



**A clustered randomised trial examining the effect of social marketing and community mobilisation on the age of uptake and levels of alcohol consumption by Australian adolescents: Study protocol**

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**A clustered randomised trial examining the effect of social marketing and community mobilisation on the age of uptake and levels of alcohol consumption by Australian adolescents: Study protocol**

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## Abstract

**Introduction:** Throughout the world, alcohol consumption is common amongst adolescents. Adolescent alcohol use and misuse have prognostic significance for several adverse long-term outcomes, including alcohol problems, alcohol dependence, school disengagement, and illicit drug use. The aim of this study is to evaluate whether randomisation to a community mobilisation and social marketing intervention reduces the proportion of adolescents who initiate alcohol use before the Australian legal age of 18, and the frequency and amount of underage adolescent alcohol consumption.

**Method and Analysis:** The study comprises 14 communities matched with 14 non-contiguous communities on socioeconomic status (SES), location, and size. One of each pair was randomly allocated to the intervention. Baseline levels of adolescent alcohol use were estimated through school surveys initiated in 2006 (N=8,500). Community mobilisation and social marketing interventions were initiated in 2011 to reduce underage alcohol supply and demand. The setting is communities in three Australian states (Victoria, Queensland and Western Australia). Students (N = 2,576) will complete school surveys in Year 8 in 2013 (average age 12). Primary outcomes: (1) lifetime initiation; (2) monthly frequency of alcohol use. Reports of social marketing and family and community alcohol supply sources will also be assessed. Point estimates with 95% confidence intervals will be compared for student alcohol use in intervention and control communities. Changes from 2006 to 2013 will be examined; multilevel modelling will assess whether random assignment of communities to the intervention reduced 2013 alcohol use, after accounting for community-level differences. Analyses will also assess whether exposure to social marketing activities increased the intervention target of reducing alcohol supply by parents and community members.

**Ethics and dissemination:** The study was approved by The Deakin University Ethics Committee (reference: 2011-102). Study findings will be disseminated widely through peer-reviewed publications and conference presentations.

*Trial registration: ACTRN12612000384853*

**Article focus:**

This article describes the protocol for a cluster randomised trial of an intervention designed to reduce the proportion of adolescents who initiate alcohol use, or the frequency of alcohol consumption, before the legal age of 18.

**Key messages:**

1. Alcohol consumption is common amongst Australian adolescents
2. Community mobilisation and social marketing have been demonstrated to be effective strategies in reducing alcohol consumption
3. The findings from this study will provide a basis for other community-based trials which could focus on multiple health outcomes for adolescents in the future.

**Strengths and limitations:**

1. The study has a strong design, incorporating random allocation at a community level
2. The intervention is multileveled, and based on strong evidence and theory
3. The intervention focus is limited to adolescents. Additional interventions will be necessary to reduce alcohol use in other population groups

## Introduction

Although the legal age for purchasing alcohol is 18 in all Australian states, approximately 61% of Australian children between 12 and 17 years of age report they consumed alcohol in the last 12 months,[1]. An early age of alcohol use is shown to increase frequent adolescent alcohol use,[2] which in turn leads to increased alcohol use and harms in adulthood,[3,4]. For these reasons raising the age of first alcohol use is considered to make potentially important contributions to reducing Australia's high level of alcohol-related injury and disease burden,[5-7]. The majority of alcohol-related harms amongst young people are acute in nature, and include vehicle accidents, injuries from violent assaults, and drowning,[8]. Adolescent alcohol use and misuse also have prognostic significance for several adverse long-term outcomes, including alcohol problems, alcohol dependence, school disengagement, and illicit drug use,[9,10].

Australian National Health and Medical Research Council (NHMRC) guidelines now recommend that adolescents aged up to 15 years do not consume alcohol, and that alcohol consumption be delayed as long as possible between the ages of 15 and 18 years,[11]. The disjunction between the NHMRC guidelines and the prevalence of adolescent alcohol use and misuse reinforces the need for large-scale implementation of evidence-based policies and programs to reduce supply and demand for alcohol in this age group. Adolescents under the age of 18 frequently obtain alcohol from home (supplied by parents or siblings, or consumed without parental knowledge), from peers, or through (illegal) purchase from alcohol retail outlets. National surveys show that around 38% of students reported that parents provided them with their last alcoholic beverage, and 43-47% consume alcohol at friend's houses or at parties,[1,12]. In New Zealand, 16% of underage adolescents report purchases of alcohol from bottle shops,[13].

