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Protocol for the implementation and evaluation of a community-based behavior change intervention to reduce dietary salt intake in India

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Abstract

Excess dietary salt intake is well established as a leading cause of high blood pressure and associated cardiovascular disease, yet current salt intake in India is nearly 11 g per day, more than twice World Health Organization maximum recommended intake of 5 g per day. Although dietary survey data from India indicate that the main sources of dietary salt are salt added during cooking at home, and few salt reduction efforts have focused on interventions at the household level. As a result, there is little evidence of the effectiveness of behavior change programs to reduce salt intake at the household level. The study aims to develop and implement a community based behavioral change intervention to reduce salt intake delivered by front line community-based health volunteers; and evaluate the preliminary effectiveness, acceptability, and feasibility of delivering a salt reduction behavior change program and potential to support future scale-up. The study is a pre-post intervention design, and outcomes will be evaluated from a random sample of 1500 participants from 28 villages in two primary health centers in Siddipet, Telangana. Primary outcome is change in salt-related KAB (knowledge, attitude, and behavior) score, and secondary outcomes will be changes in salt intake measured by 24 h urinary sodium excretion and change in scores using the subscales of the COM-B ("capability", "opportunity", "motivation" and "behavior") tool. Findings will be used to inform future public health policies to support implementation of scalable community-based interventions to reduce salt intake and control hypertension, the leading-cause of death in India.

KEYWORDS
behavior change intervention, blood pressure, community-based health volunteers, dietary sodium reduction, home cooking

1 | INTRODUCTION

Excess sodium intake is strongly associated with high blood pressure, a leading risk factor for cardiovascular disease (CVD) in India.[1–3] The available evidence shows a strong relationship between the amount of salt consumed and raised levels of blood pressure.[4] High dietary salt consumption has been reported as the seventh leading cause of mortality worldwide, resulting in an estimated 1.89 million deaths each year.[5]

Recent research in India reported that average population salt intake was around 11 g salt per day, which is more than twice the amount recommended by the World Health Organization (WHO).[6] More than 80% of dietary salt consumed in India is either added during cooking or at the table.[7] In addition, there has been an increase in the consumption of processed, packaged foods high in salt content. This is due to their increased availability in both rural and urban areas, including small shops and larger supermarkets.[8] All key stakeholders, including government and policy makers, agree on the importance of reducing population salt intake and the urgent need for a national salt reduction program in India.[9] However, there has been very little action on population-level salt reduction, largely due to lack of evidence on which population approaches would work, particularly to reduce sodium in home cooked foods.

A global review of behavior change interventions to reduce population salt intake found that, from 22 studies, only four were conducted in low and middle-income countries.[10] Of these, none were representative of South Asian populations whose dietary patterns are heavily influenced by the cultural and familial context.[11] Evidence of effectiveness of population-level behavior change interventions in reducing salt intake and improving salt-related behaviors is varied.[10] Studies using an objective measurement of salt intake, such as 24 h urinary sodium excretion, were limited and of these, only 50% found significant reduction in salt intake or improvement in salt lowering behaviors. Therefore, behavioral interventions, which are tailored to a specific community context and implemented through existing health systems using objective measurements for salt intake, will provide crucial evidence to support implementation of salt reduction strategies.

Behavior change studies focused on implementing healthcare management programs for Indians with type II diabetes highlight the importance of family relationships in affecting dietary behavior.[12] Meal planning and cooking for the family impacts the levels of salt and other ingredients added during meal preparation.[13] As such, dietary behavior change interventions have to be culturally adapted to target different family members to improve diets.[11]

There is limited evidence on the effect of targeted behavioral change interventions at the household level in the Indian context, despite the urgent need to address salt-related non-communicable diseases (NCDs).[14] This protocol paper outlines how this study will utilize the Government appointed front-line community-based health volunteers also known as Accredited Social Health Activists (ASHAs) to deliver the community-based salt reduction intervention in households. The protocol should assist others interested in designing complex community-based interventions to reduce salt intake. The results of the study will be used to support strategies to gradually reduce salt consumption in India to realize the goal of decreasing premature mortality from NCDs by 30% by 2025.

