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Brief interventions for older adults (BIO) delivered by non-specialist community health workers to reduce at-risk drinking in primary care: a study protocol for a randomised controlled trial

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ABSTRACT

Introduction Evidence suggests that brief interventions are effective in reducing alcohol consumption among older adults. However, the effectiveness of these interventions when delivered by community health workers (non-specialists) in a primary healthcare setting is unknown. To our knowledge, this will be the first randomised trial to examine this.

Methods and analysis Two hundred and forty-two individuals considered at-risk drinkers (Alcohol Use Disorders Identification Test-Consumption, AUDIT-C score ≥4) will be recruited and randomly allocated to usual care (waiting-list) or usual care plus an intervention delivered by trained community health workers (non-specialists). Seven primary care units (PCUs) in Sao José dos Campos, Brazil. PCUs are part of the Brazilian public healthcare system (Sistema Único de Saúde).

Follow-up
6 months.

Outcomes
The primary outcome will be the proportion of participants considered at-risk drinkers (AUDIT-C score ≥4). Secondary outcomes will include alcohol consumption in a typical week in the last 30 days (in units per week) assessed by the AUDIT, service use questionnaire, cognitive performance—assessed by The Health and Retirement Study Harmonised Cognitive Assessment, physical activity—assessed by the International Physical Activity Questionnaire, depression—assessed by the Geriatric Depression Scale and quality of life—assessed by the Control, Autonomy, Self-realisation and Pleasure-16 instrument. The analysis will be based on intention-to-treat principle.

Ethics and dissemination This study has been approved by the Ethics Committee of the Universidade Federal de São Paulo, CEP/UNIFESP Project n: 0690/2018; CAAE: 91648618.0.0000.5505. All eligible participants will provide informed consent prior to randomisation. The results of this study will be published in relevant peer-reviewed journals and in conference presentations.

Strengths and limitations of this study

- This will be the first randomised trial to investigate the efficacy of a Brief Intervention for Older adults (BIO) delivered by non-specialists (community health workers) to reduce at-risk drinking.
- The BIO is a simple, fast, low-cost intervention that could be translated and easily applied by non-specialist professionals working in low-resource settings worldwide.
- The trial was designed to have broad inclusion criteria and to be implemented in primary care settings in the Brazilian public health system, and will be conducted in an everyday environment, rather than in specialised centres with highly selected participants.

Trial registration number RBR-8rcxkk.

BACKGROUND AND RATIONALE

Context

The number of older adults is growing globally, particularly in low-income and middle-income countries (LMICs). For example, with a swiftly ageing population, Brazil is projected to have a senior population of approximately 32 million by 2025.[1] In Latin America and the Caribbean, the utilisation of medical services and healthcare spending associated with an ageing population is even more pronounced compared with some other nations due to recent trend towards the deterioration of health among older adults in the region attributed to a rising prevalence of chronic and infectious diseases, sedentarism, tobacco use, unhealthy eating behaviours and harmful alcohol consumption.[2] Previous

studies indicate that harmful alcohol use in later life may be linked not only to major health problems, such as cardiovascular diseases, hypertension, digestive diseases, and cancer but also to a high-risk of all-cause mortality.[3]

In this respect, our research group recently identified evidence for a high prevalence of harmful alcohol consumption among older Brazilians, and recognised this age group as an important target for interventions aimed at reducing excessive alcohol consumption.[4]

However, while substantial work has been conducted worldwide to understand the determinants for alcohol use and harmful use among older adults,[5] there is still a need to identify efficient, large-scale, low-cost strategies aimed at reducing alcohol intake in older adults.

Knowledge gaps

Previous cumulative evidence suggests that brief interventions offered to older adults are effective at reducing alcohol consumption, although the effects can be small to moderate.[6–8] However, most randomised trials are from high-income countries and few studies have been conducted in primary care settings. To date, to the best of our knowledge, all available clinical trials targeting older population relied on delivery strategies that depended primarily on licensed practitioners, specialised nurses or counsellors with clinical training.[9] As a result, there are concerns about the cost-effectiveness of these interventions, because of the high costs associated with the routine use of highly skilled professionals. If the same intervention could be delivered without the need for highly trained healthcare professionals, effective low-cost intervention strategies could be achieved, particularly when targeted toward populations at a high risk of drinking. A study carried out in India provided evidence of the effectiveness of an intervention for harmful drinking provided by non-specialised health professionals in primary care, but was designed and assessed specifically for an adult male population.[10] Currently, the effectiveness of delivering brief interventions for older adults at-risk of drinking via non-specialists is unknown.