**Methods and analysis**

**Study Aim**

The aim of this intervention is to mobilise local community coalitions to improve awareness of and adherence to NHMRC guidelines on adolescent alcohol use and restrict the supply of alcohol to adolescents via parents and alcohol retail outlets. The primary outcomes of the intervention are to (1) lower levels of lifetime initiation of alcohol use by early adolescents, and (2) lower levels of monthly frequency of alcohol use.

**Study design**

The intervention evaluation study will use a repeat cross-sectional, parallel group cluster randomised controlled trial (see Figure 1). Repeat cross-sectional evaluation studies are common practice for interventions designed to influence behaviour at a population level,[14]. A cluster design will be employed as the intervention will occur within Statistical Local Areas (SLA: An Australian Standard Geographic Classification structure consisting of non-overlapping spatial units),[15]; data will be collected through schools, and the core elements of the intervention will be delivered through both communities and schools. SLAs were allocated to either intervention or control conditions in 2006 (see below). The primary outcomes of the evaluation trial will be assessed through cross-sectional surveys of school children.

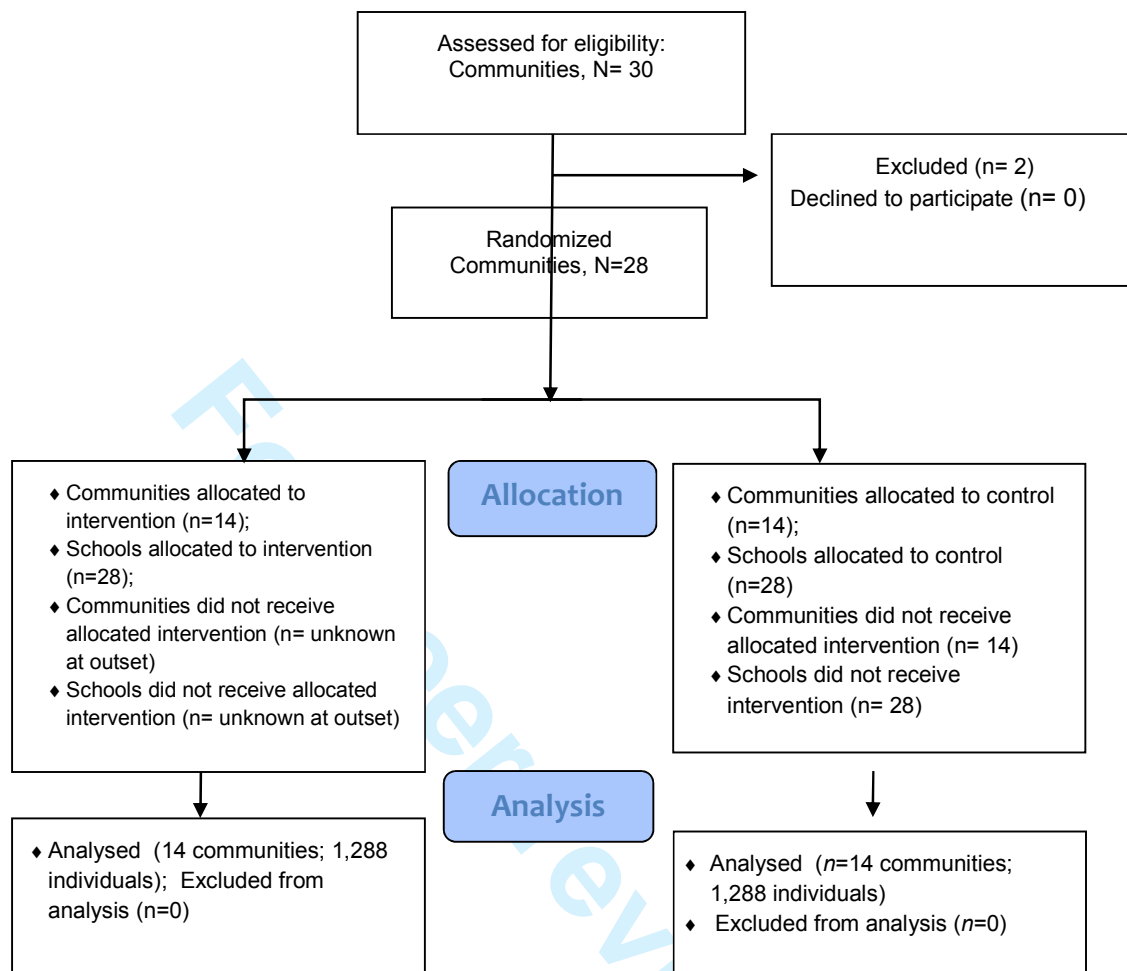


Figure 1: Consort flow chart estimating the progress of communities, schools and participants through trial. Trial registration: ACTRN12612000384853.

