Community-based alcohol education intervention (THEATRE) study to reduce harmful effects of alcohol in rural Sri Lanka: design and adaptation of a mixed-methods stepped wedge cluster randomised control trial

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ABSTRACT

Introduction Alcohol consumption is a leading cause of mortality, morbidity and adverse social sequelae in Sri Lanka. Effective community-based, culturally adapted or context-specific interventions are required to minimise these harms. We designed a mixed-methods stepped wedge cluster randomised control trial of a complex alcohol intervention. This paper describes the initial trial protocol and subsequent modifications following COVID-19.

Methods and analysis We aimed to recruit 20 villages (approximately n=4000) in rural Sri Lanka. The proposed intervention consisted of health screening clinics, alcohol brief intervention, participatory drama, film, and public health promotion materials to be delivered over 12 weeks. Following disruptions to the trial resulting from the Easter bombings in 2019, COVID-19 and a national financial crisis, we adapted the study in two main ways. First, the interventions were reconfigured for hybrid delivery. Second, a rolling pre-post study evaluating changes in alcohol use, mental health, social capital and financial stress as the primary outcome and implementation and ex-ante economic analysis as secondary outcomes.

Ethics and dissemination The original study and amendments have been reviewed and granted ethical approval by Rajarata University of Sri Lanka (ERC/2018/21—July 2018 and February 2022) and the University of Sydney (2019/006). Findings will be disseminated locally in collaboration with the community and stakeholders. The new hybrid approach may be more adaptable, scalable and generalisable than the planned intervention. The changes will allow a closer assessment of individual interventions while enabling the evaluation of this discontinuous event through a naturalistic trial design. This may assist other researchers facing similar disruptions to community-based studies.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ The preregistered trial protocol evaluated the scale-up of a piloted context-specific multifaceted intervention; the new less intensive approach may be more generalisable but likely less effective and/or acceptable.
⇒ The study modifications are relevant to both trials and community-based interventions disrupted by the pandemic and its sequelae.
⇒ The delivery of educational entertainment materials on reducing harms from alcohol online may be difficult in rural settings where internet coverage is poor. Using community advocates from the villages may enhance the uptake of the intervention.
⇒ The mixed-methods nested cohort study takes advantage of our extensive pre-COVID-19 baseline assessment, eliminating recall bias in evaluating a naturalistic public health intervention, enhanced with pre-existing extensive routine data surveillance.
⇒ Evaluating such interventions will directly relate to other interventions in lower-middle-income community settings.

INTRODUCTION

Alcohol is in the top five causes of disability and death worldwide, contributing to more than 1 in 20 (5.9%) deaths globally, 17% of
deaths from unintentional injuries and 16% of gastrointestinal deaths. South-East Asia has the second highest rate of harm per litre of alcohol globally (after Eastern Europe). Sri Lanka’s per capita consumption of legally produced alcohol has quadrupled between 1980 and 2003 (1.8 L vs 7.37 L, per person). These figures underestimate actual levels as up to half of the alcohol consumed in rural areas of Sri Lanka is the illicitly produced spirit ‘kasippu’. Illicit alcohol largely falls outside the scope of established regulation approaches used in high-income countries, such as taxation, pricing, marketing and limits on availability and requires alternate approaches.

In rural Sri Lanka, the medical sequelae of excess alcohol use are predominantly confined to men. A national cross-sectional study from 2014 showed that currently women drinking at 1.2% and men drinking at 48.1%. Alcohol-related cirrhosis cases, accidents and deaths are well documented in Sri Lanka. The cirrhosis mortality rate of 33.4 per 100,000 men is among the highest globally, over double the rate of 14.1 in the UK. In lower middle-income countries, including Sri Lanka, alcohol is linked with road traffic and other injuries. Sri Lankan injury rates are high, with an annual mortality rate of 177 and disability rate of 290 per 100,000 people (about threefold higher than the global average). The broader psychosocial and culturally deleterious impacts are also borne by others, including family violence, female mental ill-health and poverty. Alcohol consumption is strongly linked with Sri Lanka’s high annual incidence of suicide (14.2 per 100,000 in 2019) and deliberate self-harm (346 per 100,000). Thus, the burden from harmful use of alcohol requires interventions that not only address individual drinking but also consider the harms that drinking causes to others.

Interventions targeted for, and integrated into local village cultural contexts, as seen in rural villages, may be more effective than interventions designed for urban settings or applied in less integrated and more dissociated higher income communities. For instance, community-initiated fines for illicit alcohol have been successful in an Indian village, and family-based interventions in Indigenous communities have been shown to be effective (eg, Australia, Canada, Aotearoa/New Zealand).

