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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.

Trial registration The trial is registered with the Sri Lanka Clinical Trials Registry; https://slctr.lk/trials/slctr-2018-037.

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.[1 2] South-East Asia has the second highest rate of harm per litre of alcohol globally (after Eastern Europe).[2] 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).[3] 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'.[1 4] 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[4–7] and requires alternate approaches.[8]

In rural Sri Lanka, the medical sequelae of excess alcohol use are predominantly confined to men.[9 10] A national cross-sectional study from 2014 showed that currently women drinking at 1.2% and men drinking at 48.1%.[10] Alcohol-related cirrhosis cases, accidents and deaths are well documented in Sri Lanka.[11] 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.[12] In lower middle-income countries, including Sri Lanka, alcohol is linked with road traffic and other injuries.[13 14] Sri Lankan injury rates are high, with an annual mortality rate of 177 and disability rate of 290 per 100 000 people[15] (about threefold higher than the global average). The broader psychosocial and culturally deleterious impacts are also borne by others, including family violence,[16 17] female mental ill-health and poverty.[9 18 19] Alcohol consumption is strongly linked with Sri Lanka's high annual incidence of suicide (14.2 per 100 000 in 2019)[20] 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.[21]

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.[22] For instance, community-initiated fines for illicit alcohol have been successful in an Indian village,[23] and family-based interventions in Indigenous communities have been shown to be effective (eg, Australia, Canada, Aotearoa/New Zealand).[24]

Pilot intervention
In 2010, we completed a controlled pilot study examining the effect and acceptability of a multimodal community alcohol education intervention.[25] 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.[25] 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.[26] 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.[27 28]

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.[29 30] Qualitative work from these studies highlighted two problematic drinking patterns: daily drinking and solitary drinking.[9 31]

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.[30] 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
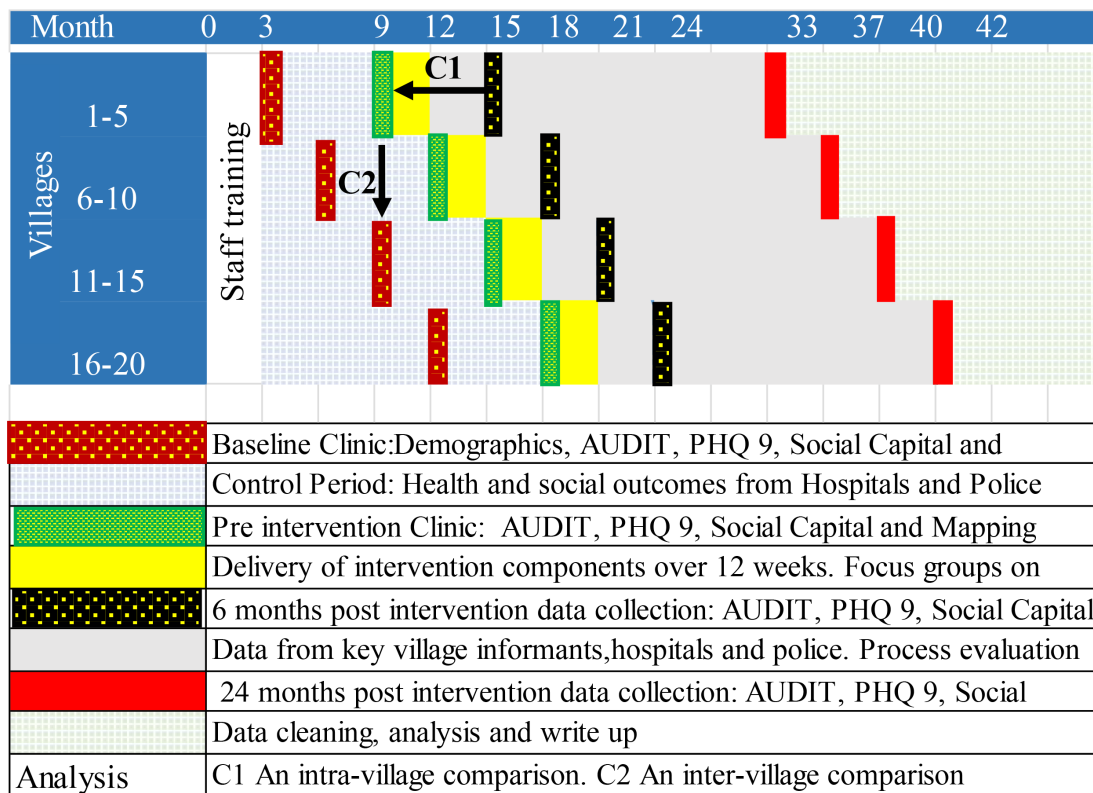
Figure 1 Original THEATRE intervention stepped wedge cluster RCT design and sequencing. AUDIT, Alcohol Use Disorders Identification Test; PHQ-9, Patient Health Questionnaire; RCT, randomised control trial; THEATRE, Theatre-based Harm-reduction Education about Alcohol Trial in Rural Environments.