2 | METHODS

2.1 | Aims

The overarching aims of this study are to: develop and test a community based behavioral change intervention focused on salt reduction in households through community health volunteers (accredited social health activists, ASHAs); evaluate the preliminary effectiveness, acceptability, and feasibility of delivering a salt reduction behavior change program, including economic analysis of the intervention, and potential for scale up.

2.2 | Study design

This study is a pre-post intervention design involves a baseline assessment, followed by community-wide intervention implementation, and then an end of study assessment to evaluate intervention effectiveness (as shown in Table 1). The trial is registered on Clinical Trials Registry of India, with the registration number CTRI/2020/06/025591. Registration date: June 4, 2020.

2.3 | Study sites

The study will be conducted in selected villages (total–28) from two Primary Health Care Centers (PHCs) in the Siddipet district of Telangana, India. The selected villages include all villages ($n = 14$) under PHC Pullur and randomly selected 14 villages from 28 villages under PHC Rajagopalpet.

2.4 Outcome measures

The primary outcome is change in self-reported salt related knowledge, attitude, and behavior (KAB) score. An overall score is created from summing the individual items (Likert-scale format) in the KAB questionnaire. Secondary outcomes are change in subscales of the COM-B ("capability", "opportunity", "motivation", and "behavior") score (eg, Do you know how to cook tasty dishes with less salt?), which measure the socio-psychological behavior towards reduction of salt for each target group (household cooks, decision-makers and general (other)) at household level; and change in salt intake level measured by 24 h urinary sodium excretion.

TABLE 1 Schedule of community-based behavior change intervention for salt reduction

	Baseline assessment	Intervention	End of assessment
Total months	6	6	6
Informed consent	X		X
Demographics data collection	X		X
NCD risk factors	X		X
Disease history	X		X
Medication use	X		X
Blood pressure	X		X
Anthropometric measurements[a]	X		X
Training of ASHA[b]	X		
Key behavioral messages on sodium reduction-Poster 1, 2, 3		X	
Salt reduction themed videos 1 and 2		X	
Collect 24-h urine sample	X		X
Collect Spot-urine sample	X		X
Knowledge, attitude, and behavior survey	X		X
Socio-psychological determinants of salt-related behaviors	X		X

[a]Weight, height measurements.
[b]ASHA, Accredited Social Health Activists.

2.4 | Selection criteria for recruitment of participants

The village head, panchayat and other elders will be informed about the study and their approval will be sought before finalizing a village. Individuals will be eligible to participate if they are aged ≥18 years and have been residing in the selected villages for more than 6 months. Individuals with known kidney disease and their family members will be excluded from the study.

2.5 | Recruitment of participants

Before the baseline data collection begins, village mapping and household listing, including information about the age and sex of all inhabitants and the role of each member in the household, will be collected and compiled for each village. Recruitment of participants will be done using stratified random sampling to recruit individuals from the selected twenty-eight (n = 28) study villages. Sample selection will ensure that there are equal numbers of participants from each age and sex group from individual villages. Participants will be randomly selected for three target household groups: household cooks, decision-makers and general (other) household members and stratified according to sex and two age groups (18–44 and >44). However, given the social structure in these rural communities, it is expected that many household cooks will be women and decision-makers will be men.

After selection of an eligible participant from one household, the participant will be asked to sign a participant information and consent form. A participant identification number will be assigned using an android smartphone application for baseline and follow up data collection. The data will be uploaded and managed on a secure server. The process of selection of study participants will continue until the required quota is filled: 500 household cooks; 500 decision makers; and 500 general (other) household members. In the endline survey, the same villages will be sampled for three target groups with the same approach as the baseline survey.