Pilot intervention
In 2010, we completed a controlled pilot study examining the effect and acceptability of a multimodal community alcohol education intervention. The intervention comprised a series of traditionally based street dramas with a poster campaign and leaflets on alcohol harms, and a brief individual intervention for at-risk drinkers, identified using the Alcohol Use Disorders Identification Test (AUDIT). The dramas provided messages about consequences for individuals, families and society from harmful alcohol consumption and the positive gains from reducing consumption. A significant (30%) reduction in the median AUDIT score and improvement in all AUDIT categories were seen in the intervention village (male n=121) but not in the control village (male n=125) at 6 months and sustained at 24 months. Illicit alcohol consumption was reduced in the intervention village from 50.4% at baseline to 11.1% of drinkers at 6 months, and 0% at 24 months. In addition to reducing male alcohol use, there was a significant improvement in female depression symptoms in the intervention village. After 5 years, focus groups reported that the restoration of village social structure and changes in drinking norms had been sustained (unpublished data).

Our pilot study provided remarkable and sustained change from a targeted community-level intervention in a village where harmful use of alcohol consumption was a problem. The intervention appeared to offer individual, family and community-level benefits and suggested that it was important to determine whether it was feasible to deliver this on a larger scale.

Initial research question
Could we scale up a community-based alcohol education programme to reduce alcohol use and associated harms in villages with problematic alcohol use in rural Sri Lanka?

METHODS AND ANALYSIS
Pre-COVID study design (2018–2020)
We originally designed a mixed-methods stepped wedge cluster randomised trial (swRCT) of community-based alcohol education and community mobilisation intervention to reduce negative impacts from alcohol across 20 villages (figure 1).

The stepped wedge design was selected as it is feasible to roll out sequentially, locally more acceptable, as all communities receive the intervention, and allows for two comparisons: (1) between villages randomised to control time versus intervention time and (2) preintervention and postintervention comparisons for each village. The stepped wedge design has become a favoured design for complex intervention trials but requires attention to study timing, cluster equivalence and uptake of the intervention.

Setting and recruitment
The study is based in a rural area in the North Central Province of Sri Lanka (figure 2). The villages were selected from within the six District Secretariats that were identified as ‘high risk’ for alcohol-related harm based on findings from previous studies. Qualitative work from these studies highlighted two problematic drinking patterns: daily drinking and solitary drinking.

Village selection
The prevalence of drinking patterns was ascertained in a cross-sectional survey of 8800 households from 162 villages of the ‘Safer storage of Agrochemicals’ study. Villages were identified as ‘high risk’ for alcohol by using a weighted sum of three variables from the surveys: solitary drinking, daily drinking and problems related to
alcohol. A cluster (village) percentile was created for each variable, and then the cluster (village) was categorised into high, medium, and low tertiles for each domain. The three variables were then summed in ArcGIS to identify clusters (villages) at the highest risk. A cut-off score of 9 out of a possible 12 was used to determine the 30 highest risk villages.

Cluster randomisation
The 30 high-risk villages were stratified according to population size (<600, 600–999, ≥1000). Villages were randomised (for order of implementation), within each stratum, by a masked study statistician (JR), and then each village was approached for consent. The baseline assessments and subsequent intervention were initially rolled out in the smaller villages (in random order), then the medium, and then larger villages to hone logistics. Enrollment of villages was to continue until the target number of 24 villages, calculated as likely to enable meeting sample size requirements, was reached.

Village consent and enrolment procedures
Field supervisors initially contacted the District Secretariat (local government unit) and Grama Niladhari (the smallest local government area, typically a village) to introduce the study and gain consent from the authorised representative to (a) approach households in the village and (b) use village data from routine health and social sources. Research officers employed by the project contacted each household in the area to publicise the free health clinics (eg, including time, date and clinic location). This invitation was prompted by letters delivered to each household offering a brief introduction to the clinic and the study. Presentations at village society meetings such as the Farmers Association, Funeral Society and other local regular meetings also promoted the clinic.

Individual participant recruitment and consent
In the individual stage, any villager attending the free medical clinic had the study explained to them by a research officer (not the clinic medical officer) and was asked for consent to participate and for collection of their health data. As this may underascertain hazardous drinkers, who might be unwilling to attend a clinic, recruitment was supplemented by a complete door-to-door household survey where informed consent and baseline data were sought from each residing adult (>18 years old) who had not attended the clinic.

Inclusion criteria
The inclusion criterion for this study was being an adult (age ≥18) and living in the selected villages.

Exclusion criteria
Individuals were excluded from the study if they had (1) evidence of cognitive impairment identified at the baseline clinic/survey that precluded informed consent, measurement completion or (2) factors likely...
to prevent attendance at later clinics or exposure to the intervention (eg, temporary resident, contract for impending overseas work). Lists of household members of the villages were compiled during the household survey.

**Intervention: pre-COVID**

The intervention was adapted from the pilot study to be scaled up guided by behaviour change theory. The multifaceted intervention consisted of the following components:

**Individual level**
- Free health and well-being check clinic delivered by locally qualified medical officers.

**Community level**
- Four community drama performances to be delivered over 11 weeks.
- Health promotion materials.

In each village, the intervention was to be delivered over 12 weeks. All villages would eventually receive the intervention within 1 year.

