


BMJ Open Innovative equipment to monitor and control salt usage when cooking at home: iMC SALT research protocol for a randomised controlled trial

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To cite: Gonçalves C, Silva-Santos T, Abreu S, *et al*. Innovative equipment to monitor and control salt usage when cooking at home: iMC SALT research protocol for a randomised controlled trial. *BMJ Open* 2020;**10**:e035898. doi:10.1136/bmjopen-2019-035898

► Prepublication history for this paper is available online. To view these files, please visit the journal online (<http://dx.doi.org/10.1136/bmjopen-2019-035898>).

Received 21 November 2019
Revised 10 March 2020
Accepted 08 April 2020



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ABSTRACT

Introduction Excessive salt intake is a public health concern due to its deleterious impact on health. Most of the salt consumed come from those that are added when cooking. This study will improve knowledge on the effectiveness of interventions to reduce salt consumption among consumers.

Methods and analysis In this randomised clinical trial, we will be evaluating the efficacy of an intervention—the Salt Control H, an innovative prototype equipment to monitor and control use of salt when cooking—among workers from a public university, with the aim of reducing their dietary salt intake. We will randomly select 260 workers who meet the eligibility criteria and who are enrolled to an occupational health appointment and randomise them into one of the two arms of the study (either control or intervention), with matched baseline characteristics (sex and hypertension). The intervention will last for 8 weeks, during which the participants will use the equipment at home to monitor and control their use of salt when cooking. The main outcome will be 24-hour urinary sodium excretion at baseline, at fourth and eighth weeks of intervention, and at 6 months after intervention.

Ethics and dissemination Ethical approval for the study has been obtained from the Ethics Committee of the Centro Hospitalar Universitário São João. The results of the investigation will be published in peer-reviewed scientific papers and presented at international conferences.

Trial registration number NCT03974477

Equipment provisional patent number Registered at INPI: 20191000033265.

INTRODUCTION

Dietary salt intake has been causally linked to high blood pressure and increased risk of cardiovascular problems.¹ Cardiovascular diseases, including coronary heart diseases and cerebrovascular diseases, are the main causes of morbidity and mortality in the European Union, including Portugal.² In 2014, inadequate dietary habits were the major risk factors that contributed to the total disability adjusted life years in the Portuguese

Strengths and limitations of this study

- A researcher independent of the recruitment and intervention process will perform stratified randomisation.
- Laboratory analysis will be performed by technicians who are unaware of the origin of the samples for analysis (control or intervention group).
- Dietary salt consumption will be assessed by 24-hour urine collection.
- Statistical analyses will be carried out by an independent researcher.
- Double-blinded study design is not possible in the current study.

population. Low fruit intake and eating salty food were particularly the main factors responsible for the loss of years of healthy life.³

Excessive salt intake is one of the greatest risks to public health in Portugal,^{4–6} making it urgent to propose measures to reduce its intake. Small reductions in consumption can bring great benefits to the health of the population, not only in terms of cardiovascular diseases, but also in relation to other chronic diseases prevalent in Portugal.⁷

In European countries, a large proportion of salt ingested by consumers come from food prepared outside home and which are added during food production (75%–85%), while around 10%–12% come from food prepared at home.^{7,8} In the Portuguese population, the main source of salt consumption is the salt that are added during food preparation and cooking (29%).⁹

Despite it being naturally present in some foods, a large majority of salt are added to food during processing or cooking.¹⁰ The quantity of sodium ingested could vary greatly depending on the food product that



a person chooses to eat.⁷⁻¹¹ A study that analysed sodium content present in vegetable soups served in several canteens concluded that the mean salt content varies greatly between canteens, with no clear pattern with regard to the amount of salt added when cooking.¹² In fact, most chefs recognise that even when cooking meals for children they use an arbitrary amount of salt based on flavour.¹³ The difference in salt content found in food at the market-place and at restaurants makes it difficult for consumers to meet dietary guidelines.