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. Enrolment 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
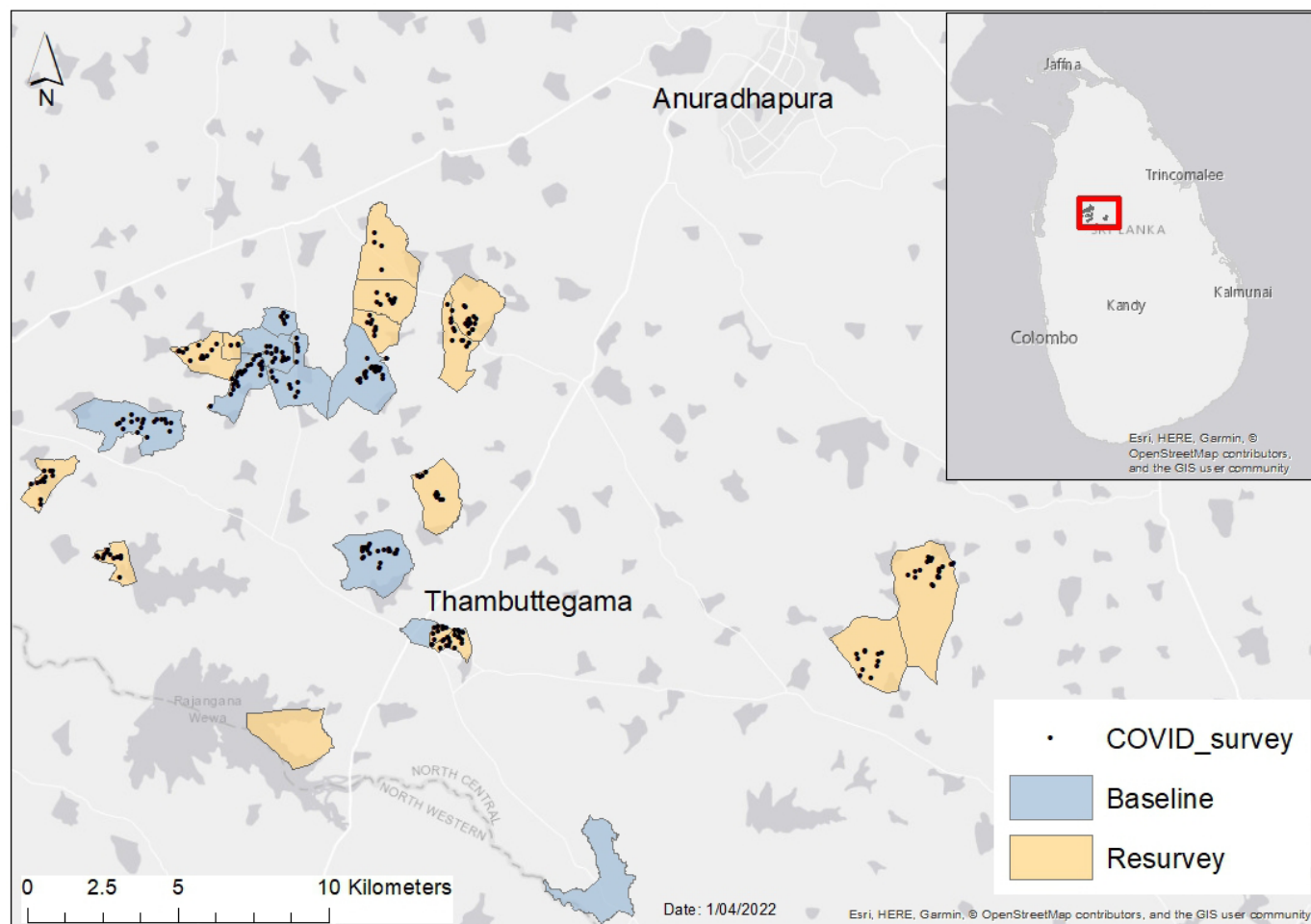
Figure 2 Study location and cluster selection for THEATRE study. THEATRE, Theatre-based Harm-reduction Education about Alcohol Trial in Rural Environments.