**Health and well-being check clinics**

The first ‘baseline’ clinic provided a general health check. Attendees with acute health conditions were triaged to the local hospital. Attendees were assessed for risky alcohol use and depressive symptoms using the Sinhala versions of the AUDIT and Patient Health Questionnaire (PHQ-9), respectively. No intervention was provided in response unless a life-threatening condition was found. These clinics took place during the baseline phase (Figure 1).

In the second ‘intervention’ clinic 6 months later, in addition to the general health check and screening, defined intervention /and/or referral pathways were planned for people returning positive screening scores for alcohol (≥7 on the AUDIT) and/or depressive symptoms (≥10 on PHQ9, or scoring >1 on the item assessing suicidality). These thresholds have been validated in Sri Lankan settings. The brief alcohol interventions were to be delivered by research staff trained in the WHO alcohol brief interventions (ABIs), using the training manual used and promoted by the Sri Lankan National Alcohol and Tobacco Authority. The researchers were trained and assessed for fidelity by a senior clinician involved in the study. The ABI had been adapted to the

![Figure 2](https://example.com/figure2.jpg)

**Figure 2** Study location and cluster selection for THEATRE study. THEATRE, Theatre-based Harm-reduction Education about Alcohol Trial in Rural Environments.
context by local investigators, according to the following AUDIT thresholds:

- AUDIT 7–15: a simple visual handout on alcohol risk and harm reduction strategies.
- AUDIT 16–20: as above, plus brief individual alcohol intervention
- AUDIT >20: as above, plus referral to local services.

Individuals who scored above 10 on the Sri Lankan version of the PHQ-9 or were deemed as a potential self-harm risk (based on PHQ-9 question nine and/or medical officer clinical judgement) were to be managed through local clinical protocols developed to support staff assessing and managing depression and suicide (online supplemental appendix 1).

Community drama

The participatory dramas used in the pilot study provided messages about the consequences for an individual, family and society due to risky alcohol consumption and the positive gains from reducing consumption. We aimed to deliver a series of four drama performances over 12 weeks incorporating these messages. The dramas were to be promoted during the intervention clinics, household interviews and by key informants. Each drama focused on different aspects of the risks and responses to alcohol use.

Alcohol-related health promotion materials

Local research staff and faculty from collaborating universities adapted posters, pamphlets and other alcohol-related information materials (see online supplemental materials S1). Posters were to go up at the time of the intervention (6-month) clinic. Pamphlets and alcohol-related information would have been distributed to individuals or households during clinic or household visits.

Outcomes—pre-COVID

Personal data were to be collected via interview at baseline, 6-month intervention clinic and 24 months. At baseline and 24 months, measures of financial stress and social capital would have been additionally undertaken. The data analysis plan was to be preregistered prior to the analysis. The outcomes of interest include individual consequences of drinking and impact of drinking on others, including female depression, social capital and financial stress and routine indicators of family and community-level health.

Individual level

Alcohol use: the AUDIT (Sinhala version) is a 10-item screening tool developed by the WHO to identify adults at risk of alcohol harm, scored 0–30.

Depressive symptoms: the PHQ-9 is a 9-item depression scale with a translated, validated version that can be used to provide both a scale score (0–27) and a dichotomous approximation of Major Depressive Disorder. The PHQ-9 and AUDIT questionnaires have been validated for the Sri Lankan setting or undergone cognitive validation.

Social capital: the Social Capital Survey is an 18-item Sinhalese language scale examining trust, cognitive, structural, participation and collection action dimensions of social capital, developed and validated in the study area.

Financial stress: the Financial Stress Survey is a 17-item questionnaire adapted from a similar tool developed in a rural Asian setting. The questionnaire focuses on two components: financial shortfall to cover essential items and support sought to cover living expenses.

Village level

Routine health data on harms were prospectively collected from local hospital medical records (eg, alcohol-associated injury; deliberate self-harm, road accidents, hospital presentations with domestic and interpersonal violence, sexual assault, and alcohol withdrawal) starting at the time of the baseline clinic in that village.

Routine data from police reports were to be collected retrospectively at the completion of the study on secondary outcomes aggregated at the village level: domestic and interpersonal violence, alcohol-related road traffic crashes, suicide and illegal alcohol sales and public drunkenness.

Analytic and sample size approach—pre-COVID

The primary outcome of the swRCT was to be the change in individual alcohol use between at-risk (AUDIT≥7) and not-at-risk levels (AUDIT<7) at 24 months. Sample size calculations were modelled at detecting a reduction in the proportion of at-risk adult male drinkers, using an average sample of 105–145 (in increments of 10) adult men per village, with an assumed proportion of 0.25 adult men per village having at-risk AUDIT scores at baseline. Calculations at various estimates of the intraclass correlation (ICC) with the Power and Sample Size software package indicated that, when aiming for the power of 80%, at an ICC of 0.1, 23 villages could detect an absolute reduction of 10% (to 0.15) for 145 adult men per village, and 24 villages could detect the same change for 135 adult men per village, with these values improving (notably, the ability to detect this change at smaller average village sizes) as the ICC increased.