Salt is a learnt taste preference. With exposure to consistently high levels of salt in food, high levels of salt become appetising and so people start to choose food with higher salt content. Research suggests that the preferred level of salt in food is dependent on the level of salt consumed, and that this preferred level can be lowered when sodium intake is reduced.¹⁴

The reduction of salt intake has been recognised by the WHO as a priority,¹⁵⁻¹⁶ and recommends that daily sodium intake should be less than 2000 mg/day (5 g/day).¹⁷ In 2013, all WHO member states committed to reaching the target reduction in salt intake of 30% by 2025, aiming a target of 5 g per day in the adult population.¹⁸

In 2015, the Portuguese government assumed that salt reduction was imperative to public health and promoted the creation of an interministerial working group,¹⁹ which elaborated on a consensus document²⁰ that highlights the necessity to set quantifiable reduction targets and monitor salt consumption.

Almost all countries have failed to reduce the quantity of salt added to catered food as well as during food preparation at home. The development of a quick and user-friendly instrument to monitor and control salt added to food when cooking is a potential solution. This study will provide important evidence on salt reduction and its sustainability, which can then help policymakers design as well as reformulate effective strategies to help consumers manage their salt intake. Indeed, previous community intervention studies using spoons to restrict salt intake have shown encouraging effects.²¹

As such, the main objective of this study is to verify the impact on participants' salt consumption, of an intervention, that is the use of the Salt Control H equipment during the preparation and cooking of meals (innovation to monitor and control salt - iMC SALT project).

METHODS AND ANALYSIS

Trial design

Participants were recruited from the staff of the University of Porto who were enrolled to occupational health appointments. Occupational health appointments are annual health appointments mandatory for all workers of the university (white-collar and blue-collar workers). Recruitment was carried out by the doctor responsible for the appointment, which started in June 2019 and will last until enough number of participants have been obtained for the study (n=260) or until March 2021.

The participants were randomised into two groups: control group (CG) or intervention group (IG). The intervention lasts 8 weeks, during which the participants use the Salt Control H equipment to dose salt when preparing and cooking food at home. At 6 months after the first intervention, the participants will be reassessed (follow-up) (figure 1).

The Salt Control H equipment has been patented (INPI, N° 20191000033265)²² and consists of a dosing device that provides doses of salt according to the number and age (children or adult) of the person who will consume the meal. The prototype is available only for testing, and not for commercial distribution. It will be tested by researchers in controlled dietary studies. This prototype system relates to a dosing device that comprises a dosing mechanism that dispenses 0.8 g of salt (for adult) or 0.2 g of salt (for children) for meals, and 0.2 g of salt for every 250 mL of soup for adults or 0.1 g of salt for every 250 mL of soup for children. Between each group of participants, the prototype equipment will be sanitised, disinfected and packed in an airtight bag.

The trial is registered at ClinicalTrials.gov.²³

Hypothesis

The main hypothesis of this study is that by using the Salt Control H equipment to prepare and cook meals, participants will reduce their overall daily intake of salt in order to achieve WHO's recommended intake. Nevertheless, this intervention could have an impact on other parameters, such as the sodium to potassium ratio of diet,²⁴ blood pressure,²⁵ hydration status²⁶ and iodine intake,²⁷ as shown by previous studies.

Results of a recent research suggest that the intestinal microbiome is affected by diet, with potential consequences for the host organism and the immune system.²⁸ Therefore, in our study we address the role of diet in shaping the microbiome and the influence of salt consumption on gut microbiota composition. Other parameters will be analysed in an exploratory way, such as knowledge on dietary salt requirements, quality of life, quality of diet and participants' culinary skills. Since the intervention can promote behavioural change among individuals, namely the need to adapt new culinary knowledge with regard to cooking with lower salt content, the search continues for more information on topics such as salt food sources and the potential to change some home cooking habits and family conviviality routines.

Participants

The following were the eligibility criteria used by the doctor responsible for the occupational health appointment: adult (>18 years), frequently eats home-cooked meals (more than 4 days a week and at least 3 Sundays per month), one annual occupational health appointment at the hospital and reports motivation to control dietary salt consumption. The following were the exclusion criteria: pregnant, with hypotension, kidney disease, active infection that impacts renal function, urinary incontinence,