Current study

The protocol proposed here describes the first randomised controlled trial aimed at testing the efficacy of using non-specialists (community health workers, CHWs), to deliver a brief intervention for older adults (BIO) targeting at-risk drinkers in primary care settings, which, in the case of Brazil, currently provide care for approximately 70% of the older adult population. The intervention examined here, and hereinafter referred to as the BIO, is a simple and fast tool and has been designed for Brazilian older adults, but would be easily to adapt for use with other populations in primary care settings in different cultures.

Aims of the study

This trial is designed to address two main research questions:

1. What is the efficacy of BIO compared with usual care (wait list) for reducing alcohol consumption in primary care?
2. What are the effects of BIO on physical activity, cognition, quality of life (QoL) and depression?

METHODS AND DESIGN

We followed the Standard Protocol Items: Recommendations for Interventional Trials guidelines.[11]

Trial design

This is an open-label, multicentre, parallel, randomised waiting-list controlled trial. Compared with previous trials in which the brief intervention was delivered by licensed practitioners, specialised nurses or counsellors with a clinical training,[12] this trial will examine the potential of CHW to deliver the intervention. Publications related to the trial will comply with the Consolidated Standards of Reporting Trials recommendations. The study will begin in January 2022 and will end in December 2023.

Patient and public involvement

The booklet on alcohol consumption among older adults used in the intervention was developed with the involvement of patients and the public. The development of the booklet was part of a previous study, which developed the booklet specifically for the older population. The methodology for preparing the booklet involved focus groups with older adults (drinkers and non-drinkers) that occurred at different stages of the booklet's development, in order to verify comprehension, feasibility, adequate language, colours and text size. However, patients and the public were not involved in the development of the research question and outcome measures, the design of the study, recruitment and conduct of the study.

Community health workers

In Brazil, the functions of the CHWs are to identify individuals and families exposed to risks and undertake basic interventions to benefit children, adolescents, women, workers and older people. CHWs do not need to have a graduate degree or prior knowledge in health sciences, but all CHWs are supervised by a trained nurse. Their role is more social than technical, and they form a link between the community and local health services. They are responsible for health promotion, disease prevention and mapping community needs; their work is normally carried out through home visits and local meetings. CHWs need to know their community very well, have a spirit of leadership and solidarity and meet the following requirements: minimum age of 18; excellent communication skills in spoken and written Brazilian Portuguese; have resided in the community for the last 2 years and have full-time availability to perform their activities.

Setting

This study will be performed in the city of São José dos Campos, with participants aged 60 years or older

registered in public primary healthcare units. São José dos Campos is a city with 688 595 inhabitants and is located 90 km from the capital, São Paulo.

Primary healthcare units

Primary care units (PCUs) in Brazil offer free primary care in convenient locations across the country. These units are operated by the government and are part of the Unified Health System (Sistema Único de Saúde). Each PCU provides continuous care for inhabitants from a defined area. In the city of São José dos Campos there are a total of 12 PCUs that are part of the Family Health Strategy with CHWs, from which seven will be selected to participate in this study: three from the North and four from the East regions. For this trial, PCUs will be selected based on convenience sampling. At each PCU, one or two CHWs will be trained to deliver the intervention.

Eligibility criteria (participants)

Inclusion criteria for participants included: (1) 60 years or older; (2) registered at PCUs in São José dos Campos; (3) identified as at-risk drinkers based on Alcohol Use Disorders Identification Test-Consumption (AUDIT-C) score ≥4. Exclusion criteria: (1) received previous treatment for substance use disorders, except tobacco, in the last 90 days; (2) Severe mental or physical illness that may impair the acquisition of alcohol consumption data; (3) Patients requiring hospitalisation and (4) Patients who are unable to communicate clearly and/or who are intoxicated at the time of screening.