Secondary outcomes were to be reductions in the PHQ-9 scores and proportion categorised as mild depression or worse (PHQ≥5) and improved social capital and financial stress scores at the individual level. Aggregate village-level outcomes were a reduction in alcohol-related injury as measured by: legal outcomes, road accidents, domestic/interpersonal violence, sexual assault, public drunkenness and medical outcomes (eg, reduction in hospital presentations with deliberate self-harm/suicide, liver failure and alcohol withdrawal).

Implementation and process data—pre-COVID

We were to undertake a detailed and generalisable implementation analysis. The effect of variation of implementation in villages was a further unit of analysis. We intended to include a range of measures based on the RE-AIM framework (Reach, Effectiveness, Adoption,
Implementation and Maintenance). This framework focuses on five dimensions of implementation: Reach, Effectiveness, Adoption, Implementation and Maintenance. Mixed methodologies were planned to explore dimensions of the framework and allow robust reporting of implementation variables.

**Economic evaluation—pre-COVID**

A modelled economic evaluation was to be carried out to assess the cost-effectiveness of the intervention from a societal perspective. Following a standard approach, the proposed evaluation is in online supplemental material S2.

### Table 1 Characteristics of original THEATRE recruitment sample and baseline data

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<tr>
<td>Severe (≥20)</td>
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AUDIT, Alcohol Use Disorders Identification Test; PHQ-9, Patient Health Questionnaire; THEATRE, Theatre-based Harm-reduction Education about Alcohol Trial in Rural Environments.
Study progress prior to COVID pandemic

The first village was recruited in December 2018. In January 2020, the first cases of COVID-19 were detected in Sri Lanka. At this point, all 24 villages and 6868 villagers had been recruited through participation in either the baseline health check clinics or household survey, although with some delays due to political unrest and public control measures following the Easter bombings of 2019, effectively completing the baseline data set. In February 2020, island-wide curfews were imposed since when the banning of public gatherings and implementation of further curfews have continued periodically with new waves of infection. As a consequence, none of the originally planned interventions was able to be implemented. The following baseline data had been collected from 6868 adult participants (table 1). These data confirmed our estimates of the likely proportion of men who were categorised as ‘hazardous drinking’.

As a result of COVID-19, the research group undertook study design and intervention modifications to enable the trial to continue.

Post-COVID design, intervention and evaluation modifications (2022–2023)

Trial design modifications

The modified interventions will now be delivered sequentially to villages, as and when allowed by local restrictions. As this disrupts the timing required for the stepped wedge design and the ability to randomise, the swRCT design was abandoned in favour of a rolling pre–post study evaluating changes in outcomes within individuals and at an aggregate level in villages (figure 3). The number of villages to be recruited for the intervention was reduced from 24 to 15 due to the changes to the design (requiring a low sample size), time scales and funding implications of the prolonged delay due to COVID-19. The 15 villages were purposively selected to maximise heterogeneity including size, location, accessibility and presence of high-risk drinkers assessed at baseline. Further details of the characteristics of the 15 villages are available in online supplemental materials S3.

Intervention modifications

The prolonged and uncertain length of restrictions on public gatherings forced us to redesign the intervention, particularly in rural settings.

**Individual level:** the originally proposed 6-month and 12-month community health intervention clinics were abandoned and replaced by non-medical research staff conducting household surveys including measurement of AUDIT and PHQ-9 scales. Brief alcohol interventions and information will now be delivered by trained research staff to household participants who meet the risk thresholds previously described for the intervention clinic.

**Village level:** drama materials have been modified to enable hybrid delivery, utilising postal and online (m-health) delivery of the community drama components, supported by local community advocates. There is evidence of the effectiveness of m-health interventions for alcohol and substance use, although there are limited studies from low and middle-income countries.

The four proposed dramas have been converted to three films and a graphic novel. These will be delivered or accessible online, on four occasions over 12 weeks.
with the same original sequencing. They will focus on the same themes but use varying script and characterisations. The participatory aspects of the original street dramas were intended to include opportunities for audience interaction. In the current context, we cannot fully replicate the whole village experience, but in each village, we will employ and train local villagers to promote the intervention, troubleshoot technical difficulties, gather people who have no internet access for viewings and encourage participation in online workshops provided in a similar fashion to moderated chat groups. We will run workshops online on story making, film and drawing to complement the materials we have developed. We will run competitions to motivate communities to engage in the materials, contribute their stories of change and cocreate compilations in each village. An award ceremony is planned for each village.

**Modifications to assessments and data collection**

In addition to the data collection measures mentioned above, we will use tools to measure specific aspects of the hybrid delivery. This will include online viewer metrics, questions that are content specific, assessing satisfaction and digital confidence. Additional qualitative interviews will be conducted to capture voices from study participants who both took part in the intervention and those who did not. These will be designed to measure knowledge, participation, feasibility and acceptability of the hybrid delivery, community readiness, barriers and facilitators for hybrid alcohol prevention measures. An outline of the Schedule of enrolment, interventions and assessments for THEATRE study is seen in **Table 2**.