**Research Setting**

The present intervention research will occur within the 28 SLAs,[15] selected across the Australian states of Victoria, Queensland, and Western Australia. The intervention (in the 14 intervention communities) will be delivered by mobilising communities using a process based on the Communities That Care (CTC) approach. This approach aims to form a coalition of local organisations and services, who are trained to assist, design and deliver prevention strategies,[16,17].

CTC interventions are planned based on community profiles that use epidemiologically valid community surveys of local youth to document levels of preventable health and social problems (e.g. local rates of youth alcohol use) and modifiable predictors of problems (risk and protective influences) for each respective community,[16,17]. The primary strategies will be delivered through communities and schools and are described below. The community interventions focus on reducing the sale of alcohol to minors and will be centrally coordinated. The coalitions will work with schools to assist them to deliver the relevant school-based social marketing strategies. While coalitions were specifically contracted to deliver interventions within two nominated schools within intervention SLAs,[15] (see below “Random Allocation”), all schools within the SLA or the broader Local Government Area (LGA) containing year 8 students will be eligible to participate where coalitions have the resources to support this.

**Outcome participants and research eligibility**

A minimum of two secondary schools containing year 8 students will be targeted to take part in the intervention activities (in the intervention communities), as well as in the outcome study in each of the intervention and control communities. The participating schools were randomly selected in 2006 from all Government, Independent and Catholic schools across the randomly selected SLAs,[18](see below “Random Allocation”). A minimum of 92 year 8 students will be surveyed in each community in 2013.



Students at participating schools will be eligible to take part in the survey if they satisfy the following criteria:

1. Are in Year 8 secondary school classrooms (average age 12);
2. Have signed informed consent from their parents; and
3. Have provided individual assent.

### **School recruitment procedures**

For each school the principal will be sent a letter inviting their school to participate in the study. Four weeks after the distribution of the letter, the principal will be telephoned to assess the interest of participating in the trial. Follow up phone calls will be made until a school representative is able to make an informed decision regarding the schools participation in the trial. It is expected that some representatives will need to consult with the school's management committee. If required, research staff will attend these meetings. All consenting schools will be sent a letter confirming their agreement to participate in the study. All recruitment procedures will be managed by a dedicated member of the research team. In cases where schools refuse, a replacement school will be randomly selected for approach from the originally sampled schools within the same community.

### **Individual recruitment**

Recruitment procedures for individuals in schools will be based on strategies found to maximise research participation,[19]. The study information will be printed on institutional letterhead and distributed to all eligible children in the targeted Year 8 classrooms in each community. The distribution of consent forms will be administered by the "home room" teacher within each school. Individuals whose parents have provided consent will need to return the consent form to this teacher. Approaching all eligible children is used to minimise selection bias and provide a representative sample of the school. The "home room" teacher will be informed of all students returning consent forms and agreeing to participate in the study and will receive a small reward (e.g. \$100 school library voucher) in return for maximising consent form returns.

## Intervention

### *Intervention development*

The intervention is grounded in social ecological theory, which postulates that behaviour is influenced at a number of levels: individual, family and organisational, and policy and environmental,[20]. Using these multiple leverage points, the intervention aims to 1) reduce alcohol availability to adolescents aged under 18 years, and 2) reduce adolescents' intentions to consume alcohol before the age of 18, or if adolescents are already consuming alcohol, reduce the frequency of alcohol consumption.

Individual behaviour change is based on the Integrated Behavioural Model (IBM),[21], a more developed version of the Theory of Planned Behaviour (TPB) and the Theory of Reasoned Action (TRA),[22]. These theories postulate that intention is the strongest predictor of behaviour,[23]. The IBM also proposes that intention to behave in a particular way is moderated by multiple competing environmental influences,[22]. These theories receive support from Cochrane reviews,[24] as a scientific basis for designing social marketing materials.

In the current project, individual behaviour change is reinforced by two alcohol supply reduction strategies. First, individual behaviour change strategies will involve communication to parents with the aim of increasing parents' intentions to refuse supply of alcohol to adolescents. Second, local alcohol sales outlets will be monitored for the sale of alcohol to underage youth (using confederate surveys) and given feedback to assist them to comply with the enforcement of liquor licensing regulations.