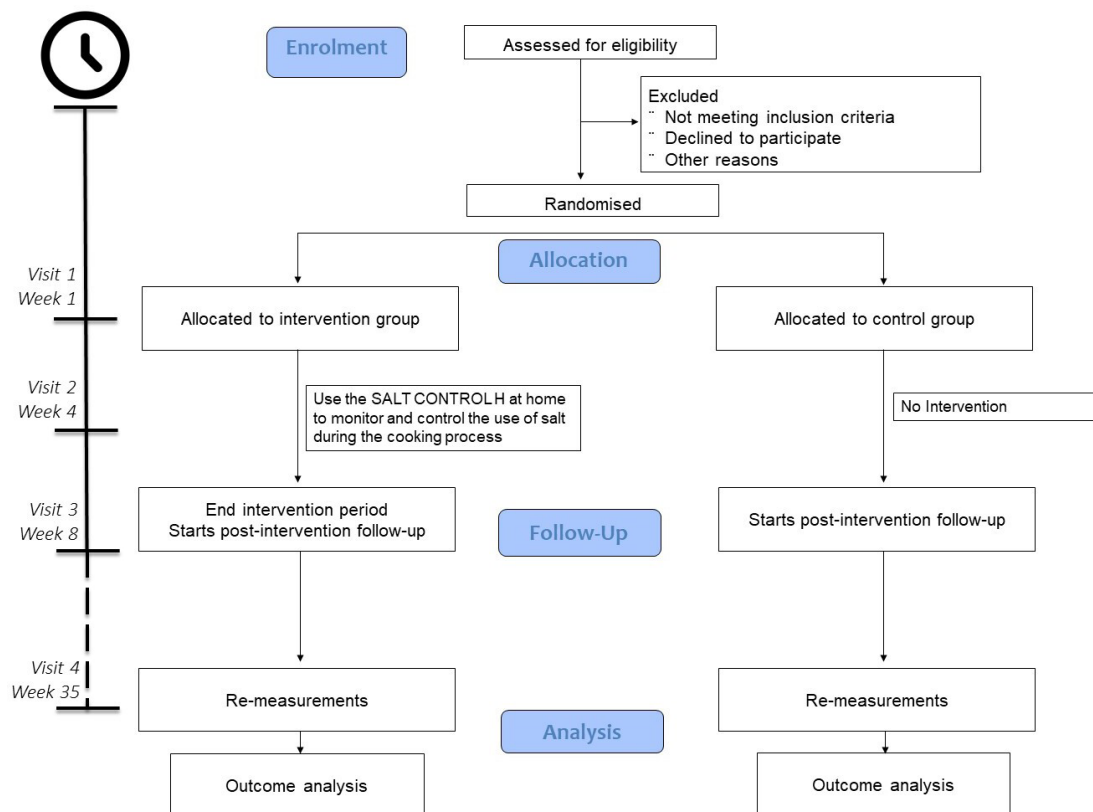


Figure 1 Study design.

acute coronary syndrome, severe liver disease or heart failure, not using salt for cooking, and staff member of the faculty that promotes the study.

Sample size

The sample size was calculated to provide more than 80% statistical power at a significance level of 0.05 bicaudal, assuming a difference in the mean 24-hour urinary sodium excretion equal to or greater than 27mmol/day between IG and CG, with an SD of 70mmol/day.²⁹ In addition, this calculation was adjusted considering a 20% participant dropout, resulting in a sample size of 260 participants. A subsample of participants (n=20) will be used for intestinal microbiota analysis.

Randomisation

Considering differences in salt intake between sex and the clinical condition of arterial hypertension,⁶ stratified randomisation of participants was done taking into account the following steps:

- ▶ Stratification of participants by sex (1:1 ratio).
- ▶ Stratification of participants according to diagnosis of arterial hypertension (0.4:0.6 ratio)⁶.
- ▶ Allocation of participants to the control or intervention group (1:1 ratio) using computerised random numbers.

A researcher independent of the recruitment and intervention process will perform the randomisation, and the allocation sequence was concealed until visit 1, during which the participants and the researchers discover

the group to which the participant belongs by opening sequentially numbered, opaque and sealed envelopes.

Blinding

Participants and researchers were not blinded because the study compares interventions with one equipment that cannot be masked. Nevertheless, the laboratory analysis (sodium, potassium, iodine and so on) was performed by laboratory technicians who are unaware of the origins of the samples for analysis (control or intervention group and the identity of the participant). In addition, the researcher responsible for randomisation and statistical analysis was not involved in the recruitment, nor did the researcher has contact with the participants during data collection. The researcher was also unaware of the participants' origin (ie, control or intervention group and the identity of the participant).