Routine hospital outcome data collection was abandoned due to restrictions imposed on accessing hospitals and patients. Staff were required to confirm eligibility in the study village and this was not possible. The total follow-up time has now been reduced to 6 months after the commencement of the intervention in each village. A third and final household survey will collect health, social capital and financial stress data, complemented by an online survey of participants in the digital intervention who have consented to online follow-up. Pre–post analyses will be conducted using both the combined and stratified (by online participation) individual data, and the proportion of each village participating digitally used as a confounder in analyses of aggregate village data.

**Modified economic evaluation**

An ex-ante economic evaluation will be performed to assess the costs of the community-based multi-component complex community drama intervention programme and its potential for cost-effectiveness. Total programme costs will be estimated, together with a cost-effectiveness threshold analysis to assess the potential for cost-effectiveness. The analyses will be informed by the intervention implemented in the 15 villages, including the EQ-5D quality of life measure that has been validated for use in Sri Lanka. The ex-ante economic evaluation will follow the approach outlined by Damerow et al and is detailed in online supplemental material S4.

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</table>

AUDIT, Alcohol Use Disorders Identification Test; EQ-5D, EuroQol Quality of Life; PHQ-9, Patient Health Questionnaire; THEATRE, Theatre-based Harm-reduction Education about Alcohol Trial in Rural Environments.
Opportunisti
car nalistic trial of the effect of nationwide prohi

The onset of the COVID-19 pandemic and its sequelae led to both a curfew and the closing of establishments selling alcohol, both on or off-premises. This produced an effective prohibition on alcohol use, the only access being to illegally distilled spirits such as ‘Kasippu’. In May 2020, a further household survey was undertaken to evaluate the impact of COVID, curfew and prohibition on alcohol (misuse), depression, health, social capital and financial stress at the individual level. Routine data from police will enable an interrupted time series analysis evaluating the impact of the combined prohibition and COVID-19 on assaults, suicides, and road traffic injuries.

Patient and public involvement

The intervention was developed using a codesign process with the original village where the pilot study was undertaken. We developed the intervention materials based on their stories.

At recruitment, villages are contacted and informed of the research. Community mobilisation forms part of the intervention and locally recruited advocates will work with the research team to disseminate the materials and findings.

Ethics and dissemination

Ethics Review Committee, Faculty of Medicine and Allied Sciences, Rajarata University of Sri Lanka (ERC/2018/21) and the University of Sydney Human Research Ethics Committee (2019/006) reviewed and approved this protocol. The revisions to the protocol following the design modifications were reviewed and approved on 22 February 2022.

Dissemination activities are planned with the communities to share their contributions to stories of change and artworks. In addition, the results of the studies will be shared with local stakeholders and within academic journals and conferences.

DISCUSSION

We started the recruitment for the scaled up swRCT in December 2018. By December 2019, 24 villages and were recruited and baseline data commenced. In total, data on 6868 participants were collected, although with prolonged delays. The first delays were due to political unrest following a major terrorist attack in Sri Lanka that killed more than 290 people and injured many more on Easter Sunday in 2019. After the restrictions were lifted, village life largely returned to normal. The delayed original swRCT was to be implemented in 2020. Then, in January 2020, Sri Lanka had its first cases of COVID-19, and major restrictions were imposed on movements and gatherings. These two significant crises within 12 months during the recruitment phase of our trial prevented delivery of any of our interventions and created tremendous challenges to the trial’s successful implementation.

Following discussions with collaborators and funders, we modified our trial in two significant ways: the swRCT design of the trial and delivery of the intervention have been modified to reflect changed conditions in the villages. The trial no longer has a contemporaneous control group or randomisation. The substantial changes to the intervention require additional emphasis on evaluation implementation aspects. This will include the impact, accessibility and acceptability of the hybrid interventions (particularly the modified drama interventions). It is anticipated that the hybrid delivery may have advantages in generalisability to other settings and be scalable at a lower cost. The potential risks with significant online content are that people in a rural setting may not be able to access the materials. The use of community advocates will aim to mitigate these risks.

While these are pragmatic and necessary changes, the pre-post trial design, ability to hold together a skilled research team through difficult times, and the large pre-COVID baseline data collection, has also provided an opportunity to evaluate the impact of the pandemic and associated restrictions on everyday village life and the unique alcohol restrictions imposed in Sri Lanka. This can generate important insights from a rural community in an LMIC that may be transferrable to other similar country contexts.