INTERVENTIONS

After randomisation, patients will be allocated in a 1:1 ratio to usual care plus the BIO or usual care (waiting list) (figure 1).

- Group 1 (Control—waiting list): the participants allocated to this group will receive usual care during the period of study. For this group, we will offer the intervention immediately after the 6-month follow-up.

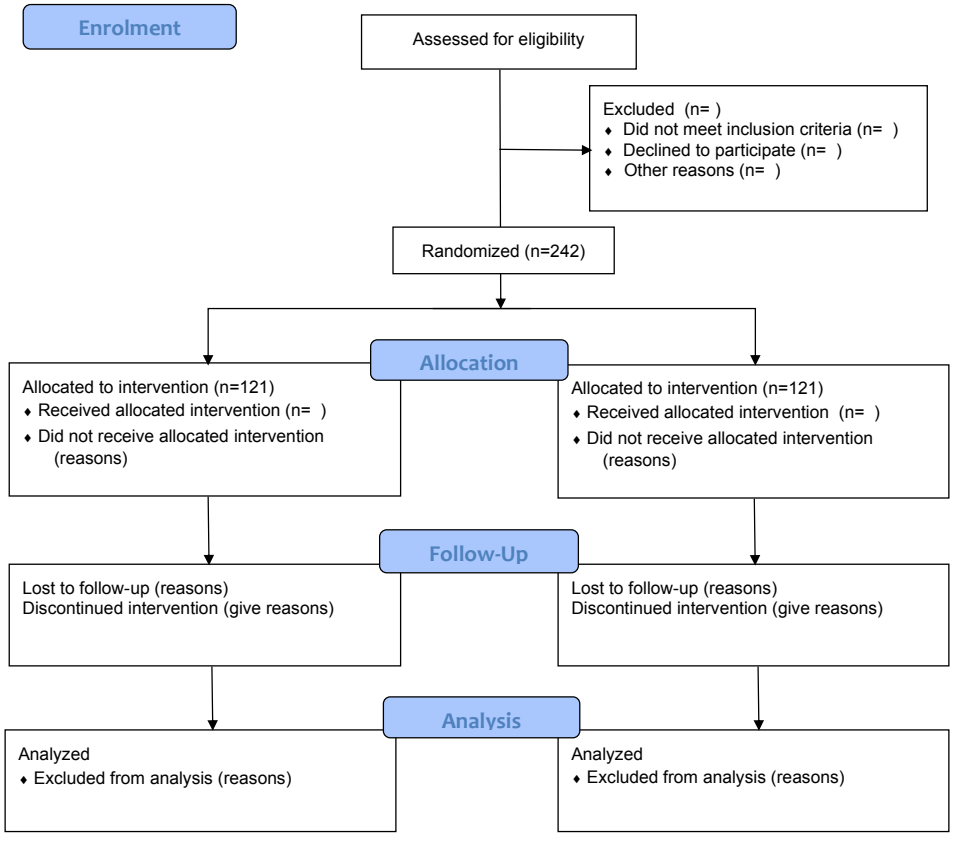

Figure 1 Flow diagram.

- Group 2 (BIO): the participants will receive the same usual care as the control group plus the BIO delivered by CHWs in a 10–15 min single session.

The BIO adults: BIO

The BIO is a technique with a duration 10–15 min that is designed to change behaviour and includes seven components: (1) feedback; (2) identification; (3) information; (4) reflection; (5) normative; (6) construction; (7) booklet. The intervention will be delivered by CHWs, who will receive specific training in the methodology. This BIO) was based on the intervention toll 'Brief Advice' (https://www.sips.iop.kcl.ac.uk)[13] and adapted for the older adult and Brazilian population (details in online supplemental appendix 1).

