUSIONS/DISCUSSION in abstract for negative trials

Conclusions/Discussions in abstract for negative trials: Discuss the primary outcome - if the trial is negative (primary outcome not changed), and the intervention was not used, discuss whether negative results are attributable to lack of uptake and discuss reasons. (Note: Only report in the abstract what the main paper is reporting. If this information is missing from the main body of text, consider adding it)

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Does your paper address subitem 1b-v?

Copy and paste relevant sections from the manuscript abstract (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

"The evaluated intervention packages and tailored components will be promoted for salt reduction in China and worldwide."

INTRODUCTION

2a) In INTRODUCTION: Scientific background and explanation of rationale

2a-i) Problem and the type of system/solution

Describe the problem and the type of system/solution that is object of the study: intended as stand-alone intervention vs. incorporated in broader health care program? Intended for a particular patient population? Goals of the intervention, e.g., being more cost-effective to other interventions, replace or complement other solutions? (Note: Details about the intervention are provided in "Methods" under 5)

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Does your paper address subitem 2a-i? *

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

"Humans only need a very small amount of salt, i.e. around 1 gram/day (g/d) to maintain physiological function.[1-3] High salt intake is the major cause of raised blood pressure (BP).[4], and the leading risk factor of total death and disability adjusted of life years in China.[5] Compelling evidence has shown that a lower salt intake is associated with a reduced risk of cardiovascular disease (CVD) and total mortality.[6, 7] Salt reduction is one of the most cost-effective measures to prevent hypertension and CVD.[4, 8] The World Health Organisation (WHO) has recommended a 30% reduction in population salt intake by 2025, and also set a target of <5 g/d for all adults and lower levels for children". "Responding to the national call for salt reduction, several regional salt reduction projects have been undertaken in various regions of China, as part of routine work in disease control and prevention system. However, none of the programmes have been properly evaluated for effectiveness and sustainability, and it is not known whether they can be rolled out across the whole country." "ASC is running two national health campaigns and four randomised controlled trials (RCTs) testing interventions on major sources of salt intake. Although the protocols and results of each RCT will be published separately, it is worthwhile to report the overall design of ASC, to help people understand its rationale and design as a whole. With this aim, the present paper will introduce ASC's overall goals and strategies, governance, proposed solutions to main challenges in salt reduction, uniformed design of intervention packages and evaluations, plan for scaling-up, as well as other ancillary work. "

2a-ii) Scientific background, rationale: What is known about the (type of) system

Scientific background, rationale: What is known about the (type of) system that is the object of the study (be sure to discuss the use of similar systems for other conditions/diagnoses, if appropiate), motivation for the study, i.e. what are the reasons for and what is the context for this specific study, from which stakeholder viewpoint is the study performed, potential impact of findings [2]. Briefly justify the choice of the comparator.

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Does your paper address subitem 2a-ii? *

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

This paper is an overall design of ACS, with the purpose like: "ASC is running two national health campaigns and four randomised controlled trials (RCTs) testing interventions on major sources of salt intake. Although the protocols and results of each RCT will be published separately, it is worthwhile to report the overall design of ASC, to help people understand its rationale and design as a whole. With this aim, the present paper will introduce ASC's overall goals and strategies, governance, proposed solutions to main challenges in salt reduction, uniformed design of intervention packages and evaluations, plan for scaling-up, as well as other ancillary work. " AS a result, the rationals have been summarised in the METHODS section, not in the background part.

2b) In INTRODUCTION: Specific objectives or hypotheses

Does your paper address CONSORT subitem 2b? *

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

"Although the protocols and results of each RCT will be published separately, it is worthwhile to report the overall design of ASC, to help people understand its rationale and design as a whole. With this aim, the present paper will introduce ASC's overall goals and strategies, governance, proposed solutions to main challenges in salt reduction, uniformed design of intervention packages and evaluations, plan for scaling-up, as well as other ancillary work. "

METHODS

3a) Description of trial design (such as parallel, factorial) including allocation ratio

Does your paper address CONSORT subitem 3a? *

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

This paper describes the overarching design of ASC. "To achieve its goal and objectives, the ASC unit developed six programmes targeting the low health literacy of the public on salt reduction and the three major sources of salt intake in China, i.e. home cooking, restaurant foods, and pre-packaged foods. Programme 1 is a salt reduction education campaign, which will form the basis of all the other programmes. Programme 2 is a primary school-based programme delivering salt reduction activities for the home of schoolchildren, based on the assumption that parents and grandparents are more likely to change their habit of high salt intake for the health of their children and grandchildren. [18, 19] Programme 3 will establish a community-level training and support system to help family chefs reduce salt use in home cooking. Programme 4 aims to create an environment in restaurants that is conducive to consumers opting for less salty foods, and to train the cooks to use less salt while cooking. Programme 5 simulates the real-world implementation of all the intervention packages or components developed in Programmes 1-4 with the purpose of identifying barriers and facilitators when scaling up. Programme 6 is a two-fold campaign with the aims of educating and supporting consumers choosing less salty food (Programme 6.1), and convincing food manufacturers to reformulate their food products by gradually reducing the amount of salt added (Programme 6.2)". Due to the space limit, we have try to summarise the key components of study design for each component RCT of ASC, but not to such a detail.