2.6 | Data collection

Data collection will be conducted by trained field interviewers based on previous well-established and acceptable methods. These methods have been used successfully in previous research undertaken in the area.[15,16] All materials including electronic questionnaires, consent forms, information sheets, and instructions for urine collection will be translated into Telugu, which is the regional language of Telangana. Demographic data will include questions relating to age, education level, sex, employment, NCD risk factors, and history of the disease. Anthropometric data will be collected, including recording of weight, height, blood pressure, and measurement of sodium and potassium levels by 24 h urine, and spot urine samples. Weight will be measured in kilograms to the nearest 100 g using digital bathroom scales (Dr. Gene Health & Wellness) on a flat surface and height will be measured in centimeters to the nearest millimeter using a stadiometer.[17] An automated BP monitor (A&D Company Limited Kitamoto-shi, UA-767 PBT)[18] will be used to measure blood pressure, according to established standardized methods, in millimeters of mercury (mmHg).[19] Three measurements will be performed on the participant's left arm with an interval of 1 min between each measurement. Final blood pressure will be calculated as an average of the second and third measurements.

Twenty-four hour and spot urine samples will be obtained from 500 general (other) household participants in two age and two sex groups until each stratum is complete, in baseline and after 6 months of intervention. Selected participants will be provided with a 24 h urine collection kit also including a 100 ml container. During the morning of the 24 h collection, participants will be asked to collect a spot urine sample into the 100 ml container provided. They will be asked to discard the first void of urine collected in the morning, and then begin collection with the following urine onwards for the next 24 h, including the first urine of the following morning. Urine collected will be stored in a 5-L clean nonmetal container without preservatives and will be stored in a cool, dry area, with the lid on tight. Urine samples will be collected by field researchers within 24 h of completion and will then be transferred to a local laboratory where the volume of both the spot and 24 h urine sample will be measured and aliquots will be drawn for

assay. Urinary sodium, potassium and creatinine will be measured for both the samples. Urinary sodium and potassium will be determined using the ion selective electrode method on electrolyte analyzer (XI-921) and reagents from Caretium, Shenzhen, China. Urinary creatinine will be measured by the Jaffe method using an autoanalyzer (C 311) with reagents from Roche Diagnostics, Switzerland. Urinary control from RANDOX will be used as internal quality control.

For each target group, socio-psychological determinants of salt-related behaviors will be assessed using a self-reported questionnaire including questions related to knowledge, attitudes and behaviors (KAB) (Appendix A), and the constructs of the COM-B model of behavior change: "capability", "opportunity", and "motivation".[20] The COM-B lies at the center of the Behavior Change Wheel (BCW), which was developed, not only to aid intervention design, but also to improve the process of intervention evaluation. It provides a systematic way of characterizing interventions that enable their outcomes to be linked to mechanisms of action, and it can help to diagnose why an intervention may have failed to achieve its desired goal. The questionnaire was translated to Telugu and undertook complete validation procedure.

2.7 | Community based salt reduction intervention

Intervention materials and measurement tools have been designed with the goal to gradually reduce the amount of salt added, during cooking and at the table while eating, for three target groups. The COM-B model was used as an underpinning theoretical framework based on its ability to successfully predict health behaviors,[20] such as reduction of salt intake in diets, that comes mainly from home cooking. This framework captures a range of mechanisms that may be involved in change, including those that are internal (psychological and physical) and those that are external, involving changes to the environment.

Intervention materials were developed through a design sprint process that involved validating ideas through design, prototyping, and testing with users as part of pre-intervention phase. This process helped to develop and test messages targeting key behaviors and produce a change package for the intervention. The intervention is multi-level and focuses on individuals and families at the household level, and key influencers in the villages at the community level. The intervention materials consist of communication and education materials including videos, posters and community meetings which have been designed to increase capability, motivation, and opportunity among the participants of the study. All materials have been developed in English and translated into Telugu, the spoken regional and official language in Telangana. The intervention will be delivered by ASHAs, across a 6-month period, integrating salt reduction messages into the existing health programs related to NCD prevention and therefore aligning salt reduction initiatives through State Government's existing health care systems.