Stages of the BIO

The CHWs will use a script that guides them through the following sequential steps:

1. Feedback: The intervention starts with personalised feedback on the participant's alcohol consumption pattern in the last month, identified through AUDIT-C.
2. Identification: The main potential consequences associated with the participants' alcohol consumption is presented to them.
3. Information: Information is provided on the risks associated with alcohol consumption, on the possible interactions between alcohol and prescribed, or non-prescribed drugs as well as on other relevant health-related aspects.
4. Reflection: The participant is invited to reflect on the information presented in order to ensure that they have understood the information and reinforce their understanding of the possible risks.
5. Normative: The CHWs will show how the individuals' level of alcohol consumption compares to the general population, and the benefits they could obtain from reducing their alcohol intake.
6. Construction: The CHWs and the participant will together develop a patient-centred plan to reduce alcohol consumption, based on an investigation of diverse aspects associated with their consumption (context and partners), suggestions for alternative activities or changes in their behaviour, guided by harm reduction strategies.
7. Booklet: At the end of the intervention, the participant will receive a booklet on alcohol and ageing, specially developed for this intervention, called 'Alcohol Consumption among Older Adults: a guide for a sensible drinking' that will reinforce the information discussed and be a supportive instrument for behavioural change.

Usual care

The control participants will be offered the standard care suitable for their condition, but will be offered the BIO protocol, as delivered to the intervention group, immediately after the 6-month follow-up.

Outcomes

Primary outcome

The primary outcome will be the proportion of participants considered at-risk drinkers, defined as those with an AUDIT-C score ≥4.[14]

Secondary outcome measures

Secondary outcomes will include alcohol consumption in a typical week in the last 30 days, in units per week, based on the self-reported number of drinks per week. The alcohol consumption will also be assessed by AUDIT. To ensure the accuracy of the information in respect of the amount of alcohol consumed, a card will be provided to help participants to calculate the corresponding number of units This can be found in online supplemental appendix 1. We will also examine cognitive performance assessed by a battery of cognition tests (Health and Retirement Study Harmonised Cognitive Assessment, HRSHCA), physical activity assessed by the International Physical Activity Questionnaire (IPAQ), the use of health services, depression assessed by Geriatric Depression Scale (GDS) and QoL assessed by Control, Autonomy, Self-realisation and Pleasure (CASP-16). Detailed information on these scales and tools is given below.

Screening

During the screening, with an estimated application time of 10 min, the following variables will be collected:

1. Sociodemographic data: sex, age, marital status, ethnicity, educational level and income.
2. General Health information: This includes general health data (previous and current diseases), including The Patience Health Questionnaire, which consists of two items asking about the frequency of depressed mood and anhedonia over the past 2 weeks.[15 16] It also includes questions about substance use, such as drugs for sleep disorders and anxiety, illicit drugs (eg, cannabis, cocaine/crack), tobacco and indirect questions about alcohol consumption in a typical week.
3. AUDIT-C (short version) will be used as an instrument for quantifying alcohol consumption. The AUDIT-C encompasses items 1 to 3 from the original 10-item AUDIT, addressing specifically alcohol consumption. Each AUDIT-C question is scored on a 0–4 scale, resulting in a total score ranging from 0 to 12 points.[17] Studies on the validation of AUDIT-C for older populations indicated a sensitivity of 94% and a specificity of 80% when using a score cut-off of 4.[14] We adapted the third question on binge drinking. Specifically, in our trial, we use the question 'How often have you had five or more units on a single occasion in the last month?' for male and 'How often have you had four or more units on a single occasion in the last month?' for women to identify binge drinking behaviour.[18]

Baseline and follow-up assessments

1. Service use questionnaire: use of public and private medical services and medications. The use of public

and private services refers to medical care and other health services in the last 3 months.[19] The medications investigated will be: analgesics and anti-inflammatory drugs, antacids, hypnotics and anxiolytics, vasodilators, anticoagulants, antidiabetics, antihypertensive, antihistamine and antiallergic medications. Understanding how the utilisation of services is modified by the intervention is essential to demonstrate the potential of BIO in health systems.