Study intervention

The monitoring points (visits) of the study need to be carried out on days when the participant consumed meals prepared at home (preferably data collection was done on Sundays). Visits for data collection were as follows:

Screening visit (week 0)

During the first visit, participants' eligibility criteria are verified by the doctor. If eligible, the participant signs the informed consent form and is given the questionnaires. The participant then undergoes anthropometric and blood pressure measurements and is also given 24-hour

urine collection containers. The participant will then be randomly allocated to CG or IG.

Visit 1 (week 1)

One week after the screening visit, the participant will be in contact with the researchers to deliver the 24-hour urine container and to fill out the questionnaires.

IG participants will receive one standardised presentation session that explains, through a tutorial video, how the Salt Control H equipment works to ensure adequate salt content during food preparation and cooking. A researcher will also explain some culinary strategies on how to prepare meals with adequate salt content. Participants are also given food education book, as well as a leaflet on Portuguese food guide.³⁰ CG participants will only receive a leaflet on Portuguese food guide.³⁰

In one subsample of IG participants, a kit for collection of intestinal microbiota sample will be provided.

Visit 2 (week 5)

After the first month of intervention, the participants will be in contact with the researchers to deliver the 24-hour urine container. Anthropometric and blood pressure data will also be collected during this visit.

Visit 3 (week 9)

After the second month of intervention, the participants will be in contact with the researchers to deliver the 24-hour urine container and the intestinal microbiota sample and to fill out the questionnaires. Anthropometric and blood pressure data will also be collected during this visit. IG participants will stop the use of equipment after this visit.

Visit 4 (week 35)

Six months after the intervention, the participants will be in contact with the researchers to deliver the 24-hour urine container and to fill out the questionnaires. Anthropometric and blood pressure data will also be collected during this visit.

Outcomes

Primary outcome

The primary outcome is the difference in the 24-hour urinary sodium between the control and the intervention group from baseline over the 8-week follow-up. The 24-hour urine collection will be performed on any day of the week (preferably on Sunday, but not on Friday and Saturday due to laboratory availability), and a total of four urine collections will be obtained by each participant: before the intervention, on the fourth and eighth week of the intervention, and 6 months after intervention. Urine collection will be performed using sterile containers that were provided to the participants. The containers were coded to conceal their provenance.

The 24-hour urine collection procedure was explained to each participant and a pamphlet was given with indications about the procedure.

On receipt of the containers on the day immediately following the 24-hour urine collection, the researcher sends the containers to a certified laboratory. The following parameters were analysed: volume, sodium (by indirect potentiometry), potassium (by indirect potentiometry), iodine (by ammonium persulfate digestion with spectrophotometric detection of the Sandell-Kolthoff reaction), osmolality (by osmometry), creatinine (by photometry), density (by reflection refractometry) and pH (by dual wavelength reflectance). The validity of urine specimen collection will be assessed by volume, creatinine and complete collection reported by the participant.

Secondary outcomes

The assessment of each secondary outcome will be described separately. All secondary outcomes except one (intestinal microbiota) will be assessed at baseline, at fourth and eighth weeks, and at 6 months after intervention.

Intestinal microbiota

To collect intestinal microbiota samples, participants were provided with an EasySampler Collection Kit, which was used according to the instructions, and an explanatory leaflet. Participants collect their samples at home, and the researcher will forward the samples to a certified laboratory. The samples will be thoroughly analysed and the parameters will address the following: alpha and beta diversity indices (by new generation sequencing of ribosomal RNA (rRNA) subunit 16 gene in the intestinal microbial community, followed by bioinformatic analysis) and filo-level distribution of operational taxonomic unit (OTUs) (by bacterial categorisation based on similarities between 16S rRNA gene sequence variants). The samples will be collected before the intervention and at the eighth week of intervention. The analysis will be performed on the first 20 IG participants who agreed to collect a sample. This analysis will be an exploratory study performed in a subsample of participants determined by the number of collection kits available according to our budget (n=20).