3b) Important changes to methods after trial commencement (such as eligibility criteria), with reasons

Does your paper address CONSORT subitem 3b? *

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

If approved by working group, adaption is acceptable and should be recorded, especially for those in the comprehensive intervention study (CIS). However, we did not mention this in the overall design paper, and will be clarified separately in protocol paper of each RCT.

3b-i) Bug fixes, Downtimes, Content Changes

Bug fixes, Downtimes, Content Changes: ehealth systems are often dynamic systems. A description of changes to methods therefore also includes important changes made on the intervention or comparator during the trial (e.g., major bug fixes or changes in the functionality or content) (5-iii) and other "unexpected events" that may have influenced study design such as staff changes, system failures/downtimes, etc. [2].

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Does your paper address subitem 3b-i?

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

This is an overarching design paper, does not mention this in the MS. During the implementation, the major three mHealth intervention tools (AppSalt, KnowSalt and FoodSwitch) did have several minor updates.

4a) Eligibility criteria for participants

Does your paper address CONSORT subitem 4a? *

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

Yes, but only a summary: "The study subjects are grade 3 primary school students and their parents/ grandparents (1 student and 2 adults for each family) in AIS, home cooks and their family members (1 home cook and one other adult member for each family) in HIS, and adults (1 adult from each participating family) in CIS. The participant recruitment may vary among AIS, HIS and CIS, but at least they are local residents with no plan to move within 24 months, and agree to participate in the studies. The exclusion criteria are (1) pregnant women and those in lactation period; (2) individuals who currently participates in any other clinical trials; (3) those with severe psychiatric or physical diseases that might impact intervention and follow-up; (4) individuals who are unable or not suitable to collect 24-hour urine due to the following conditions: a) aconuresis; b) acute/chronic urinary tract infection, vaginal infection and perianal infection; c) acute hemorrhagic diseases in urinary tract, vagina and digestive tract; and d) severe vomiting and diarrheic symptoms. In RIS, the study subjects are restaurants with dish salt content as primary outcome, which will be evaluated using the average sodium content of 5 best-selling dishes."

4a-i) Computer / Internet literacy

Computer / Internet literacy is often an implicit "de facto" eligibility criterion - this should be explicitly clarified.

essential subitem not at all important

Does your paper address subitem 4a-i?

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

Not to such detail in this overall design paper, to be reported in each RCT protocol.

4a-ii) Open vs. closed, web-based vs. face-to-face assessments:

Open vs. closed, web-based vs. face-to-face assessments: Mention how participants were recruited (online vs. offline), e.g., from an open access website or from a clinic, and clarify if this was a purely webbased trial, or there were face-to-face components (as part of the intervention or for assessment), i.e., to what degree got the study team to know the participant. In online-only trials, clarify if participants were quasi-anonymous and whether having multiple identities was possible or whether technical or logistical measures (e.g., cookies, email confirmation, phone calls) were used to detect/prevent these.

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Does your paper address subitem 4a-ii? *

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

"At stage 1, the different intervention packages of each of the Programmes 2-5 are evaluated with open label cluster RCTs in various settings."

4a-iii) Information giving during recruitment

Information given during recruitment. Specify how participants were briefed for recruitment and in the informed consent procedures (e.g., publish the informed consent documentation as appendix, see also item X26), as this information may have an effect on user self-selection, user expectation and may also bias results.

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Does your paper address subitem 4a-iii?

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

Only summarised like "The study subjects are grade 3 primary school students and their parents/ grandparents (1 student and 2 adults for each family) in AIS, home cooks and their family members (1 home cook and one other adult member for each family) in HIS, and adults (1 adult from each participating family) in CIS. The participant recruitment may vary among AIS, HIS and CIS, but at least they are local residents with no plan to move within 24 months, and agree to participate in the studies. The exclusion criteria are (1) pregnant women and those in lactation period; (2) individuals who currently participates in any other clinical trials; (3) those with severe psychiatric or physical diseases that might impact intervention and follow-up; (4) individuals who are unable or not suitable to collect 24-hour urine due to the following conditions: a) aconuresis; b) acute/chronic urinary tract infection, vaginal infection and perianal infection; c) acute hemorrhagic diseases in urinary tract, vagina and digestive tract; and d) severe vomiting and diarrheic symptoms. In RIS, the study subjects are restaurants with dish salt content as primary outcome, which will be evaluated using the average sodium content of 5 best-selling dishes."

4b) Settings and locations where the data were collected

Does your paper address CONSORT subitem 4b? *

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

Only summarised like "The study subjects are grade 3 primary school students and their parents/ grandparents (1 student and 2 adults for each family) in AIS, home cooks and their family members (1 home cook and one other adult member for each family) in HIS, and adults (1 adult from each participating family) in CIS. The participant recruitment may vary among AIS, HIS and CIS, but at least they are local residents with no plan to move within 24 months, and agree to participate in the studies. The exclusion criteria are (1) pregnant women and those in lactation period; (2) individuals who currently participates in any other clinical trials; (3) those with severe psychiatric or physical diseases that might impact intervention and follow-up; (4) individuals who are unable or not suitable to collect 24-hour urine due to the following conditions: a) aconuresis; b) acute/chronic urinary tract infection, vaginal infection and perianal infection; c) acute hemorrhagic diseases in urinary tract, vagina and digestive tract; and d) severe vomiting and diarrheic symptoms. In RIS, the study subjects are restaurants with dish salt content as primary outcome, which will be evaluated using the average sodium content of 5 best-selling dishes."