2. The IPAQ will be used to measure physical activity. The IPAQ was translated and validated for the Brazilian population.[20] This instrument contains questions related to the frequency (days per week) and duration (minutes per day) of physical activities performed in the week prior to the interview, considering only those performed for at least 10 continuous minutes at a time, including (1) walking; (2) moderate activities and (3) vigorous activities. The co-occurrence of positive health behaviours is a well-known phenomenon. We hypothesised that older adult participants involved in a behavioural change programme such as the BIO might also engage in additional healthy behaviours, such as exercise and social engagement; thus, increasing physical activity.
3. AUDIT will be used as a tool to measure alcohol consumption. The AUDIT consists of 10 questions addressing alcohol consumption in the last 12 months. Besides questions 1–3 that are focused on at-risk drink (questions 1–3), AUDIT also includes questions on dependency (question 4–6) and harmful drinking (questions 7–10), according to ICD-10 criteria. The maximum score is 40 points, with non-older adult participants with scores of 8 or higher being considered at risk drinkers.[21 22] For older adults, this cut-off is 4 or more points.[14]
4. Alcohol intake is an important risk factor for cognitive impairment in older adults, thus the HRSHCA.[23] It will be used to assess memory (self-rated memory, orientation in time, word-list learning, prospective memory, names of people and things) and executive function (word-finding/verbal fluency).
5. The CASP-16 scale will be used to evaluate QoL. CASP-16 is a well-established measure of the quality of later life and comprises 16 items in four domains: control (C)—four items, autonomy (A)—five items; self-realisation (S)—four items and pleasure (P)—three items. The CASP-16 was validated in Brazil, and demonstrated good psychometric properties as well as adequate internal consistency. CASP-16 has proved to be easy to apply, comprehend and interpret to evaluate QoL among older Brazilians.[24] Pragmatic interventions like the one tested here have changed their focus from not only preventing major health problems, but also to improving the QoL among older adults. Therefore, QoL assessments are of fundamental importance in capturing the full impact of BIO; thus, allowing a more in-depth understanding of the potential of this intervention in old age.
6. Depression symptoms are commonly associated with alcohol consumption, therefore the GDS[25] will be employed to investigate the effect of BIO on the depression symptoms of the studied participants. The (GDS) will be used to evaluate depression symptoms. It is one of the most applied instruments for screening depression among older adults. The GDS-15 is quick to apply, and the ideal cut-off point is ≥4 points (range 0–5). A validation study showed a high reliability and internal consistency in a Brazilian population indicating a sensitivity of 86.8% (95% CI 71.1% to 95.1%) and a specificity of 82.4% (95% CI 75.9% to 87.5%).[26]

The data quality assurance will be performed by comparing key variables obtained at baseline with the same information obtained at follow-up (eg, marital status, education, family financial support, among others). The questionnaires applied at baseline and follow-up have an estimated application time of 25–30 min.

Participant timeline

Table 1 shows the participant timeline for enrolment, assessments, interventions and follow-up.

Sample size

We assumed that 95% of the participants in the waiting-list group would continue to be classified as at-risk drinkers 6 months after randomisation (eg, a 5% absolute reduction rate). Besides, based on previous studies,[27] we hypothesised that the brief intervention would result in a 13% risk difference in the rate of older adults at-risk drink (95% vs 82%).

Thus, allowing for a potential 10% dropout rate we calculated that 121 participants per group (a total of 242) would be required to give the trial 80% power to detect this difference assuming a type-I error of 5% (two tailed).

Recruitment of patients

All those over 60 years old attending the PCUs during the study period will be invited to participate.

Randomisation

Patients selected following screening will be randomised through a computer-based 1:1 allocation sequence generated by an investigator not involved in patient recruitment, treatment and/or follow-up. The random allocation will be performed by block randomisation, with random block sizes of 2, 4 and 6 patients. Random numbers will be generated with Stata V.16 (StataCorp).

Allocation concealment

We will use sequential numbered opaque sealed envelopes. For this trial, envelopes will be labelled with a deidentified number for each patient. After consent, the investigator will open the sealed envelope and will assign the treatment group accordingly.

Blinding

Given the inherent open-label design of this trial, only outcome assessors will be blinded to treatment allocation.