Anthropometric variables

Height (SECA 213 portable stadiometer, Hamburg, Germany) and waist and hip perimeter (SECA 201 tape) were measured according to international standard procedures.³¹ With participants wearing light clothing and without shoes, body composition (fat, fat free mass, bone mass, basal metabolic rate, total body water and body mass index (BMI)) was assessed using Tanita MC180MA body composition analyser (Tanita, Illinois, USA). Only weight was taken from participants with pacemaker using SECA 813.

Blood pressure

Blood pressure was measured using a portable sphygmomanometer (Edan M3A, Edan Instruments, China) with participants seated and was taken after a 5 min rest. Blood pressure measurements were done in both arms during the first assessment to determine possible arm-related

measurement differences. Using the arm with the highest blood pressure value as a reference, the blood pressure was assessed twice. If the difference between the first two evaluations was higher than 10 mm Hg, one more evaluation is done.

Dietary intake

Dietary intake was assessed by a 24-hour dietary recall and a semiquantitative Food Frequency Questionnaire (FFQ). This semiquantitative FFQ has been validated among Portuguese adults³² and adapted to include a variety of typical Portuguese food items. The FFQ administered at visit 1 covers the previous 12 months before inclusion in the study, while that at visit 4 covers the previous 8 months after inclusion in the study.

With regard to 24-hour dietary recall, participants were asked to recall all foods and drinks consumed the previous day (during the time of urine collection) and to estimate the portion size with the help of an illustrated book³³ and household measures. Energy and nutritional intake were estimated using an adapted Portuguese version of the nutritional analysis software Food Processor Plus (ESHA Research, Salem, Oregon, USA). The nutritional content of local food was taken from standard nutrient tables, whereas the content of commercial food (eg, pizza and ready-to-eat-food) was derived from labelled ingredients and nutrients. The intake of dietary supplements such as multivitamin/minerals/vitamin supplements will also be evaluated in an interview, covering dosage and frequency of intake.

Quality of life

The WHOQOL-Bref (World Health Organization Quality of Life Instruments - Bref) Questionnaire adapted to and validated in the Portuguese population will be used.³⁴

Additional variables

Covariates as descriptive variables or potential confounders for the analyses will be collected and are described separately.

Physical activity

The level of physical activity will be characterised using the International Physical Activity Questionnaire-Short Form, validated and adapted to the Portugal population,³⁵ and will be assessed at baseline, at eighth week of intervention and at 6 months after intervention.

Sociodemographic and health characterisation

The sociodemographic questionnaire was based on the WHO STEPS questionnaire,³⁶ and some pertinent questions to characterise our study were also included, such as the district where the participant resides (iodine), medication consumption, and probiotic and nutritional supplement consumption. Skin phenotype was characterised according to Fitzpatrick's classification,³⁷ classified as redhead with freckles, blond, brunette, Latino, Arab, Asian or black. To characterise knowledge and habits with regard to salt consumption, a translation of the

questionnaire proposed by WHO³⁶ and the Pan American Health Organization³⁸ will be used. The doctor responsible for the recruitment appointment will perform hypertension diagnostics on participants. These variables will be assessed at baseline, at eighth week of intervention and at 6 months after intervention.

Culinary skills characterisation

A questionnaire developed by the research team based on the questionnaire used by Santos³⁹ will be administered at baseline, at eighth week of intervention and at 6 months after intervention.

Salt consumption

Participants collected a 20 g (one tablespoon full) sample of salt used on the Salt Control H equipment while cooking and placed the sample in a coded plastic bag. The iodine content of the sample was then analysed by potentiometric determination. Only IG participants will perform this collection during the intervention period. This is to determine the iodine content of salt usually used at home by IG participants.

Non-participants and subjects lost to follow-up

A questionnaire about simple sociodemographic questions was administered to the participants who drop out or do not agree to participate in the study. Missing data will be imputed using multiple imputation.

Treatment fidelity

Instructions about the use of Salt Control H equipment to prepare and cook meals were presented to participants through a short video. After watching the video, participants were asked to verbally confirm their understanding of the use of the equipment. If participants had doubts, the researcher reinforces the instructions using practical examples.

Monitoring of the correct use of equipment was carried out by a researcher through telephone, email and at visit 2 in order to clarify doubts about its use and to verify compliance with its use. At visit 3 a questionnaire on the frequency of use of the Salt Control H equipment to prepare and cook meals was administered.