Together this challenging period has provided opportunities to adapt a promising intervention, implement it in a changed context and better understand the influences on drinking brought about by the COVID-19 pandemic in Sri Lanka. The study should also result in a better understanding of cost-effective and community-wide approaches to reduce risky alcohol consumption that might be feasible both in Sri Lanka and in other regions, including low or middle-income countries.
CONTRIBUTORS

MP: writing—original draft (lead), conceptualisation (supporting), methodology (supporting), supervision (lead); AD: conceptualisation (lead), writing—original draft (lead); funding acquisition (lead); methodology (lead); JR: conceptualisation (supporting), writing—original draft (supporting); methodology (supporting); LS, PHGJP: writing—review and editing (equal); methodology (supporting); supervision (supporting); KC, KSKL, TR, SS, JBS, FK, SJ, ADJ, NB: writing—review and editing (equal); methodology (Supporting); RA, PS, PA: conceptualisation (supporting); CP: writing—review and editing (equal); supervision (supporting); PSH: writing—review and editing (equal); MD: project administration (lead); NG: conceptualisation (lead), writing—original draft (lead); funding acquisition (lead); methodology (lead).

FUNDING

This work was supported by NHMRC grant number 1146354 as part of the Global Alliance for Chronic Disease mental health projects (MH18). Sydney University provided additional funding under the DVC Support Fund for COVID-19 impacted research (G194173). KC was supported by an NHMRC Practitioner Fellowship (APP1117582). PH is supported by an MRF/NHMRC Practitioner Fellowship (MRF1155320). NG’s involvement was supported (partially or fully) by the Australian Government through the Australian Research Council’s Centre of Excellence for Children and Families over the Life Course (Project ID CE200100025).

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COMPETING INTERESTS

None declared.

PATIENT AND PUBLIC INVOLVEMENT

Patients and/or the public were involved in the design, or conduct, or reporting, or dissemination plans of this research. Refer to the Methods section for further details.

PATIENT CONSENT FOR PUBLICATION

Not applicable.

PROVENANCE AND PEER REVIEW

Not commissioned; externally peer reviewed.

SUPPLEMENTAL MATERIAL

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ACCESS

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REFERENCES

2 WHO. Global status report on alcohol and health World Health organization; 2014.


41 EuroQol Research Foundation. EQ-5D-3L user guide; 2018.

Administer AUDIT questionnaire

- Low Risk
  - AUDIT score 0-7
    - Public Health materials
    - Local support services list
    - Brief Intervention for Alcohol
    - Refer to local health services

- Increasing risk
  - AUDIT score 8-15
    - Public Health materials
    - Local support services list

- Harmful drinking
  - AUDIT score 16-19
    - Public Health materials
    - Local support services list

- Hazardous drinking
  - AUDIT score 20+
    - Public Health materials
    - Local support services list

Administer PHQ 9

- Low Risk
  - PHQ score 0-4
    - Public Health materials

- Mild to moderate risk
  - PHQ score 5-10
    - Local support services list

- Moderate to severe risk
  - PHQ score >10
    - Local support services list
    - Refer for psychiatric assessment
Community based alcohol health promotion materials

Posters, pamphlets and other information materials will be developed by local health promotion students and faculty from collaborating universities.

Poster content used in the pilot

- We don’t socialize to drink. We drink to socialize. (This was the poster that puzzled most village folk and had the most impact eventually)
- Drinking a little is fine, but it is the hard drinking that brings all the problems
- Drink half a quarter bottle of arrack; you are fine. But drink a quarter bottle of arrack, you are in trouble
- Drinking hard is tough on your body, isn’t it? Try drinking a little. You will only be jolly then
- Are you going to drink till your ear is in the pocket? Aren’t you in the pit then? (This idiom is common in rural areas to indicate drunkenness. There is no equivalent in English)
Supplementary materials 2

S2 Original Economic Evaluation

A Markov model was developed in which changes in alcohol consumption observed in the trial (intermediate outcome) will be extrapolated to long term costs and outcomes (survival and disability) in the study population. This will be done by identifying relevant alcohol consumption related events (e.g., hospitalisation for serious injury, depression and death) and the annual transition of individuals between these states (including death) over a lifetime. The probabilities of these transitions will be derived from the published evidence. Other parameters in the model will include: costs of the intervention, including training and materials estimated from financial statements; disability adjustment values associated with disease events drawn from published evidence; and costs of hospitalisation events derived from the trial data and published evidence. The model would enable lifetime accumulated costs and disability life years averted to be estimated for both intervention and control arms. When discounted at an appropriate rate, generate an estimate of the incremental cost per disability adjusted life year (DALY) averted. Probabilistic and multiple one-way sensitivity analyses will be carried out to account for uncertainty. The findings will be benchmarked against the standard threshold—an incremental cost effectiveness ratio of three times per capita gross national income per DALY averted—to determine whether the program is cost-effective.
Supplementary materials 3

### S3 Comparison of characteristics of baseline cohort and selected villages for resurvey

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<td>Adult (Females)</td>
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Supplementary materials 4

S4 Proposed Ex-Ante Economic Evaluation or Modified Intervention

The ex-ante economic evaluation will apply a two-year analytic horizon in line with the proposed implementation of the intervention. All analyses will be conducted from a governmental perspective using real-life conditions attributable to a Sri Lankan governmental agency responsible for future implementation. Research costs, costs borne by non-governmental stakeholders, and indirect costs such as productivity and tax losses will be excluded from the analysis. All costs will be expressed in 2022 US Dollars (USD).