### *Intervention content*

The intervention comprises two key components: 1) community mobilisation; and 2) a social marketing campaign. These components will be reinforced by a more specific intervention to reduce the sale of alcohol to underage youth from packaged liquor outlets (i.e. bottle shops/take away liquor stores). The key components of the intervention are outlined in more detail in Box 1.

## Box 1: Three Key Intervention Components

**1: Community mobilisation** is based on the Communities That Care (CTC) approach, and aims to reinforce the reach and impact of the key interventions by engaging a cross-section of local organisations. The CTC approach is organised into five phases to assist local organisational development and planning, and the building of understanding and skills relevant to effective prevention strategies. Once communities achieve basic organisational readiness, later phases include identifying the major risk and protective factors that are influencing local child and adolescent adjustment outcomes, creating an effective prevention plan to address prioritized risk and protective factors, and implementation and monitoring of planned activities,[16,17]. Through the current trial communities will be supported to initiate the early phases of the CTC process and will be given practical instruction on how CTC is used to plan and deliver prevention strategies. As a secondary outcome, the project is expected to lead to most communities undertaking to complete the full CTC program.

**2: The social marketing campaign** is targeted at 2012 Year 7 and 2013 Year 8 students and their parents. The purpose of this component is to promote three key messages:

1. Based on Australia's National Health and Medical Research Council's (NHMRC) alcohol guidelines for children, adolescents should avoid drinking alcohol before the age of 18.
2. Based on secondary supply legislation (applicable in QLD and VIC) and liquor sales laws (in all states), adults are breaking the law if they supply or sell alcohol to adolescents under the age of 18.
3. Parents should set a rule for their household that their children will not consume alcohol before the age of 18.

Campaign activities, including the distribution of purpose designed resources that promote the project messages, are based on specific social marketing plans devised by each community coalition. The plans describe how the messages will be promoted over three phases: (1) raising awareness of the message, (2) reinforcing the message, and (3) keeping the community engaged (see Box 2). Social marketing dissemination to children and parents will take place primarily through the schools (e.g. dedicated lessons, parent nights, mail-outs to parents), although coalitions may also plan to promote the messages through other activities (e.g. information stalls at community functions, community health clinics, interactive events) and other media (e.g. school website or newsletter).

**3: Reduction of alcohol sales:** The reduction of sales to underage youth will be further reinforced by directly monitoring packaged liquor outlets, through the use of covert assessment of whether adolescents that have the appearance of being underage can purchase alcohol from packaged outlets. Protocols employed for use in similar projects will be followed,[25-29]. In the 14 intervention communities monitored packaged outlets will receive feedback on what was observed, and will be informed if they have been observed serving alcohol to individuals who appear to be under the age of 18. It is a regulation requirement in Australia to check the age of patrons with relevant identification for individuals who look under the age of 21 years. The aim of this component of the intervention is to reinforce compliance with liquor licensing regulations and thereby reduce the availability of alcohol to people who are underage.

The social marketing plans guide the distribution of resources and delivery of activities in the community using three phases. This is outlined in Box 2.

Box 2: Developing a Social Marketing Plan

**Phase 1: Raising awareness of the key messages**

This phase focuses on distributing the social marketing resources to Year 7 (2012) and Year 8 (2013) students and their parents. Distribution of resources to students will take place in the school setting during dedicated lessons. The resources and the key project messages will be discussed by the teacher and students. Distribution of resources to parents will also be through the target schools, primarily via a mailout that will include a cover letter detailing the project objectives and promoting the key messages.

**Phase 2: Reinforcing the key messages**

This phase requires coalitions to plan and implement activities that support and reinforce the project messages. As with the previous phase, these activities will take place predominantly within the school environment in 2012 and 2013(targeting the relevant students and parents), in the form of parent nights, student competitions, articles in the school newsletter, and follow-up classroom lessons or interactive sessions run by external facilitators.

**Phase 3: Keeping the community engaged**

This phase aims to engage the wider community in the project by publicising the key messages more broadly (i.e. through the local newspaper and other media, on council or health service websites, via posters and resource displays at local health services and other relevant organisations etc.).

**Hypothesis**

Overall, we hypothesise that through youth and parent exposure to the social marketing campaign resources and activities which promote the three key messages (see Box 1), in conjunction with the implementation of family rules that forbid alcohol use until the age of 18, and the reduction of sales of alcohol to individuals under the age of 18, the intervention will reduce supply and modify adolescents’ intention to consume alcohol, resulting in a 15% reduction in adolescent alcohol use,[30].