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[25] was adapted from the pilot study to be scaled up guided by behaviour change theory.[32] 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.[33 34] 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.[35] The researchers were trained and assessed for fidelity by a senior clinician involved in the study. The ABI had been adapted to the

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[34] 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.[33 34]

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.[36]

Financial stress: the Financial Stress Survey is a 17-item questionnaire adapted from a similar tool developed in a rural Asian setting.[37] 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 intracluster correlation (ICC) with the Power and Sample Size software package[38] 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 (PHQ9≥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,

Table 1 Characteristics of original THEATRE recruitment sample and baseline data

	Women		Men		Total	
	N	**%**	**N**	**%**	**N**	**%**
Sex	4047	58.9	2821	41.1	6868	
Age						
Median (IQR)	*44.0*	*(33–56)*	*46.0*	*(34–58)*	*44.0*	*(33–57)*
Missing	255	5.0	187	4.5	442	4.8
18–19	117	2.9	114	3.7	231	3.2
20–29	561	13.4	370	12.8	931	13.2
30–39	816	21.4	462	16.8	1278	19.5
40–49	877	22.8	582	22.9	1459	22.9
50–59	694	17.0	521	18.8	1215	17.7
60–69	516	13.1	370	12.8	886	13.0
≥70	211	4.4	215	7.8	426	5.8
Ethnicity						
Missing	9	0.2	9	0.1	18	0.2
Sinhala	3837	99.2	2688	99.3	6525	99.3
Tamil	3	0.1	2	0.1	5	0.1
Other	198	0.6	122	0.5	320	0.5
AUDIT						
Missing	0	0.0	4	0.0	4	0.0
No drinking (0)	4016	99.7	1208	41.9	5224	76.2
Low-risk (1–6)	16	0.1	725	26.5	741	10.8
Hazardous (7–15)	12	0.1	750	26.6	762	10.9
Harmful (16–19)	1	0.0	83	3.2	84	1.3
Dependent (≥20)	2	0.1	51	1.8	53	0.8
PHQ-9						
Missing	1	0.0	5	0.0	6	0.0
No symptoms (0–4)	2741	67.5	2143	77.2	4884	71.4
Mild (5–9)	925	23.2	481	16.5	1406	20.5
Moderate (10–14)	275	6.8	146	4.8	421	6.0
Moderately severe (15–19)	79	1.8	41	1.3	120	1.6
Severe (≥20)	26	0.8	5	0.2	31	0.5

AUDIT, Alcohol Use Disorders Identification Test; PHQ-9, Patient Health Questionnaire; THEATRE, Theatre-based Harm-reduction Education about Alcohol Trial in Rural Environments.

Implementation and Maintenance).[28] 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.

Data management and storage

Study data were collected and managed using Research Electronic Data Capture (REDCap) electronic data capture tools hosted at University of Sydney.[39 40] REDCap is a secure, web-based software platform designed to support data capture for research studies, providing (1) an intuitive interface for validated data capture, (2) audit trails for tracking data manipulation and export procedures, (3) automated export procedures for seamless data downloads to common statistical packages and (4) procedures for data integration and interoperability with external sources.