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4b-i) Report if outcomes	WALE (SAIT	–1266E66H	through	Online	allestionnaires
TO 1/ Neport II outcomes	WC1 C (3C11	/43363364	unougn		questionianes

Clearly report if outcomes were (self-)assessed through online questionnaires (as common in web-based trials) or otherwise.

subitem not at all important

essential

essential

Does your paper address subitem 4b-i? *

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

"Table 2 Data collection in the four randomized controlled trials in Action on Salt China (ASC) Programmes 2-5"

4b-ii) Report how institutional affiliations are displayed

Report how institutional affiliations are displayed to potential participants [on ehealth media], as affiliations with prestigious hospitals or universities may affect volunteer rates, use, and reactions with regards to an intervention. (Not a required item - describe only if this may bias results)

subitem not at all important

Does your paper address subitem 4b-ii?

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

"The governance and management structure of the ASC Unit and programmes are illustrated in Figure 1"

5) The interventions for each group with sufficient details to allow replication, including how and when they were actually administered

5-i) Mention names, credential, affiliations of the developers, sponsors, and owners

Mention names, credential, affiliations of the developers, sponsors, and owners [6] (if authors/evaluators are owners or developer of the software, this needs to be declared in a "Conflict of interest" section or mentioned elsewhere in the manuscript).

essential

subitem not at all important

Does your paper address subitem 5-i?

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

"To facilitate implementation, ASCloud, a cloud-based information system, has been designed and developed by Beihang University to support health education and promotion to the public, restaurants and the food industry, intervention delivery, and project and data management for all programmes. "

5-ii) Describe the history/development process

Describe the history/development process of the application and previous formative evaluations (e.g., focus groups, usability testing), as these will have an impact on adoption/use rates and help with interpreting results.

subitem not at all important essential

Does your paper address subitem 5-ii?

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

"This is based on our experience in delivering research projects[20], and systematic reviews on nutrition improvement[21] and salt reduction[22] using mHealth technology."

5-iii) Revisions and updating

Revisions and updating. Clearly mention the date and/or version number of the application/intervention (and comparator, if applicable) evaluated, or describe whether the intervention underwent major changes during the evaluation process, or whether the development and/or content was "frozen" during the trial. Describe dynamic components such as news feeds or changing content which may have an impact on the replicability of the intervention (for unexpected events see item 3b).

3

subitem not at all important

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essential

Does your paper address subitem 5-iii?

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

Not to such detail, but updates or revisions of mHealth tools are unavoidable.

5-iv) Quality assurance methods

Provide information on quality assurance methods to ensure accuracy and quality of information provided [1], if applicable.

subitem not at all important









essential

Does your paper address subitem 5-iv?

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

"Our study will have three major data outputs: (1) the data from the evaluation of each RCT's effectiveness (Table 2); (2) the data from the process monitoring and evaluation, which will consist of quantitative data automatically generated by smartphone applications used as intervention tools in the RCTs, as well as qualitative data collected for process evaluation; (3) the monitoring and evaluation data on the coverage and usage of the salt reduction materials and tools, which will be recorded by ASCloud during the scaling-up. Except for the routine work log and the qualitative data collected for process evaluation, most data will be collected using specially designed electronic systems including a mobile device-based electronic data capture system (mEDC) and the ASCloud server, which can capture activities such as log-in/log-out and access to certain features through different kinds of front ends, web portals and mobile applications. The mEDC has an improved process and quality control, compared with the traditional EDC, and has been validated and is widely used in other clinical trials.[20]"

5-v) Ensure replicability by publishing the source code, and/or providing screenshots/screen-capture video, and/or providing flowcharts of the algorithms used

Ensure replicability by publishing the source code, and/or providing screenshots/screen-capture video, and/or providing flowcharts of the algorithms used. Replicability (i.e., other researchers should in principle be able to replicate the study) is a hallmark of scientific reporting.

5

subitem not at all important essential

Does your paper address subitem 5-v?

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

Not mentioned because the eHealth tools are only parts of interventions for each RCT. However, the screenshots/screen and flowcharts of the algorithms could be published later, and the pathway of KnowSalt has been published (Zhang Lu, Zhao Fang, Zhang Puhong*, Gao Jianmei, Liu Caixia, He Fengjun, Lin CP. A pilot study to validate a standardized oneweek salt estimation method evaluating salt intake and its sources for family members in China. Nutrients. 2015;7(2):751-63.)

5-vi) Digital preservation

Digital preservation: Provide the URL of the application, but as the intervention is likely to change or disappear over the course of the years; also make sure the intervention is archived (Internet Archive, webcitation.org, and/or publishing the source code or screenshots/videos alongside the article). As pages behind login screens cannot be archived, consider creating demo pages which are accessible without login.