Data collection Total Programme Costs (TPC) will be estimated using an ingredients approach to identify, quantify, and value required resource inputs in line with the program intervention model. All resource inputs will be assigned to cost categories (direct personnel, travel, catering, program administration, training materials and equipment, and communication). The valuation will be performed according to economic cost principles (opportunity costs). Tradable goods and services will be valued according to Sri Lankan gross market prices and salaries and wages according to locally customary remunerations, including fringe benefits, allowances and taxes. TPC will be estimated by totalling all resource input quantities multiplied by their unit values.

Data sources comprised key informant interviews supplemented by accounting data from the research study undertaken in the 15 villages, local price quotations and estimates from WHO’s Choosing Interventions that are Cost-Effective Project (WHO-CHOICE)(41). Sri Lankan Rupee (LKR) will be converted to USD based on official exchange rates obtained from the World Bank. Adjustments for inflation will be based upon consumer price index rates derived from the International Monetary Fund.

Time units across resource input items will be harmonized, assuming 17.7 monthly working days and eight daily working hours. Following standard practice, capital costs will be converted into equivalent annual costs (EACs), as were program start-up costs over the
imputed program lifetime [in line with WHO recommendations]. Following standard recommendations, discounting will be performed at an annual real discount rate of 3%. 
1. Study Management

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<th>Email</th>
<th>Telephone number</th>
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</tbody>
</table>

1.3 Statistician

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Email: Jacques.raubenheimer@sydney.edu.au

1.4 Internal Trial Committees

Trial Steering Committee
Andrew Dawson (Chair)
Melissa Pearson
Nicholas Glozier
Katherine Conigrave
Kylie Lee
Nicholas Buckley
Stephen Jan
Lalith Senarathna
Ranil Abeyesinghe
Indika Gawarammana
Jacques Raubenheimer
Monika Dzidowska
1.5 Independent Safety and Data Monitoring Committee

Safety and Data Monitoring Committee
Shaluka Jayamanne (Chair)
Michael Eddleston

Scientific Advisory Committee
Palitha Abeykoon (NATA: Co-Chair)
Prof Andrew Dawson (University of Sydney; Co-Chair)
Dr Chitramalie de Silva Director of Mental Health, Ministry of Health
Dr Suvendran WHO Sri Lanka
Dr. Sajeewa Ranaweera, Technical Consultant to the National Authority on Tobacco and Alcohol
Mr. D Mellawa - Deputy Commissioner General of Excise

1.6 Sponsor

International Sponsor: The University of Sydney
Local Sponsor, Sri Lanka: South Asian Clinical Research

1.7 Funding and sources

NHMRC Global Alliance for Chronic Diseases – Mental Health

4. ADVERSE EVENT REPORTING

a. Definitions

Adverse event
An adverse event for this study would arise in 3 possible scenarios
- Medical clinics - possible bruising resulting from the venepuncture. Additionally, there is the possibility of needle stick injury to staff.
- Community tensions - there is a possibility that tensions related to illegal alcohol production could be exacerbated by the intervention. This could create a safety risk to staff or participants
- Increased levels of community hazardous drinking or depression

b. Assessment and Documentation of Adverse Events

All potential adverse events will be documented by study personnel and highlighted to research manager within 24 hours. A report on the details and nature of events will be compiled in collaboration with local officials within one week or sooner for more serious events. The adverse events will be reported to the Trial Steering Committee and the Data Monitoring Committee. Local ethics committee will be notified of any serious adverse event.

c. Eliciting Adverse Event Information
Individuals or participants who highlight adverse event will be followed up by a senior member of staff. Consultation with local collaborators on the scope of information required will be undertaken before contacting individuals. Community adverse events will be monitored by local Provincial Health officials. Senior members of staff will work in collaboration with local officials to determine the scope of investigation required. Local collaborators will provide advice and support to reporting requirements.

5. USE OF DATA AND PUBLICATIONS POLICY

Strong links are maintained with the community during the trial and will provide a platform to engage the communities with the research outcomes. The links at village level with GN’s and Community Based Organisations will enable us to have a range of meetings to discuss the results of the trial. Through the Provincial Department of Health Services we will coordinate meetings with all hospital units to disseminate the findings. In addition, academic publications and presentations at local and international scientific meetings will be undertaken following the publication of results. We would expect significant dissemination in Sri Lanka through our collaboration with the National Authority on Tobacco and Alcohol this may include lay press and other media.

Authorising the use of data

All use of trial data including secondary analyses and publication has to be submitted to the trial’s Principal Investigator who will refer the request to the trial management committee or data safety and monitoring committee as appropriate.