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, ethnicity 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,[41] 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
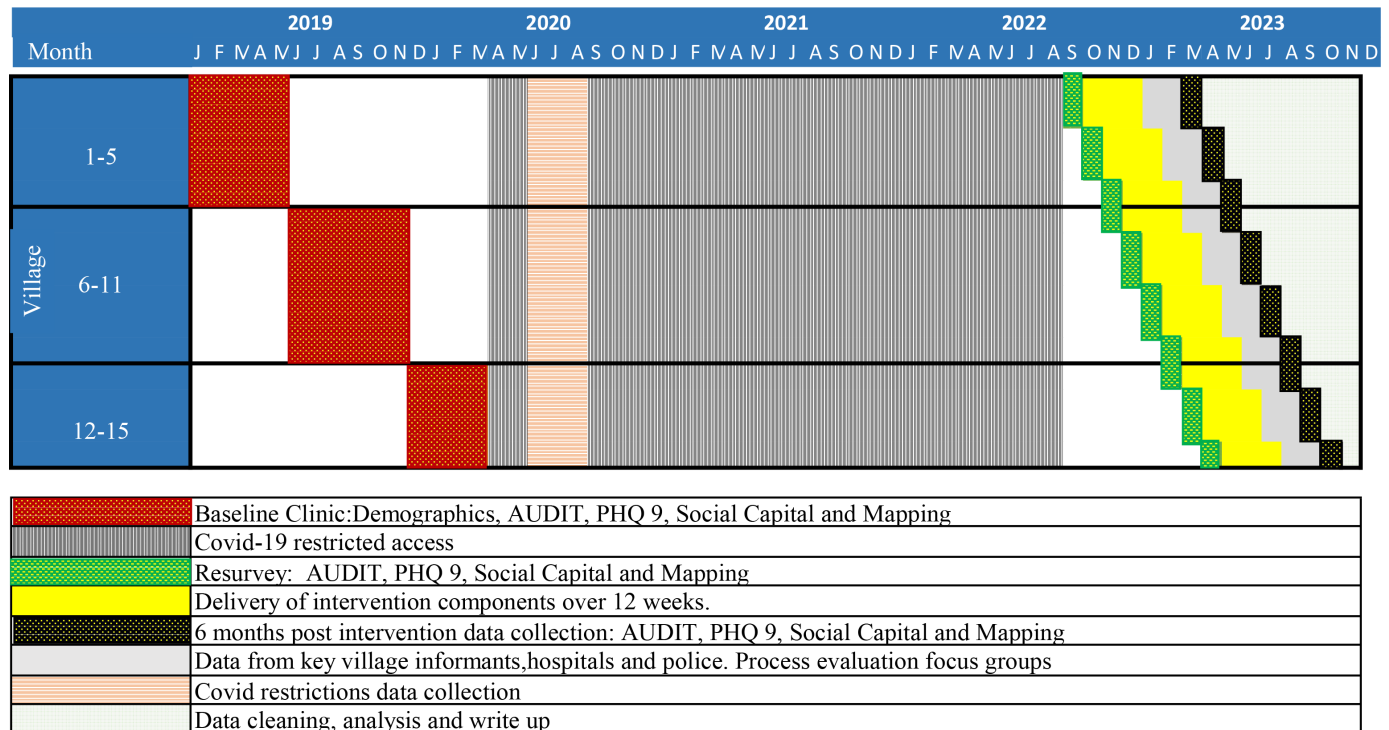

Figure 3 Modified study timeline of the hybrid THEATRE intervention. AUDIT, Alcohol Use Disorders Identification Test; PHQ-9, Patient Health Questionnaire; THEATRE, Theatre-based Harm-reduction Education about Alcohol Trial in Rural Environments.

with the same original sequencing. They will focus on the same themes but use varying script and characterisation. 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[42] 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[43] and is detailed in online supplemental material S4.

Table 2 Post-COVID schedule of enrolment, interventions and assessments for the THEATRE study

| Timepoint** | Enrolment | Intervention | | | | | Close-out |
	Baseline Pre-COVID	Resurvey Post-COVID	Comic	Film 1	Film 2	Film 3	6-month follow-up
Enrolment:							
Village consent	X						
Individual informed consent	X						
Health clinics	X						
Interventions:							
Screen and treat (ABI)		X					
Community drama			X	X	X	X	
Community mobilisation			X	X	X	X	
Assessments:							
AUDIT	X	X					X
PHQ9	X	X					X
Social capital	X	X					X
Financial stress	X	X					X
Implementation			X	X	X	X	X
Digital readiness		X					X

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.

Opportunistic naturalistic trial of the effect of nationwide prohibition

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.