3

subitem not at all important

essential

Does your paper address subitem 5-vi?

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

Will be mentioned in the protocol papers for separate RCT.

5-vii) Access

Access: Describe how participants accessed the application, in what setting/context, if they had to pay (or were paid) or not, whether they had to be a member of specific group. If known, describe how participants obtained "access to the platform and Internet" [1]. To ensure access for editors/reviewers/readers, consider to provide a "backdoor" login account or demo mode for reviewers/readers to explore the application (also important for archiving purposes, see vi).

5

subitem not at all important essential

Does your paper address subitem 5-vii? *

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

AppSalt is only available for participants. KnowSalt and FoodSwitch are free and open in WeChat and App store.

5-viii) Mode of delivery, features/functionalities/components of the intervention
and comparator, and the theoretical framework

Describe mode of delivery, features/functionalities/components of the intervention and comparator, and the theoretical framework [6] used to design them (instructional strategy [1], behaviour change techniques, persuasive features, etc., see e.g., [7, 8] for terminology). This includes an in-depth description of the content (including where it is coming from and who developed it) [1]," whether [and how] it is tailored to individual circumstances and allows users to track their progress and receive feedback" [6]. This also includes a description of communication delivery channels and - if computermediated communication is a component - whether communication was synchronous or asynchronous [6]. It also includes information on presentation strategies [1], including page design principles, average amount of text on pages, presence of hyperlinks to other resources, etc. [1].

subitem not at all important essential

Does your paper address subitem 5-viii? *

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

"The key features of the six programmes of ASC at stage 1, including the theories and key intervention components of the four RCTs (Programme 2-5 at stage 1), are summarised in Table 1"

5-ix) Describe use parameters

Describe use parameters (e.g., intended "doses" and optimal timing for use). Clarify what instructions or recommendations were given to the user, e.g., regarding timing, frequency, heaviness of use, if any, or was the intervention used ad libitum.

subitem not at all important essential

Does your paper address subitem 5-ix?

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

Details have been embedded in the Apps, not included in the overarching design paper. Will include these in a paper describing the Apps.

5-x) Clarify the level of human involvement

Clarify the level of human involvement (care providers or health professionals, also technical assistance) in the e-intervention or as co-intervention (detail number and expertise of professionals involved, if any, as well as "type of assistance offered, the timing and frequency of the support, how it is initiated, and the medium by which the assistance is delivered". It may be necessary to distinguish between the level of human involvement required for the trial, and the level of human involvement required for a routine application outside of a RCT setting (discuss under item 21 - generalizability).

subitem not at all important

essential

Does your paper address subitem 5-x?

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

"the ASC unit developed six programmes targeting the low health literacy of the public on salt reduction and the three major sources of salt intake in China, i.e. home cooking, restaurant foods, and pre-packaged foods. Programme 1 is a salt reduction education campaign, which will form the basis of all the other programmes. Programme 2 is a primary school-based programme delivering salt reduction activities for the home of schoolchildren, based on the assumption that parents and grandparents are more likely to change their habit of high salt intake for the health of their children and grandchildren. [18, 19] Programme 3 will establish a community-level training and support system to help family chefs reduce salt use in home cooking. Programme 4 aims to create an environment in restaurants that is conducive to consumers opting for less salty foods, and to train the cooks to use less salt while cooking. Programme 5 simulates the real-world implementation of all the intervention packages or components developed in Programmes 1-4 with the purpose of identifying barriers and facilitators when scaling up. Programme 6 is a two-fold campaign with the aims of educating and supporting consumers choosing less salty food (Programme 6.1), and convincing food manufacturers to reformulate their food products by gradually reducing the amount of salt added (Programme 6.2). " Details for each RCT will be published separately.

5-xi) Report any prompts/reminders used

Report any prompts/reminders used: Clarify if there were prompts (letters, emails, phone calls, SMS) to use the application, what triggered them, frequency etc. It may be necessary to distinguish between the level of prompts/reminders required for the trial, and the level of prompts/reminders for a routine application outside of a RCT setting (discuss under item 21 - generalizability).

5

subitem not at all important

essential

Does your paper address subitem 5-xi? *

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

This needs big space to describe for each of Apps. Will address this in separate protocols.

5-xii) Describe any co-interventions (incl. training/support)

Describe any co-interventions (incl. training/support): Clearly state any interventions that are provided in addition to the targeted eHealth intervention, as ehealth intervention may not be designed as stand-alone intervention. This includes training sessions and support [1]. It may be necessary to distinguish between the level of training required for the trial, and the level of training for a routine application outside of a RCT setting (discuss under item 21 – generalizability.

subitem not at all important

essential

Does your paper address subitem 5-xii? *

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

"The key features of the six programmes of ASC at stage 1, including the theories and key intervention components of the four RCTs (Programme 2-5 at stage 1), are summarised in Table 1. "

6a) Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed

Does your paper address CONSORT subitem 6a? *

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

"The evaluation of the effectiveness or impact of the proposed interventions has been specially designed for each programme. In all RCTs, the one-year effectiveness of the intervention will be assessed by comparing the salt reduction achieved between the intervention and control arms between baseline and the end of stage 1, and the sustained effectiveness over the following year will be assessed by comparing the salt reduction achieved between the intervention and control arms of AIS. HIS and CIS between baseline and the end of stage 2. Figure 3 shows the design and evaluation of primary outcomes for RCTs in Programmes 2-5. Secondary outcomes will consist of process evaluation, changes in KAP on salt intake, and economic evaluation. Overall KAP on salt, and overall salt intake levels will also be estimated by pooling the data collected in AIS, HIS and CIS at baseline, at the end of stage 1 and at the end of stage 2."

