THEATRE Study
MH18: A randomised stepped wedge trial of the scaling up of a community-based alcohol education program in rural Sri Lanka

Andrew Dawson, Nick Glozier, Kylie Lee, Nick Buckley, Katherine Conigrave, Jacques Raubenheimer, Paul Haber The University of Sydney, Sydney, Australia

Indika Gawarammana, Ranil Abeyasinghe, Thilini Rajapakse University of Peradeniya, Sri Lanka

Melissa Pearson, University of Edinburgh, UK

Stephen Jan, The George Institute for Global Health, Sydney, Australia

Lalith Senarathna, Janaka Pushpakumara, Sisira Siribaddana Rajarata University of Sri Lanka.
• The Problem - Alcohol is one of top five causes of disability and death world-wide

• In Sri Lanka alcohol consumption - dramatic rises since 2000
• Estimates of 40-50% of consumption is of illicit alcohol
• Kassipu – 20% alcohol, 4 units per “shot”

• Data from Safe Storage Study n=65,233 in 171 communities
• Living in a household with alcohol problems doubled risk if self harm in both men (OR 2.66) and women (OR 1.96)
• Living in a community with a high percentage of households with a self-reported alcohol problem increased the risk of a lifetime suicide attempt by 44%
• 233 (14%) of injury patients in hospital survey were intoxicated

• Policy responses not obvious - Illicit alcohol largely falls outside scope of established regulation approaches used in HIC, such as taxation, pricing and limits on availability

Pilot Intervention: Participatory drama
Sanni Yakuma – Demon

• Traditional drama dating back 2500 years
• Series of masks represent ailments or diseases but can also be characters
• Used as a tool to interact, communicate, and to empower communities particularly on issues related to health and wellbeing

Yakædurā
(Shaman healer / Facilitator)
Āturayā (The Patient)
Community participant
Integral to the drama
Demon enters to introduce the problem
Results of 2 village c pilot

- 30% reduction in the median AUDIT score and improvement in all categories of AUDIT in the intervention village. NO change in control.
- Sustained at 24-months
- Reduction in women's depression scores in the intervention village
- Reduction in consumption of illicit alcohol from 50% to 11%
  - Villagers took action against illicit alcohol sellers,
- Physical improvements in the school, develop community working groups
- Childhood educational improvements

P. Siriwardhana et al, *Alcohol and Alcoholism* 48 250–256

Film by David Hansen & Kylie Lee
Filmed with local community from pilot
Collaborative project to develop the script, train the community in drama techniques and play characters

Http://thperfectworld.Com.Au/srilanka
SCALING UP –
Stepped Wedge Design in Higher Risk Villages

Cluster Selection Community Alcohol Intervention

Weighted Alcohol problems
4 components were used to calculated a summed score for alcohol problems.

- Household survey -
  Solitary drinking, Everyday drinking and conflicts related to alcohol.
- Community interviews -
  problems related to alcohol - mostly production or known drinking spots.

Date: 05/07/2018
Social Capital Study data
Intervention – multi component

1) **Free health clinic** – vital for implementation, engagement and pre-intervention data
   “Cold pursuit” through clinics, “hot pursuit” through HH referrals
2) **Brief alcohol intervention**
3) High scores offered treatment for alcohol and depression
4) **Alcohol Health Promotion** activities in villages (posters etc)
5) **Participatory drama** led by Dept of Theatre Studies University of Peradeniya +/-national Drama NGO who have a training centre in Anuradhapura and new movie

Outcomes – multi component

1) **Individual**
   1) Reduction in alcohol misuse (AUDIT) in Males
   2) Reduction in depression in Females
2) **Aggregate** alcohol related RTA, assaults, DSH
3) Adverse Events – clinic etc
4) **Process** (REAIM) evaluation – Reach, Effectiveness, Adoption, Implementation and Maintenance
5) **Economic Evaluation** from Societal perspective
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<th>12</th>
<th>15</th>
<th>18</th>
<th>21</th>
<th>24</th>
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- **Baseline Clinic:** Demographics, AUDIT, PHQ 9, Social Capital and Mapping
- **Control Period:** Health and social outcomes from Hospitals and Police
- **Pre intervention Clinic:** AUDIT, PHQ 9, Social Capital and Mapping
- **Delivery of intervention components over 12 weeks.** Focus groups on alcohol impact & village responses
- **6 months post intervention data collection:** AUDIT, PHQ 9, Social Capital and Mapping
- **Data from key village informants, hospitals and police.** Process evaluation focus groups
- **24 months post intervention data collection:** AUDIT, PHQ 9, Social Capital and Mapping. Focus groups on intervention implementation. Survey on recall and perceived value of intervention components
- **Data cleaning, analysis and write up**

**Analysis**
- C1 An intra-village comparison. C2 An inter-village comparison
Recruitment Status – as of 09/10/2019

Enrolment summary

- Target clusters: 20
- Total enrolled to date: 21
- Enrolment %: 105
- HHs covered %: 91
- Total adults enrolled: 5045
Outcomes

Complete hospital data

Baseline

<table>
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<th>Level of drinking</th>
<th>THEATRE villages</th>
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<tr>
<td>No drinking (0)</td>
<td>43% 821</td>
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<tr>
<td>Low-risk (1–6)</td>
<td>27% 512</td>
</tr>
<tr>
<td>Hazardous (7–15)</td>
<td>26% 492</td>
</tr>
<tr>
<td>Harmful (16–19)</td>
<td>3% 50</td>
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<tr>
<td>Dependent &gt;20</td>
<td>1% 19</td>
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<tr>
<td>Total</td>
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Lower prevalence of harmful drinking BUT- Higher levels of DSH

Baseline THEATRE villages

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Implementation Hurdles we had considered

Potential lower prevalence of primary outcome — alcohol misuse in adult males. Preliminary analysis showed correct
Solution - Remodelled sample size and cluster number calculation
Had significant “wiggle room” in sampling frame -- 7 extra villages (clusters) recruited

Primary outcome tool not as Validated and culturally translated as described in literature
Solution – new semantic translation and revalidation with pictograms for new units

RTA Death in staff family
Solution — Excellent, supportive and cohesive team
Implementation Hurdles we hadn’t predicted

Wild elephant problems in villages. Staff safety in “hot pursuit” issue
Solution - hired some vans to transport staff and work in groups.

Request for extra clinic components from villagers
Solution – Added renal focus to maintain engagement

Easter 2019 Bombs – Halted all data collection, much travel etc for nearly 2 months
“Solution” – extension of first phase clinic period

Premature Elections (17/11) – weeks where focus of village on elections
Solution - second round of clinics and intervention delayed until after election and concurrent festival