Training for the ASHAs will be focused on key behavioral messages (posters, videos, and face to face household visits) which they will deliver in four separate settings to influence individuals at the household and community level. The messages will provide information towards a gradual reduction of added salt use in household food preparation and cooking; tips for lowering salt intake; and the health risks associated with high salt diets.

2.7.1 | At village committee meetings

Village leaders will be briefed about the study by ASHAs accompanied by the research team at the beginning of the intervention phase. Key messages on sodium reduction will be delivered by ASHA's during public open-house village committee meetings (Village Sabhas) which are held monthly. Additionally, salt reduction themed videos will be shared and circulated on the smartphone WhatsApp platform, which is widely accepted among the local community. The aim in this setting is to improve the capability and motivation of village committee members, which will help them to motivate the target household groups (household cooks, decision-makers and general (other)) in the community by giving them encouragement, ideas, and opportunities to try different salt reduction techniques at household level.

2.7.2 | At women's Self-Help Group (SHG) meetings

ASHAs will connect with women involved in cooking (household cooks) at SHG meetings in each village to deliver tailored key messages and tips for gradually reducing salt whilst cooking and preparing food. These activities will be held once a month over the 6-month intervention period. Salt reduction themed videos, posters, and print material will be shared. ASHAs will be increasing capability and motivation and providing opportunity for household cooks to encourage each other about salt reduction in diet.

2.7.3 | At men's group meetings

Village social influencers, for example, village head, schoolteacher or male health worker, will be identified to mobilize the groups, and support ASHAs to disseminate behavior change messages related to the taste of a low-salt diet and the health benefits of reducing salt intake. The intervention materials will include posters and videos themed around the health risks of too much salt and acceptance of low-salt diets with altered taste. ASHAs will be increasing capability and motivation and providing opportunity for decision-makers and general members of households to discuss the adoption of low salt diets.

2.7.4 | At the household level

ASHAs will deliver salt reduction messages during routine household visits (door-to-door contacts) to target individuals engaged in cooking (household cooks). The key intervention message in this setting will be the importance of gradually reducing salt during cooking and food preparation. Additional messages will focus on lowering salt use in recipes and tips for reducing salt in home cooked foods, such as substitution with other spices. ASHAs will make two 15–30-min visits in

the first month and monthly visits for the remainder of the intervention period. ASHAs will increase capability and motivation, particularly of cooks and decision makers to gradually reduce salt in the household setting.

2.8 | Intervention materials

Two videos and three posters have been developed and pilot tested in a sample population in Siddipet, Telangana.

2.8.1 | Video 1. Gradual reduction of salt in cooking

This video depicts rural women practicing gradually reducing salt in cooking and emphasizes the acceptable taste of low salt diets. This video aims to improve the psychological capability of the participants and improve motivation, both reflective and automatic, to reduce salt consumption. It will be used after the ASHAs have promoted the salt reduction messages. The video also provides participants with an opportunity to try recipes with less salt at household level.

2.8.2 | Video 2. Health impact of high salt diets

This video depicts a rural farmer who has had a stroke due to his high salt diet. The farmer in the video realizes the importance of salt reduction and recognizes the impact on his family if he continues to eat a high salt diet. The video is targeted at improving the psychological capability of decision makers within familial space and dispel myths surrounding salt consumption. The example in the video will provide automatic motivation to reduce salt consumption which support improvements in quality of life and well-being.

2.8.3 | Posters

The key messages depicted in the posters are:

(i) The concept of gradual reduction of salt in household cooking
(ii) The concept of no salt added at the table; and
(iii) Tips for reducing salt in recipes

The posters aim to improve physical and psychological capability household participants and improve reflective motivation to adopt low sodium cooking and eating habits.