6a-i) Online questionnaires: describe if they were validated for online use and apply CHERRIES items to describe how the questionnaires were designed/deployed

If outcomes were obtained through online questionnaires, describe if they were validated for online use and apply CHERRIES items to describe how the questionnaires were designed/deployed [9].

subitem not at all important essential

Does your paper address subitem 6a-i?

Copy and paste relevant sections from manuscript text

"The mEDC has an improved process and quality control, compared with the traditional EDC, and has been validated and is widely used in other clinical trials.[20, 23]" Ref 23 is the CHERRIES check list

6a-ii) Describe whether and how "use" (including intensity of use/dosage) was defined/measured/monitored

Describe whether and how "use" (including intensity of use/dosage) was defined/measured/monitored (logins, logfile analysis, etc.). Use/adoption metrics are important process outcomes that should be reported in any ehealth trial.

subitem not at all important

essential

Does your paper address subitem 6a-ii?

Copy and paste relevant sections from manuscript text

As an overall design, not to such detail, will be defined in separate protocol papers if needed.

6a-iii) Describe whether, how, and when qualitative feedback from participants was obtained

Describe whether, how, and when qualitative feedback from participants was obtained (e.g., through emails, feedback forms, interviews, focus groups).

> 3 5

subitem not at all important essential

Does your paper address subitem 6a-iii?

Copy and paste relevant sections from manuscript text

"Our study will have three major data outputs: (1) the data from the evaluation of each RCT's effectiveness (Table 2); (2) the data from the process monitoring and evaluation, which will consist of quantitative data automatically generated by smartphone applications used as intervention tools in the RCTs, as well as qualitative data collected for process evaluation; (3) the monitoring and evaluation data on the coverage and usage of the salt reduction materials and tools, which will be recorded by ASCloud during the scaling-up. " The design of process evaluation will be described separately for each RCT.

6b) Any changes to trial outcomes after the trial commenced, with reasons

Does your paper address CONSORT subitem 6b? *

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

No changes to be allowed.

7a) How sample size was determined

NPT: When applicable, details of whether and how the clustering by care provides or centers was addressed

7a-i) Describe whether and how expected attrition was taken into account when calculating the sample size

Describe whether and how expected attrition was taken into account when calculating the sample size.

subitem not at all important

essential

Does your paper address subitem 7a-i?

Copy and paste relevant sections from manuscript title (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

As explained in the RESPONSE to the reviewers, this is an overarching design paper, have no space to illustrate the sample size calculation for each of the 4 RCTs. But the sample sizes have been summarised in Figure 3: "Figure 3 shows the design, sample size and evaluation of primary outcomes for RCTs in Programmes 2-5. "

7b) When applicable, explanation of any interim analyses and stopping guidelines

Does your paper address CONSORT subitem 7b? *

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

No such plan

8a) Method used to generate the random allocation sequence

NPT: When applicable, how care providers were allocated to each trial group

Does your paper address CONSORT subitem 8a? *

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

As stated "Separate protocols for each of the four RCTs describing study setting and participants, randomisation, intervention, sample size calculation, outcomes, and data collection and analysis, will be published before the end of stage 1"

8b) Type of randomisation; details of any restriction (such as blocking and block size)

Does your paper address CONSORT subitem 8b? *

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

As stated "Separate protocols for each of the four RCTs describing study setting and participants, randomisation, intervention, sample size calculation, outcomes, and data collection and analysis, will be published before the end of stage 1".

9) Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned

Does your paper address CONSORT subitem 9? *

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

As stated "Separate protocols for each of the four RCTs describing study setting and participants, randomisation, intervention, sample size calculation, outcomes, and data collection and analysis, will be published before the end of stage 1"

10) Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions

Does your paper address CONSORT subitem 10? *

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

As stated "Separate protocols for each of the four RCTs describing study setting and participants, randomisation, intervention, sample size calculation, outcomes, and data collection and analysis, will be published before the end of stage 1"

11a) If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how

NPT: Whether or not administering co-interventions were blinded to group assignment

11a-i) Specify who was blinded, and who wasn't

Specify who was blinded, and who wasn't. Usually, in web-based trials it is not possible to blind the participants [1, 3] (this should be clearly acknowledged), but it may be possible to blind outcome assessors, those doing data analysis or those administering co-interventions (if any).

5

subitem not at all important

essential

Does your paper address subitem 11a-i? *

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

"Statisticians will be blinded for the intervention assignments during data analysis."