Table 1 Timeline for enrolment, assessments, interventions and follow-up

	Study period				
	Enrolment	Allocation	Postallocation		Close-out
Time point			Baseline	Follow-up (6 months after)	
Enrolment					
Eligibility screening	X				
Informed consent	X	X			
Allocation		X			
Intervention:					
Brief intervention for older adults			X*		
Assessments:					
Baseline 1. Sociodemographic 2. General health. 3. Alcohol consumption.	X		X	X	
Outcome 1. Service and medication use. 2. Physical activity. 3. Problems related to alcohol consumption. 4. Cognitive function. 5. Quality of life. 6. Depression.			X	X	

*The brief intervention for older adult at-risk drinkers will be offered at baseline for the intervention group and after 6 months from randomisation for the control group (wait-list group).

Baseline and follow-up assessments will be conducted by trained investigators not involved in the intervention and without any knowledge of the participant's allocation group.

Data collection

Screening interviews will be performed daily at the PCUs until the planned sample size is reached. Participants will respond to a brief screening questionnaire administered by a trained researcher and will be informed about the objectives of the trial. Those meeting the inclusion criteria and who agree to participate will be asked to provide written consent, and will be randomly allocated to one of the study groups. Assessments will be conducted during the screening of eligible participants, at the baseline and at the 6-month follow-up.

Training of CHWs

The CHWs from each selected PCU will be trained to apply the BIO. At least two CWH from each PCU will be trained. Training will be standardised and delivered by experienced researchers with a clinical psychology background. The CWH training on the intervention included information about the specific characteristics of the older adults, namely: reasons for older adults to drink; how to avoid barriers and improve rapport with older adults (avoid stereotypes and social stigma); understanding the physical effects of alcohol on older adults; and recognising factors related to the risks of alcohol consumption in older adults. Please see online supplemental appendix 1. The training will be carried out by region (north and east, respectively). For this trial, we developed customised teaching material on the BIO as well as an educational booklet addressing alcohol and ageing information (details in online supplemental appendix 2). We will employ rapid learning methodologies, involving two brief sessions aiming at providing CHWs with the opportunity to not only assimilate the theoretical contents, but also the possibility to practice the learnt techniques. During the trial, CHWs will be monitored by experienced investigators every five patients. When necessary, retraining and re-evaluation will be performed on a case-by-case basis.

Training of interviewers (baseline and outcome assessors)

The screening interviews will be performed by trained interviewers, who will be blinded to the random sequence list. Interviewers will be trained via a structured training protocol with a 10-hour duration and will be overseen by senior personnel. Training will combine theoretical content as well as practice activities, including simulated cases.

Retention strategies

We will employ various strategies to ensure high retention rates at the 6-month follow-up. We will ensure that participants provide multiple contact information (eg, mobile and landline telephone numbers, addresses, whenever available). We will also obtain the contact details of family members, whenever possible. Participants will also receive calls and/or text messages to remind them about the

Table 2 SAP, statistical analysis plan

Variable name	Variable type	Statistical analysis	
		Baseline between group comparison	Time point (follow-up) between group comparison
Primary outcome			
Proportion of participants considered at-risk of drink. (AUDIT-C)	Binary	–	GLM (Family=Poisson, Link=log, variance estimator=robust)
Secondary outcomes			
Alcohol consumption in one typical week in the last 30 days (units/week)	Continuous	Unpaired Student's t-test	GLM (Family=Gaussian, Link=identity)—adjusted for the baseline levels of the dependent variable.
AUDIT points 0–40	Continuous	Unpaired Student's t-test	GLM (Family=Gaussian, Link=identity)—adjusted for the baseline levels of the dependent variable.
Patience Health Questionnaire Points 0–6	Continuous	Unpaired Student's t-test	GLM (Family=Gaussian, Link=identity)—adjusted for the baseline levels of the dependent variable.
Geriatric Depression Scale Points 0–15	Continuous	Unpaired Student's t-test	GLM (Family=Gaussian, Link=identity)—adjusted for the baseline levels of the dependent variable.
Control, Autonomy, Self-realisation, Pleasure 0/48 (no QoL/total satisfaction in all domains)	Continuous	Unpaired Student's t-test	GLM (Family=Gaussian, Link=identity)—adjusted for the baseline levels of the dependent variable.
International Physical questionnaire duration (minutes per week)	Continuous	Unpaired Student's t-test	GLM (Family=Gaussian, Link=identity)—adjusted for the baseline levels of the dependent variable.
Health and Retirement Study Harmonised Cognitive Assessment	Continuous	Unpaired Student's t-test	GLM (Family=Gaussian, Link=identity)—adjusted for the baseline levels of the dependent variable.