Authorship and publication policy

The project’s general policies on authorship and is in line with the Australian Code for the Responsible Conduct of Research and the ICMJE Recommendations (previously known as “The Uniform Requirements” or “Vancouver Protocol”). Researchers should make sure that they adhere to the authorship policies of their institutions.

General principles

In accordance with the abovementioned guidelines, researchers have a responsibility to their colleagues and the wider community to:

- disseminate their research as broadly as possible, in a transparent and accurate manner
- take account of any restrictions relating to intellectual property, confidentiality, privacy or culturally sensitive data
- where possible/feasible provide research participants with an appropriate summary of the research results
- correct as soon as possible any misleading or inaccurate statements about their work, they if they become aware of such instances
- cite other relevant work appropriately when disseminating research findings
Authorship policy

To be named as an author, a researcher must have made a substantial intellectual contribution to the publication in one or more of the following aspects of the work:

- Concept development or design of the project
- Analysis and interpretation of the eligibility or suitability of potential subjects of research
- Analysis and interpretation of research data
- Drafting significant parts of the work or critically revising it in a way that contributes to the interpretation

The following types of involvement do not constitute basis for attribution of authorship:

- The position or profession of the author
- The existence of a personal relationship between the authors
- Whether or not a contribution was paid or voluntary
- The provision of materials or equipment
- The provision of access to study participants or data
- The provision of routine assistance in some aspect of the project
- The provision of, or assistance with acquisition of, funding for the project
- General supervision of the research team
- Having made the measurements on which the publication is based, without other intellectual input to the project or publication

Contributions other than authorship must be properly acknowledged. Such contributors include research assistants and technical writers.

Authorship management

This section describes the authorship procedures which should be adopted by all investigators publishing research results related to this research program. Authorship of a publication should be discussed and agreed upon as soon as possible, preferably prior to the publication being developed. A meeting should be convened to discuss the following aspects of authorship:

- Authorship attribution – who will be the authors?
- Authorship order
- Expected level of involvement and contribution
- Responsibilities of each author (e.g. workload division, nomination of corresponding author etc)
- Acknowledgements and affiliations

Permission should be sought in writing for inclusion or exclusion as authors from all those who qualify as authors according the authorship policy. Authorship meetings should be comprehensively recorded either by means of meeting minutes or a formal agreement template (if available) and distributed to all parties concerned as the official record of agreement.
A written record of subsequent correspondence/decisions regarding authorship, authorship order, acknowledgements of authorship relating to the project should be kept centrally along with all other essential study documentation and made available to persons concerned upon request.

Acknowledgement of the NHMRC

The NHMRC must be acknowledged on publications/presentations relating to work conducted in as part of the project. Recommended wording for general acknowledgements is as follows:

*This project is funded by the National Health and Medical Research Council (NHMRC), grant ID 1146354*

Recommended wording for acknowledgement in peer reviewed journal publications is as follows:

*This work was supported by an Australian National Health and Medical Research Council Project Grant (ID 1146354). The funder had no role in study design, data collection and analysis, decision to publish, or preparation of the manuscript.*
PARTICIPANT’S CONSENT FORM
RAJRATA UNIVERSITY OF SRI LANKA

STUDY ON ESTIMATING THE ROLE OF ALCOHOL IN RURAL SRI LANKAN INJURIES

Please circle your answer

Have you read the information sheet?

Yes/No

Did you have an opportunity to ask questions and discuss about the study?

Yes/No

Have you received satisfactory answers to the questions you asked about the project?

Yes/No

Who explained the study to you?

………………………………………………………………………………

Do you understand that you are free to leave the study without giving any reason?

Yes/No

Did you agree to take part on your own wish?

Yes/No

I understand that the information I give is confidential.

Yes/No

I give my consent to take part in the study and this will include:

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<th>Participant</th>
<th>AUDIT screening tool</th>
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<tr>
<td></td>
<td>PHQ 9</td>
<td>Yes/No</td>
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<td></td>
<td>Social capital questions</td>
<td>Yes/No</td>
</tr>
<tr>
<td></td>
<td>Blood test*</td>
<td>Yes/No</td>
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<td></td>
<td>Brief Intervention*</td>
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*Recommended by Medical Officer

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<th>Investigator(s)</th>
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<tbody>
<tr>
<td>Dr Lalith Senerathna</td>
<td>0777635254</td>
<td>Department of Health Promotion, Rajarata University of Sri Lanka</td>
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<tr>
<td>Prof. Sisira Sirribaddana</td>
<td>0252234462</td>
<td>Faculty of Medicine, Rajarata University of Sri Lanka</td>
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Name ............................................................
Signature ......................................................
Date ............................................................

Name of the witness .............................................
Signature ......................................................
Date ............................................................

If you have any complaints about this research or its conduct, please contact:
Secretary,
Ethics Review Committee,
Faculty of Medicine and Allied Sciences,
Rajarata University of Sri Lanka

Phone number: +94(0) 25 2053633 (please contact during working hrs 8 am – 4 pm)
E-mail: ethicsreviewcommittee@gmail.com