11a-ii) Discuss e.g., whether participants knew which intervention was the "intervention of interest" and which one was the "comparator"

Informed consent procedures (4a-ii) can create biases and certain expectations - discuss e.g., whether participants knew which intervention was the "intervention of interest" and which one was the "comparator".

subitem not at all important

essential

Does your paper address subitem 11a-ii?

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

This is an overall design containing 2 campaigns and 4 RCTs. We did not describe this in the manuscript. Considering "open label cluster RCTs", all the subjects should know the intervention assignment.

11b) If relevant, description of the similarity of interventions

(this item is usually not relevant for ehealth trials as it refers to similarity of a placebo or sham intervention to a active medication/intervention)

Does your paper address CONSORT subitem 11b? *

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

Will be described in separate RCT protocols

12a) Statistical methods used to compare groups for primary and secondary outcomes

NPT: When applicable, details of whether and how the clustering by care providers or centers was addressed

Does your paper address CONSORT subitem 12a? *

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

The preliminary formula have been illustrated in Figure 3, as "effectiveness Figure 3 shows the design, sample size and evaluation of primary outcomes for RCTs in Programmes 2-5. "

12a-i) Imputation techniques to deal with attrition / missing values

Imputation techniques to deal with attrition / missing values: Not all participants will use the intervention/comparator as intended and attrition is typically high in ehealth trials. Specify how participants who did not use the application or dropped out from the trial were treated in the statistical analysis (a complete case analysis is strongly discouraged, and simple imputation techniques such as LOCF may also be problematic [4]).

subitem not at all important

essential

Does your paper address subitem 12a-i? *

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

Will be described in separate protocol paper for each RCT

12b) Methods for additional analyses, such as subgroup analyses and adjusted analyses

Does your paper address CONSORT subitem 12b? *

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

Will be described in separate protocol paper for each RCT

X26) REB/IRB Approval and Ethical Considerations [recommended as subheading under "Methods"] (not a CONSORT item)

X26-i) Comment on ethics committee approve	:6-i) Com	ment on	ethics	committee	approva
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subitem not at all important

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essential

Does your paper address subitem X26-i?

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

"All trials have been approved by Queen Mary Research Ethics Committee in the UK (QMERC2018/13 for the Application-based Intervention Study (AIS), QMERC2018/15 for the Housewife-based Intervention study (HIS), QMERC2018/16 for Comprehensive Intervention Study (CIS), and QMERC2018/14 for the Restaurant-based Intervention Study (RIS)) and the Institutional Review Boards of China including Peking University (IRB00001052-18051 for AIS), Chinese Center for Disease Control and Prevention (No. 201801 for HIS), National Center for Chronic and Noncommunicable Disease Control and Prevention, China CDC (No. 201807 for CIS) and National Institute for Nutrition and Health, China CDC (20180314 for RIS). "

x26-ii) Outline informed consent procedures

Outline informed consent procedures e.g., if consent was obtained offline or online (how? Checkbox, etc.?), and what information was provided (see 4a-ii). See [6] for some items to be included in informed consent documents.

subitem not at all important

Does your paper address subitem X26-ii?

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

"Written consents have been obtained from all participants according to well-established practices. For children, participant assent and parental written consent have been obtained.

X26-iii) Safety and security procedures

Safety and security procedures, incl. privacy considerations, and any steps taken to reduce the likelihood or detection of harm (e.g., education and training, availability of a hotline)

subitem not at all important

essential

essential

Does your paper address subitem X26-iii?

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

This is a behavior change intervention on salt reduction. It is safe but also noted that "All participants are free to discontinue their participation at any time with no explanation required."

RESULTS

13a) For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome

NPT: The number of care providers or centers performing the intervention in each group and the number of patients treated by each care provider in each center

Does your paper address CONSORT subitem 13a? *

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

"Intention to treat approach will be adopted when the primary outcomes are analysed."

13b) For each group, losses and exclusions after randomisation, together with reasons

Does your paper address CONSORT subitem 13b? (NOTE: Preferably, this is shown in a CONSORT flow diagram) *

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

Not applicable because this is an overall design of a Unit programme which contains 6 subprogrammes. Details will be published separately.

13b-i) Attrition diagram

Strongly recommended: An attrition diagram (e.g., proportion of participants still logging in or using the intervention/comparator in each group plotted over time, similar to a survival curve) or other figures or tables demonstrating usage/dose/engagement.

2 3

subitem not at all important

Does your paper address subitem 13b-i?

Copy and paste relevant sections from the manuscript or cite the figure number if applicable (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

Not applicable because this is an overall design of a Unit programme which contains 6 subprogrammes. Details will be published separately.

14a) Dates defining the periods of recruitment and follow-up

Does your paper address CONSORT subitem 14a? *

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

Not applicable because this is an overall design of a Unit programme which contains 6 subprogrammes. Details will be published separately, but as a summary, noted "The duration of ASC is from 1st June 2017 to 31st March 2021, with 31st March 2020 as the split point for stage 1 and stage 2. The preparation of the four RCTs and their baseline investigations have been completed by the end of March 2019. Protocols of the intervention packages or intervention components that proved to be effective at stage 1 will be made available and scaled up by combining them into the existing national initiative such as Healthy Lifestyle Campaign for All[25] for stage 2. The status of all ASC programmes are summarised in Table 3. "

14a-i) Indicate if critical "secular events" fell into the study period

Indicate if critical "secular events" fell into the study period, e.g., significant changes in Internet resources available or "changes in computer hardware or Internet delivery resources"

	1	2	3	4	5	
subitem not at all important	0	0	•	0	0	essential

Does your paper address subitem 14a-i?