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REFERENCES

1. Rehm J, Mathers C, Popova S, *et al*. Global burden of disease and injury and economic cost attributable to alcohol use and alcohol-use disorders. *Lancet* 2009;373:2223–33.
2. WHO. Global status report on alcohol and health World Health organization; 2014.
3. Nugawela MD, Lewis S, Szatkowski L, *et al*. Rapidly increasing trend of recorded alcohol consumption since the end of the armed conflict in Sri Lanka. *Alcohol Alcohol* 2017;52:550–6.
4. Burton R, Henn C, Lavoie D, *et al*. A rapid evidence review of the effectiveness and cost-effectiveness of alcohol control policies: an English perspective. *Lancet* 2017;389:1558–80.
5. Anderson P, Chisholm D, Fuhr DC. Effectiveness and cost-effectiveness of policies and programmes to reduce the harm caused by alcohol. *Lancet* 2009;373:2234–46.
6. Patel V, Chisholm D, Dua T, *et al*. Disease control priorities, third edition (volume 4): mental, neurological, and substance use disorders. In: Patel V, Chisholm D, Dua T, et al, eds. *Mental, Neurological, and Substance Use Disorders: Disease Control Priorities, 3rd ed*. 2016.
7. Rehm J, Taylor B, Room R. Global burden of disease from alcohol, illicit drugs and tobacco. *Drug Alcohol Rev* 2006;25:503–13.
8. Holder HD. The public policy importance of the Northern Territory's living with alcohol program, 1992-2002. *Addiction* 2005;100:1571–2.
9. Sørensen JB, Agampodi T, Sørensen BR, *et al*. 'We lost because of his drunkenness': the social processes linking alcohol use to self-harm in the context of daily life stress in marriages and intimate relationships in rural Sri Lanka. *BMJ Glob Health* 2017;2:e000462.
10. Katulanda P, Ranasinghe C, Rathnapala A, *et al*. Prevalence, patterns and correlates of alcohol consumption and its' association with tobacco smoking among Sri Lankan adults: a cross-sectional study. *BMC Public Health* 2014;14:612.
11. Dissanayake P, Navaratne NM. 24 % of male deaths alcohol related. *Ceylon Med J* 1999;44:40.
12. Leon DA, McCambridge J. Liver cirrhosis mortality rates in Britain from 1950 to 2002: an analysis of routine data. *Lancet* 2006;367:52–6.
13. Edirisinghe AS, Kitulwatte ID, Senarathne UD. A study into blood alcohol concentration in fatal accidents among vulnerable road users in a tertiary care hospital Sri Lanka. *Int J Inj Contr Saf Promot* 2015;22:158–64.
14. Odero W, Garner P, Zwi A. Road traffic injuries in developing countries: a comprehensive review of epidemiological studies. *Trop Med Int Health* 1997;2:445–60.
15. Navaratne KV, Fonseka P, Rajapakshe L, *et al*. Population-Based estimates of injuries in Sri Lanka. *Inj Prev* 2009;15:170–5.
16. Ramachandran S, Lahie YK, Herath CA, *et al*. Recent aspects of alcoholism in Sri Lanka -- an increasing health hazard. *Alcohol Alcohol* 1986;21:397–402.
17. Senanayake SJ, Gunawardena S, Wickramasinghe S, *et al*. Prevalence and correlates of interpersonal violence among in-school adolescents in Sri Lanka: results from the 2016 Sri Lankan global school-based health survey. *Asia Pac J Public Health* 2019;31:147–56.
18. Ranaweera S, Amarasinghe H, Chandraratne N, *et al*. Economic costs of alcohol use in Sri Lanka. *PLoS One* 2018;13:e0198640.
19. Bandara P, Page A, Senarathna L, *et al*. Domestic violence and self-poisoning in Sri Lanka. *Psychol Med* 2022;52:1183–91.
20. Knipe D, Silva T, Aroos A, *et al*. Hospital presentations for self-poisoning during covid-19 in Sri Lanka: an interrupted time-series analysis. *Lancet Psychiatry* 2021;8:892–900.
21. Laslett A-M, Room R, Waleewong O, *et al*. Harm to others from drinking: patterns in nine societies. World Health Organization; 2019.
22. Sorensen G, Emmons K, Hunt MK, *et al*. Implications of the results of community intervention trials. *Annu Rev Public Health* 1998;19:379–416.
23. Chinai R. Indian women impose unofficial drinking fines. *Bull World Health Organ* 2002;80:175.
24. Calabria B, Clifford A, Shakeshaft AP, *et al*. A systematic review of family-based interventions targeting alcohol misuse and their potential to reduce alcohol-related harm in Indigenous communities. *J Stud Alcohol Drugs* 2012;73:477–88.
25. Siriwardana P, Dawson AH, Abeyasinge R. Acceptability and effect of a community-based alcohol education program in rural Sri Lanka. *Alcohol Alcohol* 2013;48:250–6.