Patient and public involvement

Patients or the public were not involved in the design, conduct, reporting or dissemination of the research.

Statistical analysis plan

Statistical analysis will be performed using the latest version of Statistical Package for Social Sciences (SPSS Version 25) for Windows. All statistical analyses and CIs will be two-sided, with $p < 0.05$ regarded as significant.

Differences in baseline characteristics between the control and the intervention group will be reported for primary and secondary outcomes. Descriptive statistics (mean, mode, median, SD and IQR, number and percentages) will be used taking into account the characteristics of the variables. Normality of variables will also be studied



using the Kolmogorov-Smirnov statistical test. Differences between the control and the intervention group will be analysed using independent t-test or Mann-Whitney U test for continuous variables and χ^2 test for categorical variables.

The primary effect parameter will be the difference in the 24-hour urinary sodium between the control and the intervention group, and will be done using an intention-to-treat approach with participants analysed according to initial randomisation. Linear mixed model will be conducted to test the change in 24-hour urinary sodium from baseline over the 8-week follow-up. Additionally, a per-protocol analysis will be performed on all participants with valid urine collection both at baseline and at 8-week follow-up. Linear mixed model will be adjusted for potential confounders (age, BMI and other variables that differ between the trial arms). There are preplanned subgroup analyses for sex and hypertension.

The aim of the secondary analysis is to test the effect of intervention on intestinal microbiota, anthropometric measurements, blood pressure and dietary intake (macronutrients, micronutrients and percentage contribution of dietary sources to total intake of sodium). As described for the primary outcome, an intention-to-treat analysis will be performed for each of the secondary outcomes and linear mixed models will be applied. Adjustment for potential confounders will be done for age, BMI and other variables due to their differences between the control and the intervention group.

For primary outcome and each secondary outcome, we will estimate the mean differences during the 8-week intervention with 95% CI.

One possible limitation of our study is the contamination of CG participants by IG participants since all participants will be recruited from the same university, although the total number of blue-collar workers is 2436 while that of white-collar workers is 1593, distributed in 14 faculties that are geographically dispersed. In order to mitigate this situation, we will perform a contamination-adjusted intention-to-treat analysis.

DATA MANAGEMENT

Only the principal investigator (PI) will have access to the encoding file and will be responsible for keeping it separately from the data set, ensuring data confidentiality. To promote data quality, one researcher will introduce data to the databases, and a double data entry check and verification of strange values outside the possible range will be carried out. The PI has the responsibility to reserves the paper questionnaires generated after data collection. Access to totally anonymised and complete data set by other researchers from the team requires prior agreement with the PI.

ETHICS AND DISSEMINATION

The project was approved by the Ethics Committee of the Centro Hospitalar Universitário São João. Good clinical

practices regarding clinical trials with intervention⁴⁰ and the Clinical Investigation Law guidelines were followed.⁴¹ All participants signed an informed consent statement and received a document containing information about the study. The results of the investigation will be published in peer-reviewed scientific papers and presented at international conferences.

TRIAL STATUS

Recruitment began in June 2019 and is estimated to be complete by March 2021. The results of the trial will be available in 2021.

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Acknowledgements The authors would like to thank Sarah Maggioli for help with the grammatical review of the article, as well as Pedro Castro Lacerda, Adriano A Bordalo e Sá and Altin Ndrilo for help with the laboratory analysis of the samples.

Contributors Study design: CG, SA, PP, PM and OP. Drafting of the manuscript: CG and TS-S. Critical revision of the manuscript: SA, PP, PG, LO, SE, PN and PM. Approval of the final version for publication: all coauthors.

Funding This work was supported by Fundação para a Ciência e Tecnologia (Grant POCI-01-0145-FEDER-029269). The Research Center in Physical Activity, Health and Leisure (CIAFEL) is supported by FCT/UIDB/00617/2020, The CITAB is supported by FCT/UIDB/04033/2020.

Competing interests The study will use one prototype system that has been submitted with a provisional patent number (INPI, N° 20191000033265). CG, PG, LO, SE, PM and OP are inventors of the prototype system. The inventors have intellectual property rights.

Patient consent for publication Not required.

Provenance and peer review Not commissioned; externally peer reviewed.

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