2.9 | Sampling approach and sample size calculations

Making a conservative assumption about intra-cluster correlation (ICC = .07) gives our sampling approach a design effect of 2.12. With a total sample of at least 500 of each type of participants from each target group (household cooks, decision makers and general (other) household members) with a power of .8 for:

1. The primary outcome, a .66 change in a knowledge, attitude, and behavior (KAB) score assuming the score has a standard deviation of 2.5. A pilot version of a KAB score from previous salt research in India had a SD of 1.69. An overall score created from summing the individual items (Likert-scale format) in the KAB questionnaire consisting of eight main questions.
2. An absolute proportion change in a specific component of the KAB (eg, do you add salt to food in cooking yes/no?) of .13 (eg, 50%–37% reporting this outcome from baseline to follow-up) assuming the most conservative option of 50% prevalence at baseline.
3. Secondary outcome is change in subscales of the COM-B score measured using COM-B tool; and a change in salt intake of 1.32 g/day assuming a standard deviation of 5 measured by 24 h urinary sodium analysis. A recent salt substitution study had a standard deviation of 2.9.[21]

2.10 | Statistical analysis

The analyses of the quantitative data points will include a comparison between pre-and post-measures. Sampling and population weights will created for each stage of the survey based on the sampling strategy and the estimated population structure from the 2021 census. Mean levels for continuous variables and proportion (%) for categorical variables will be estimated for baseline and follow-up characteristics accounting for the study design (stratification and clustering) and the weights with an appropriate survey statistical procedure. Similarly, differences in the outcomes variables between the pre- and post- surveys will be estimated with similar survey regression procedures. Statistical analyses will be carried out using SAS version 9.4 (SAS Institute Inc, Cary, North Carolina, USA) or Stata 17.

2.11 | Ethical considerations

The study protocol has been approved by the Institutional Ethics Committee of the George Institute for Global Health India (#06/2020). The study is also registered in Clinical Trials Registry of India (CTRI/2020/06/025591). The study has been discussed with the panchayat and elders from the villages and a formal approval has been obtained from the Department of Health and Family Welfare, Telangana, India (No. B035/NI-IM/DMI-IO-SDPI I 2O2O). All data will be collected and managed in compliance to the national privacy law and no report will allow an individual participant to be identified. Written informed consent will be obtained from all participants as well as the freedom to withdraw from the study at any time.

2.12 | Study status

The baseline data collection was completed in September 2021 and the implementation of the planned intervention is ongoing at the time this review paper was written. The end of study follow-up will be conducted for 6 months, after the 6-month intervention phase, that is, April 2022, followed by analyses and dissemination of the findings by the fourth quarter of 2022.

3 | DISCUSSION

This study is the first behavior change intervention aimed at reducing salt intake in a household setting delivered by front-line health volunteers (ASHAs) in India. The findings will provide crucial evidence of the efficacy and feasibility of delivering a salt reduction program through front-line health volunteers at the household and community level. By integrating salt reduction messages into existing mechanisms for healthcare delivery through ASHA workers, innovative salt reduction strategies can be aligned with ongoing, sustainable systems in existing Indian healthcare structures which in turn has the potential for widespread state and national level scale-up.

The results of this study will provide valuable evidence to inform new and strengthen existing policy to reduce population salt consumption to achieve a 30% reduction in population salt intake by 2025. NCDs contribute to 62% of all disease burden and more than 60% of all deaths in India. The global epidemic of overweight and obesity is a key driver of diet related NCDs including heart disease, stroke, hypertension, and type II diabetes. India was the first country to develop specific national targets and indicators aimed at reducing the number of global premature deaths from NCDs by 30% by 2025, and there are now more than 10 national programs directly or indirectly addressing NCD prevention and control. However, there have been significant implementation challenges including lack of surveillance and effective monitoring and evaluation. Further research is required to develop evidence-based, sustainable, and scalable interventions to promote salt reduction through ASHA's and to strengthen the implementation of such interventions through existing Government frameworks policies and reduce the burden of diet-related NCDs in India.