## Intervention delivery

The intervention will be delivered over a period of two years (2012-2013).

### *Intervention implementation strategies*

In each of the intervention communities, a lead agency (e.g. local council or relevant local community organisation) has been identified, and agreement sought from them to auspice the project. The auspice agency will be required to complete the following three stages, and will receive a small grant on initiation of each stage:

#### (1) Getting Started

Representatives from the local auspice will act as community champions to engage relevant local organisations, services and schools to take necessary steps to form a local Communities That Care coalition,[16].

#### (2) Planning

Local auspice “champions” will attend trainings on how to form a local Communities That Care (CTC) coalition and develop a multi-tiered social marketing campaign. This training will be delivered by the research team on a dedicated training day. A Communities That Care Youth Survey report detailing local rates of adolescent alcohol use and modifiable factors (such as attitudes that influence youth alcohol use) will be provided to coalitions. This report will influence the development of a plan to guide the community’s social marketing campaign to communicate information to large numbers of adolescents and their parents.

#### (3) Social Marketing Campaign

The local CTC coalition will be responsible for making community-level decisions about the project and developing a social marketing plan. The research team will provide a template for the social marketing plan which will require detailed description of activities in each of the key phases of the project, (1) raising awareness of the message, (2) reinforcing the message, and (3) keeping the community engaged. Draft plans will receive review and feedback from the research team prior to

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3 submission of a final plan. The research team will provide guidance throughout the delivery and  
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5 monitoring of the 14 social marketing plans.  
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10 *Intervention quality assurance*

11 The research team will provide each community with feedback on their social marketing  
12 plan. To ensure consistency, a purpose-designed form with clear assessment criteria for the three  
13 social marketing phases will be used to provide feedback on social marketing plans to CTC coalitions.  
14 Quality assurance of intervention fidelity will be ensured by having a dedicated community relations  
15 officer who is the regular point of contact for all coalitions and schools. This person will work with at  
16 least one research team member to review all social marketing plans, ensuring that the proposed  
17 interventions target the appropriate risk factors, and are in keeping with the aims of the  
18 intervention.  
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21 Audits of the 'Phase One' school-based lesson/session with students, and the mail-out to  
22 parents, will be conducted in each intervention community. 'Phase Two' and 'Phase Three' activities  
23 will be randomly selected for auditing in each community. Audits will involve the research team  
24 making independent contact with the schools and community sites where activities were reported  
25 to have been conducted by the coalitions. Community coalitions will be told that their communities  
26 and relevant schools will be audited. However, to promote each coalition's fidelity to their  
27 submitted social marketing plan, communities and schools will not be informed of how, when, or  
28 who will undertake the audit.  
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46 *Control communities*

47 During the intervention period, communities randomised into the control condition will be  
48 monitored for their usual practices by the research team and will participate in student outcome  
49 surveys. Control communities will not receive any of the social marketing materials that promote the  
50 NHMRC safe drinking guidelines and the secondary supply laws throughout the country, and provide  
51 information explaining that it is protective for parents to set a rule about not allowing their children  
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to consume alcohol before the age of 18. Alcohol sales will be monitored without providing feedback to alcohol sales outlets.

## Data collection procedures

### *Outcome data*

Student survey data was collected prior to the intervention (in 2006) and again in 2009 or 2011 in the Victoria and Queensland communities. Surveys will be repeated again after the intervention is complete in 2013. Data will be collected via a web-based computer administered survey. All data collection will occur during school times, in computer laboratories using an online survey.

Survey measures will be based on validated measures of alcohol use, and also validated risk and protective factors,[31]. The survey instrument has been used in the large Community That Care trials in the United States of America. Risk and protective factors are organised in the survey to investigate adolescent environments in the following domains: community; family; school and peer-individual. The Cronbach alpha for these scales are 0.7 or greater,[31].

Data will be imported into the STATA 12.0 statistical analysis software package. Textual responses for open-questions will be coded by a trained member of the research team and checked by a second member.

### *Intervention implementation data*

#### *Process*

Measurement of intervention inputs and processes will be undertaken through student responses to questions relating to exposure to the project resources and key messages, through the research team monitoring of community and school activities, and through the direct monitoring of alcohol sales. In the intervention communities, intervention inputs will also be monitored through community activity reporting sheets, and through the Community Relations Officer observational audit reports,[16].