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

Not applicable because this is an overall design of a Unit programme which contains 6 subprogrammes. Details may be published separately, but it seems too detailed

14b) Why the trial ended or was stopped (early)

Does your paper address CONSORT subitem 14b? *

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

Not relevant because salt reduction is safe

15) A table showing baseline demographic and clinical characteristics for each group

NPT: When applicable, a description of care providers (case volume, qualification, expertise, etc.) and centers (volume) in each group

Does your paper address CONSORT subitem 15? *

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

Not applicable for this overall design paper, and the data are still not ready to be published.

15-i) Report demographics associated with digital divide issues

In ehealth trials it is particularly important to report demographics associated with digital divide issues, such as age, education, gender, social-economic status, computer/Internet/ehealth literacy of the participants, if known.

1 2 3 4 5

subitem not at all important

essential

Does your paper address subitem 15-i? *

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

Not applicable at present.

16) For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups

16-i) Report multiple "denominators" and provide definitions

Report multiple "denominators" and provide definitions: Report N's (and effect sizes) "across a range of study participation [and use] thresholds" [1], e.g., N exposed, N consented, N used more than x times, N used more than y weeks, N participants "used" the intervention/comparator at specific pre-defined time points of interest (in absolute and relative numbers per group). Always clearly define "use" of the intervention.

1 2 3 4 5

Does your paper address subitem 16-i? *

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

Not applicable because this is an overall design of a Unit programme which contains 6 sub-programmes. Details may be published separately in the analysis plan for each RCT

16-ii) Primary analysis should be intent-to-treat

Primary analysis should be intent-to-treat, secondary analyses could include comparing only "users", with the appropriate caveats that this is no longer a randomized sample (see 18-i).

subitem not at all important

essential

Does your paper address subitem 16-ii?

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

"Intention to treat approach will be adopted when the primary outcomes are analysed."

17a) For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)

Does your paper address CONSORT subitem 17a? *

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

Not applicable because this is an overall design of a Unit programme which contains 6 subprogrammes. Details may be published separately in the analysis plan for each RCT.

17a-i) Presentation of process outcomes such as metrics of use and intensity of use

In addition to primary/secondary (clinical) outcomes, the presentation of process outcomes such as metrics of use and intensity of use (dose, exposure) and their operational definitions is critical. This does not only refer to metrics of attrition (13-b) (often a binary variable), but also to more continuous exposure metrics such as "average session length". These must be accompanied by a technical description how a metric like a "session" is defined (e.g., timeout after idle time) [1] (report under item 6a).

subitem not at all important

essential

Does your paper address subitem 17a-i?

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

App use is not the key areas in the overall design paper. This will be described in statistical analysis plan for each RCT.

17b) For binary outcomes, presentation of both absolute and relative effect sizes is recommended

Does your paper address CONSORT subitem 17b? *

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

This is not applicable for the overall design paper. This will be described in statistical analysis plan for each RCT.

18) Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory

Does your paper address CONSORT subitem 18? *

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

This is not applicable for the overall design paper. This will be described in statistical analysis plan for each RCT.

18-i) Subgroup analysis of comparing only users

A subgroup analysis of comparing only users is not uncommon in ehealth trials, but if done, it must be stressed that this is a self-selected sample and no longer an unbiased sample from a randomized trial (see 16-iii).

subitem not at all important

essential

Does your paper address subitem 18-i?

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

This is not applicable for the overall design paper. This will be described in statistical analysis plan for each RCT.

19) All important harms or unintended effects in each group

(for specific guidance see CONSORT for harms)

Does your paper address CONSORT subitem 19? *

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

Not that important for salt reduction projects.

19-i) Include privacy breaches, technical problems

Include privacy breaches, technical problems. This does not only include physical "harm" to participants, but also incidents such as perceived or real privacy breaches [1], technical problems, and other unexpected/unintended incidents. "Unintended effects" also includes unintended positive effects [2].

5

subitem not at all important

essential

Does your paper address subitem 19-i?

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

This is not applicable for the overall design paper, will be described in App development or protocol paper for each RCT.

19-ii) Include qualitative feedback from participants or observations from staff/researchers

Include qualitative feedback from participants or observations from staff/researchers, if available, on strengths and shortcomings of the application, especially if they point to unintended/unexpected effects or uses. This includes (if available) reasons for why people did or did not use the application as intended by the developers.

3

subitem not at all important

Does your paper address subitem 19-ii?