AUDIT-C, Alcohol Use Disorders Identification Test-Consumption; GLM, generalised linear models; ;QoL, quality of life.

upcoming follow-up interview, or the intervention session for those allocated to the waiting-list group.

Data analysis

Data analysis plan

Data will be expressed as mean (SD), median (IQR) or counts (percentage) as appropriate. Demographic and clinical characteristics of participants will be compared between groups (intervention vs waiting-list) using the unpaired Student's t-test for continuous variables, whereas dichotomous variables will be tested using Fisher's exact test and its generalisations for 2xk tables. The data analysis plan is summarised in table 2. We opted to use a modified Poisson regression model for the primary outcome, because this approach allows the estimation of the relative risk via generalised linear modelling.[28] Missing outcome data will be handled via multiple imputations separately by group according to the previous recommendations.[29] Multiple imputation models will assume that data are missing at random and will be based on regression-based methods. A total of 100 data sets will be generated. A burn-in composed of 500 iterations will be adopted. Statistical significance will be set at the 5% level (two tailed). All data analyses will be performed using the Stata V.16 package (StataCorp).

Subgroup analyses

No subgroup analyses or adjustments are planned. No interim analyses and stopping guidelines will be employed.

Ethics and dissemination

This study has been approved by the Ethics Committee of the Universidade Federal de São Paulo, CEP/UNIFESP Project n: 0690/2018; CAAE: 91648618.0.0000.5505. All eligible participants will provide informed consent prior to randomisation.

Data sharing plan: All individual participant data related to the results of the publication can be shared. The final dataset shared will include: data archive; study protocol; statistical analysis plan and analytical code. The data will be allocated in the public research data repository from UNIFESP—Dataverse (https://repositoriodedados.unifesp.br/) and will be available starting 6 months after publication.

Dissemination plan: After the completion of the trial, seminars involving relevant local and national stakeholders will be conducted to disseminate the study findings. If results prove to be clinically significant in favour of the intervention, evidence synthesis reports will be

developed to guide Brazilian policy-makers in designing and preparing similar nationwide initiatives. All results will be communicated in major international scientific conferences and submitted for peer-reviewed journals of international repute and visibility.

Protocol amendments

Any changes in the trial protocol or amendments in the secondary outcomes will be explicitly mentioned to all relevant parties, including the trial registry and peer-reviewed journals.

DISCUSSION

Population ageing is rapidly accelerating in many LMICs and challenging their current health systems. Interventions to reduce alcohol consumption specifically designed for older adults are already scarce, and interventions designed for adults or mixed-age groups may fail to take into account the unique physical, psychological and cognitive features of ageing. Given that health systems in LMICs have less resource than those in high-income countries, their populations are ageing rapidly, and harmful alcohol use among older adults is often a significant problem the use of brief interventions could be a cost-effective way to address this problem. However, there are only a few studies showing that brief interventions can successfully reduce alcohol consumption among older adults when compared with other more complex interventions. However, these studies were conducted in high-income countries. The aim of this study, therefore, will be to use a clinical trial to assess the potential benefits of a brief, low-cost intervention that could easily be implemented in primary care, and incorporate specialist services if necessary. If the brief intervention proves to be effective in our trial, we plan additional analyses involving cost–utility and the budgetary impact from the point of view of the Brazilian public health system, which is why the service use questionnaire was included at this stage.

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Correction notice Funding statement has been added.

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Contributors TCSP, TVP and CF led the proposal and protocol development. TVP was the lead trial methodologist. ARN was responsible for obtained funding. CC, ARN and MLSF contributed to the development of the methodology and study protocol. All authors contributed to its critical review and read and approved the final draft.

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