*Community characteristics*

Information about communities will be gathered from publicly accessible databases. Information collected will pertain to ABS 2012 Census data relevant to SEIFA socio-economic indexes, population size, and official records of the number of liquor licenses in each community,[15].

*Overall data management*

Data management will be primarily the responsibility of the research team based at Deakin University, School of Psychology. Management of trial data will be in accordance with a data-management protocol, which has been developed and approved by the Project Advisory Group. The protocol details requirements regarding data entry, data cleaning, data backup, secure storage and transport, and analysis. The Deakin University ethics committee has approved the project with the expectation that data will be securely stored, and accessible only to primary researchers and statisticians through allocation of access rights. Confidential data on school and community contact details (e.g. phone numbers, email addresses) will be stored in a secure dataset that is not linked to survey response datasets. An independent statistician will be the only person with access to confidential participant data.

**Measures**

*Primary outcome measure: alcohol use behaviours.*

Surveyed students will be asked a variety of alcohol questions: “In your lifetime have you ever had more than just a few sips of an alcoholic beverage (like beer, wine, or spirits) (yes/no)”?”; “In the past 30 days have you had more than just a few sips of an alcoholic beverage (like beer, wine, or spirits) (yes/no)”?”; “Think back over the past 2 weeks. How many times have you had five or more alcoholic drinks in a row? (never, 1-2 times, 3-5 times, 6-9 times, 10 or more times)”?”; “Where did you get your last alcoholic beverage from (parents, brother/sister, home without permission, friends gave it to me, got someone to buy it, other)”?”; “My family has clear rules about alcohol and



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3 drug use(yes/no)”; “I do not intend to consume alcohol before I am 15 years of age (yes/no)”; “I do  
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5 not intend to consume alcohol before I am 18 years of age(yes/no)”. All included alcohol  
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7 consumption measures have been used in large scale population studies with adolescents,[1,32].  
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### 10 11 *Intervention implementation measures*

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14 Intervention measures will be based primarily on student reported exposure, with validation  
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16 based on the reports of the activities that are listed on the coalition’s social marketing plan in the  
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18 respective intervention communities. The coalition’s social marketing plans will be assessed based  
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20 on the following questions: “To what extent has the community distributed the social marketing  
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22 resources to the schools they are working with?”, “Has the community used the nominated  
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24 approved strategies to raise awareness of the program to the school and the broader community?”,  
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26 “Has the community used the nominated strategies to reinforce the three key message?”, “Has the  
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28 community used two approved strategies to keep the community engaged?” Assessments will be  
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30 based on three levels - absent/ moderate/ high-comprehensive.  
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### 35 *Process measures*

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38 The intervention acceptability will be measured through a series of questions put to focus  
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40 group participants and coalition members around various aspects of the intervention. For example,  
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42 focus group interviews were completed to ensure the social marketing materials were clearly  
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44 understood and positively appraised by the target population. Coalition members will provide  
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46 feedback at training events and at the end of each intervention component.  
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### 49 **Sample size and power calculations**

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51 Baseline data indicates that 49% of Year 8 students reported alcohol use during ‘the past 30  
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53 days. The intraclass correlation for this measure within communities was approximately 0.03. The  
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55 hypothesis for this study is that exposure to the social marketing intervention will reduce ‘past 30  
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57 day’ alcohol use by 15%. As there is some evidence that early adolescent alcohol may be slightly  
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declining, power analyses were repeated on the assumption that rates would be 40% by 2013. Analyses reveal a total of 2,576 participants will need to be surveyed in 2013 (1,288 each in control and intervention). This will be achieved by surveying a minimum of 46 students in each of the two secondary school Year 8 cohorts, across the 28 communities (a total of 92 across 2 schools). This sample size will allow 80% power to detect a 15% reduction in the intervention communities, assuming an overall rate of 40% alcohol use, a similar ICC of .03, and adjusts for the design effect for the 28 communities.

**Random allocation**

The original community sampling frame was initiated by selecting all SLAs with greater than 17,000 inhabitants across the Australian States of Victoria, Queensland, and Western Australia. These SLAs were stratified into quartiles of socioeconomic disadvantage based on Socio-Economic Indexes for Areas (SEIFA),[15]. Thirty eligible communities were then randomly selected from SEIFA quartiles to represent state distributions in advantage/disadvantage and urban and nonurban locations,[18]. Of the 30 originally sampled SLAs, two were excluded from the present study due to their prior involvement in the Communities That Care (CTC) approach (see Figure 1). The remaining 28 SLAs were paired based SEIFA scores, urban or nonurban locations and size. One of each pair was then randomly allocated to the intervention, resulting in 14 intervention and 14 control SLAs.