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

"Our study will have three major data outputs: (1) the data from the evaluation of each RCT's effectiveness (Table 2); (2) the data from the process monitoring and evaluation, which will consist of quantitative data automatically generated by smartphone applications used as intervention tools in the RCTs, as well as qualitative data collected for process evaluation; (3) the monitoring and evaluation data on the coverage and usage of the salt reduction materials and tools, which will be recorded by ASCloud during the scaling-up. "

DISCUSSION

22) Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence

NPT: In addition, take into account the choice of the comparator, lack of or partial blinding, and unequal expertise of care providers or centers in each group

22-i) Restate study questions and summarize the answers suggested by the data, starting with primary outcomes and process outcomes (use)

Restate study questions and summarize the answers suggested by the data, starting with primary outcomes and process outcomes (use).

1	2	3	4	5

subitem not at all important

Does your paper address subitem 22-i? *

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

"As a unit, the six programmes of ASC will provide a set of novel approaches to reduce salt intake in China. The expected outputs of ASC include: (1) several evidence-based intervention packages addressing major sources of salt intake; (2) evidence-based salt reduction strategies and experience on policy advocacy and scaling-up in different regions and populations; and (3) study reports and publications to highlight the gaps, needs, barriers and facilitators, and strategies in salt reduction among different populations."

22-ii) Highlight unanswered new questions, suggest future research	
Highlight unanswered new questions, suggest future research.	

1 2 3 4

subitem not at all important

essential

Does your paper address subitem 22-ii?

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

"During trial and scale-up, the effectiveness of health education on salt reduction should be designed in advance, which will be helpful to identify which components are most effective."

20) Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses

20-i) Typical limitations in ehealth trials

Typical limitations in ehealth trials: Participants in ehealth trials are rarely blinded. Ehealth trials often look at a multiplicity of outcomes, increasing risk for a Type I error. Discuss biases due to non-use of the intervention/usability issues, biases through informed consent procedures, unexpected events.

subitem not at all important

Does your paper address subitem 20-i? *

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

The overall design has no space to discuss the limitation of the Apps. More details could be discussed on the features/functions of the eHealth tools as well as their limitations. probable in papers describing the protocol or intervention for each RCT.

21) Generalisability (external validity, applicability) of the trial findings

NPT: External validity of the trial findings according to the intervention, comparators, patients, and care providers or centers involved in the trial

21-i) Generalizability to other populations

Generalizability to other populations: In particular, discuss generalizability to a general Internet population, outside of a RCT setting, and general patient population, including applicability of the study results for other organizations

3

subitem not at all important

essential

Does your paper address subitem 21-i?

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

"If the programme is implemented and sustained across China, it will reduce population salt intake and thereby prevent hundreds of thousands of strokes, heart attacks and heart failure each year, and lead to major cost-savings to individuals, their families and the health service."

21-ii) Discuss if there were elements in the RCT that would be different in a routine application setting

Discuss if there were elements in the RCT that would be different in a routine application setting (e.g., prompts/reminders, more human involvement, training sessions or other co-interventions) and what impact the omission of these elements could have on use, adoption, or outcomes if the intervention is applied outside of a RCT setting.

essential subitem not at all important

Does your paper address subitem 21-ii?

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

The overall design has no space to discuss the limitation of the Apps. More details could be discussed on the features/functions of the eHealth tools as well as their limitations, probable in papers describing the protocol or intervention for each RCT.

OTHER INFORMATION

23) Registration number and name of trial registry

Does your paper address CONSORT subitem 23? *

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

"TRIAL REGISTRATION: Registered on Chinese Clinical Trial Registry. AIS: ChiCTR1800017553; HIS: ChiCTR1800016804; RIS: ChiCTR1800019694; CIS: ChiCTR1800018119."

24) Where the full trial protocol can be accessed, if available

Does your paper address CONSORT subitem 24? *

Cite a Multimedia Appendix, other reference, or copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

Partially from "AIS: ChiCTR1800017553; HIS: ChiCTR1800016804; RIS: ChiCTR1800019694; CIS: ChiCTR1800018119."

25) Sources of funding and other support (such as supply of drugs), role of funders

Does your paper address CONSORT subitem 25? *

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

"FUNDING: UK NIHR with project number 16/136/77"

X27) Conflicts of Interest (not a CONSORT item)

X27-i) State the relation of the study team towards the system being evaluated

In addition to the usual declaration of interests (financial or otherwise), also state the relation of the study team towards the system being evaluated, i.e., state if the authors/evaluators are distinct from or identical with the developers/sponsors of the intervention.

subitem not at all important

essential

Does your paper address subitem X27-i?

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

"To facilitate implementation, ASCloud, a cloud-based information system, has been designed and developed by Beihang University to support health education and promotion to the public, restaurants and the food industry, intervention delivery, and project and data management for all programmes"

About the CONSORT EHEALTH checklist

As a result of using this checklist, did you make changes in your manuscript? *

yes, major changes

yes, minor changes

What were the most important changes you made as a result of using this checklist?

Participants and discussion

How much time did you spend on going through the checklist INCLUDING making changes in your manuscript *				
10 hours				
As a result of using this checklist, do you think your manuscript has improved? *				
yes				
O no				
Other:				
Would you like to become involved in the CONSORT EHEALTH group? This would involve for example becoming involved in participating in a workshop and writing an "Explanation and Elaboration" document				
O yes				
o no				
Other:				
Any other comments or questions on CONSORT EHEALTH				
No				
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