26 Ariyasinghe D, Abeysinghe R, Siriwardhana P, *et al*. Prevalence of major depressive disorder among spouses of men who use alcohol in a rural community in central Sri Lanka. *Alcohol Alcohol* 2015;50:328–32.

27 Roberts NA, Mudge A, Alexander K, *et al*. The ipromos protocol: a stepped-wedge study to implement routine patient-reported outcomes in a medical oncology outpatient setting. *BMJ Open* 2019;9:e027046.

28 Hughes JP, Granston TS, Heagerty PJ. Current issues in the design and analysis of stepped wedge trials. *Contemp Clin Trials* 2015;45:55–60.

29 Pearson M, Konradsen F, Gunnell D, *et al*. A community-based cluster randomised trial of safe storage to reduce pesticide self-poisoning in rural Sri Lanka: study protocol. *BMC Public Health* 2011;11:879.

30 Pearson M, Metcalfe C, Jayamanne S, *et al*. Effectiveness of household lockable pesticide storage to reduce pesticide self-poisoning in rural Asia: a community-based, cluster-randomised controlled trial. *Lancet* 2017;390:1863–72.

31 Sørensen JB, Konradsen F, Agampodi T, *et al*. A qualitative exploration of rural and semi-urban Sri Lankan men's alcohol consumption. *Glob Public Health* 2020;15:678–90.

32 Michie S, van Stralen MM, West R. The behaviour change wheel: a new method for characterising and designing behaviour change interventions. *Implementation Sci* 2011;6:42.

33 De Silva P, Jayawardana P, Pathmeswaran A. Concurrent validity of the alcohol use disorders identification test (audit). *Alcohol Alcohol* 2008;43:49–50.

34 Hanwella R, Ekanayake S, de Silva VA. The validity and reliability of the sinhala translation of the patient health questionnaire (PHQ-9) and PHQ-2 screener. *Depress Res Treat* 2014;2014:768978.

35 WHO. *WHO alcohol brief intervention training manual for primary care*. Denmark: WHO - Regional Office for Europe, 2017.

36 Agampodi T, Agampodi S, Glozier N, *et al*. How context matters: demonstrating microgeographic differences in social capital and its implications for mental wellbeing in pregnancy with a novel bubble diagram technique. *Health Place* 2019;60.

37 Essue BM, Li Q, Hackett ML, *et al*. A multicenter prospective cohort study of quality of life and economic outcomes after cataract surgery in Vietnam. *Ophthalmology* 2014;121:2138–46.

38 Pass 16 power analysis and sample size software. Kaysville, Utah, USA NCSS, LLC; 2018.

39 Harris PA, Taylor R, Minor BL, *et al*. The REDcap Consortium: building an international community of software platform partners. *J Biomed Inform* 2019;95:103208.

40 Harris PA, Taylor R, Thielke R, *et al*. Research electronic data capture (REDCap) -- a metadata-driven methodology and workflow process for providing translational research informatics support. *J Biomed Inform* 2009;42:377–81.

41 Kazemi DM, Borsari B, Levine MJ, *et al*. A systematic review of the mHealth interventions to prevent alcohol and substance abuse. *J Health Commun* 2017;22:413–32.

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

43 Damerow SM, Weerasinghe M, Madsen LB, *et al*. Using ex-ante economic evaluation to inform research priorities in pesticide self-poisoning prevention: the case of a shop-based gatekeeper training programme in rural Sri Lanka. *Trop Med Int Health* 2020;25:1205–13.