A total of 82 secondary schools were originally selected using random assignment in 2006 from all Government, Independent and Catholic schools across the 30 randomly selected SLAs,[18]. For the present trial two of the originally selected schools were randomly selected in each of the 28 SLAs, with schools in the intervention and control communities selected using equivalent strategies.

### Statistical analysis: Primary outcome:

Stata (Version 12) will be used for all statistical analyses. Descriptive statistics (means, proportions) will be used to describe the demographic and practice characteristics of intervention and control group communities, schools and students and to describe intervention implementation, process and acceptability.

To assess intervention efficacy, pre- and post-intervention data will be linked at the community and school levels and multilevel modelling will be used to examine between and within community differences on the primary trial outcomes. An xtlogit model will be used for the categorical outcomes and xtmelogit model for continuous outcomes. These models adjust for clustering within schools and communities. Imputation of data will be undertaken where pre-intervention has been collected but post-intervention data is missing.

The outcome in the logistic model will be “ever drunk alcohol in the last 30 days”. The outcome will in xtmelogit model will be “the number of times alcohol was used in the last 30 days”. The predictors will include community intervention allocation condition, indicator variables for average school and community rates of alcohol use and risk factors at pre-intervention, and variables to control factors such as level of disadvantage. As analyses reveal no pre-intervention differences in alcohol use, the p value for the community intervention allocation term will be used to determine if there is any statistically significant difference at post-intervention in the outcome for the intervention relative to the control communities over the treatment period. The *P* value for significance testing will be 0.05.

Main analyses will be based on community allocation. As a secondary exploratory analysis, both a per-protocol and subgroup analyses will be performed. A per-protocol analysis will be conducted excluding communities that who had not implemented the intervention as specified in their social marketing plan. Subgroup analyses will examine differential effects by gender, rural areas and disadvantage. No interim analyses of the data are planned.

**Research trial coordination**

A Project Advisory Group has been formed to oversee the conduct of the trial. This group is chaired by one of the Chief Investigators for the grant that is principally funding the trial. The Project Advisory Group also comprises of members of the research team and implementation team. A working group has been formed to implement the intervention in keeping with the trial protocol. This group meets weekly, and also consists of research staff and implementation staff. Data management is the responsibility of the research staff that are based at Deakin University. Management of trial data is in accordance with a data management protocol, which has been developed and approved by the Project Advisory Group.

**Trial discontinuation or modification**

There are no predetermined criteria for discontinuing or modifying the trial. There are no anticipated adverse consequences for trial participants. However, in the case of such an occurrence events will be forwarded to Deakin University's ethics committee, in accordance with the conditions of the ethics approval for the project. Any protocol modification will be communicated through the trial registration listed in the Australian New Zealand Clinical Trials Registry, and through publications disseminating the trial results.

**Discussion**

In Australia there is a lack of research examining the use of community-based approaches to delay the uptake and level of alcohol consumption by adolescents. This will be the first randomised trial to examine how community coalitions can be mobilised to work with key community stakeholders to prevent and reduce alcohol consumption by adolescents. The study has a strong design, through the use of random allocation of communities to the intervention condition, and previous validated measures employed successfully in community trials in other countries. The intervention strategy has multiple levels and is strongly grounded in theory. The intervention strategy requires the engagement of the whole community and thus will demonstrate how a multilevel intervention can be practically implemented. The findings from this study will provide a

basis for other community-based trials which could focus on multiple health outcomes for adolescents in the future.

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**Contributorship:** BR led the manuscript; JT, PK, EL secured funding for the project and together with authors JW, RS, AO, AK and JH devised research design, program intervention and measures. BR, JT and PK were responsible for sample size calculations. JW and JT were responsible for the group the randomisation of the communities. All authors either drafted or critically revised the manuscript, and all authors approved the final version of the manuscript.

