Supplementary materials 1

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 be 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>15</td>
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<tr>
<td>Adult (Females)</td>
<td>168.6</td>
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</table>
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

1.1 Principal Investigator

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1.2 Associate Investigators

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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 a 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 to 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
RAJARATA UNIVERSITY OF SRI LANKA

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

Investigator(s) | Telephone number | Address
---|---|---
Dr Lalith Senerathna | 0777635254 | Department of Health Promotion, Rajarata University of Sri Lanka
Prof. Sisira Sirribaddana | 0252234462 | Faculty of Medicine, Rajarata University of Sri Lanka

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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*Recommended by Medical Officer
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