India has already committed to salt reduction as a policy priority, paving the way for the implementation of evidence based, context specific strategies.[22] An effective Indian salt reduction program would hugely decrease the burden of disease caused by heart attack, stroke, and other blood pressure-related diseases. With CVD already the leading cause of death in most parts of India,[5] and cardiovascular disease events occurring on average a decade earlier than in the West,[23] the potential significance of salt reduction for the health of the population is enormous.

Several interventions to reduce dietary salt intake have demonstrated effectiveness in countries such as the UK,[24] South Africa,[25] and Chile.[26] In the Asia-Pacific region, countries including China and Malaysia where the main source of dietary salt is added during cooking or in sauces have started salt reduction initiatives including establishing baseline estimates to provide data for the development of a salt reduction program, but progress has been slow. Due to the limited evidence of the efficacy of behavior change interventions to reduce salt intake,[10] alternative approaches have often been prioritized. One promising intervention is the use of low sodium, high potassium salt substitutes, which have been shown to lower blood pressure and reduce cardiovascular disease mortality.[27,28] Additionally, a recent study in China demonstrated that children could play a key role in helping reduce salt intake in the whole family.[29] Key to the effective adoption and scale-up of any strategy is understanding the context including the main sources of salt in the diet and the household and community drivers of salt consumption patterns. A similar intervention but at workplace focusing on reducing consumption of salted tea was found to be effective.[30] Though the context and the mode of delivery of the intervention is different, these kinds of community-based interventions provide opportunities for overall reduction of main sources of salt in the diet.

The key strengths of the current project are the new data that will emanate from this pre-post intervention in a large area and the evaluations of the feasibility and sustainability of salt reduction interventions delivered by community health volunteers. These will be important new data for India and will underpin the case for action, specifically highlighting the potential for salt reduction integration within existing healthcare delivery systems across India. These findings may also help inform salt reduction programs in other countries that employ a large network of community health volunteers. Additionally, the intervention uses various behavior change mechanisms and has considered the social norms and household dynamics for the local region. The study also benefits with having process evaluation built in the project that will help tease out effective messages in the intervention for future scalability and as well from the use of the best current method of quantification of dietary sodium intake based on 24 h urine collection, which is the gold-standard method to for assessing salt intake.[31]

The study, however, has few limitations. The study is restricted to one state in India and does not have a control arm due to logistical and budgetary constraints. It will not provide definitive data about the effect of this intervention across the entirety of India; however, the results can be broadly generalizable to the region due to the similarities in family structure, culture, and diet, and will provide evidence of feasibility for scale-up.

4 | CONCLUSIONS

This study will generate crucial new evidence and clearly define the potential for behavior change interventions for salt reduction in India. The findings will be targeted primarily at policymakers but will be disseminated widely through other mechanisms including conference presentations and peer-reviewed publications, as well as to the participating communities.

AUTHOR CONTRIBUTION

This study was conceptualized by CJ, SRT, ACH, JW, DP, and CJ wrote the first draft of the manuscript with input from SRT Thout and final review by DP. All authors were involved with the design of the research protocol, reviewed, and agreed to the published version of the manuscript. CJ is supported by a National Heart Foundation Postdoctoral Fellowship (HF101945); JW is supported by a National Heart Foundation Future Leaders Fellowship Level II (#1082924), and through the National Health and Medical Research Council (NHMRC) Centre of Research Excellence on food policy interventions to reduce salt (#1117300). The other authors declare no conflict of interest. This project is funded by Resolve to Save Lives, Vital Strategies, Address: 100 Broadway, 4th Floor New York, NY 10005, USA. The funding bodies do not play a role in the design of the study and collection, analysis, nor in interpretation of data or in writing the manuscript.

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SUPPORTING INFORMATION

Additional supporting information can be found online in the Supporting Information section at the end of this article.

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