References

- 1 White V, Smith G. Australian secondary school students' use of tobacco, alcohol, and over-the-counter and illicit substances in 2008, 2009.
- 2 Toumbourou JW, Catalano RF. Predicting Developmentally Harmful Substance Use. In: T. Stockwell, P. Gruenewald, Toumbourou JW, et al., editors. *Preventing harmful substance use: The evidence base for policy and practice*. London: Wiley, 2005:53-65.
- 3 Toumbourou JW, Williams I, White V, et al. Prediction of alcohol-related harm from controlled drinking strategies and alcohol consumption trajectories. *Addiction* 2004;99(4):498-508.
- 4 Bonomo YA, Bowes G, Coffey C, et al. Teenage drinking and the onset of alcohol dependence: A cohort study over seven years. *Addiction* 2004;99:1520 - 28.
- 5 Collins D, Lapsley H. The costs of tobacco, alcohol, illicit drug abuse, to Australian society in 2004/5. Canberra, ACT: Commonwealth Government, 2008.
- 6 Masterman PW, Kelly AB. Reaching adolescents who drink harmfully: fitting intervention to developmental reality. *Journal of Substance Abuse Treatment* 2003;24(4):347-55.
- 7 Mathers CD, Vos ET, Stevenson CE, et al. The burden of disease and injury in Australia. *BULLETIN-WORLD HEALTH ORGANIZATION* 2001;79(11):1076-84.
- 8 Chikritzhs T, R. P. Trends in Youth Alcohol Consumption and Related Harms in Australia. Perth: National Drug Research Institute, Curtin University of Technology, 2004.
- 9 Tucker JS, Orlando M, Ellickson PL. Patterns and correlates of binge drinking trajectories from early adolescence to young adulthood. *Health Psychology* 2003;22(1):79.
- 10 Ellickson PL, Tucker JS, Klein DJ. Ten-year prospective study of public health problems associated with early drinking. *Pediatrics* 2003;111(5):949.
- 11 NHMRC. Australian guidelines to reduce health risks from drinking alcohol. Canberra, ACT: National Health and Medical Research Council, 2009.
- 12 Hayes L, Smart D, Toumbourou J, et al. *Parenting influences on adolescent alcohol use*. Melbourne Australian Institute of Family Studies 2004.
- 13 Kypri K, Dean J, Kirby S, et al. 'Think before you buy under-18s drink': evaluation of a community alcohol intervention. *Drug And Alcohol Review* 2005;24(1):13-20.
- 14 Murray D. *Design and analysis of group-randomized trials*. New York: Oxford University Press, 1998.
- 15 ABS. Information paper: An introduction to socio-economic indexes for areas (SEIFA) 2006. Canberra: Australian Bureau of Statistics, 2008.
- 16 Greenberg MT, Feinberg ME, Gomez BJ, et al. Testing a Community Prevention Focused Model of Coalition Functioning and Sustainability: A Comprehensive Study of Communities That Care in Pennsylvania. *Preventing harmful substance use: The evidence base for policy and practice*, 2005:129.
- 17 Hawkins JD, Catalano RF, Miller JY. Risk and protective factors for alcohol and other drug problems in adolescence and early adulthood: Implications for substance abuse prevention. *Psychological Bulletin* 1992;112s(64-105).
- 18 Kelly AB, O'Flaherty M, Toumbourou JW, et al. The influence of families on early adolescent school connectedness: Evidence that this association varies with adolescent involvement in peer drinking networks. *Journal of abnormal child psychology* 2012:1-11.
- 19 McMorris BJ, Clements J, Evans-Whipp T, et al. A comparison of methods to obtain active parental consent for an international student survey. *Evaluation Review* 2004;28(1):64-83.
- 20 McLeroy KR, Bibeau D, Steckler A, et al. An ecological perspective on health promotion programs. *Health Education Quarterly* 1988;15(4):251-377.
- 21 Kasprzyk D, Montano DE. Application of an integrated behavioral model to understand HIV prevention behavior of high-risk men in rural Zimbabwe. *Prediction and change of health behavior: Applying the reasoned action approach*. Mahwah, NJ: Lawrence Erlbaum Associates Publishers; US, 2007:149-72.

- 22 Montano DE, Kasprzyk D. Theory of reasoned action, theory of planned behavior, and the integrated behavioral model. In: Glanz K, Rimmer BK, Viswanath K, editors. *Health behavior and health education: theory research and practice*. San Francisco, CA: John Wiley & Sons, 2008.
- 23 Connor M, Norman P. *Predicting health behavior*. 2nd ed. Berkshire: Open University Press, 2005.
- 24 Lopez L, Tolley E, Grimes D, et al. Theory-based interventions for contraception (Review). 2009.
- 25 Paschall MJ, Grube JW, Black C, et al. Alcohol outlet characteristics and alcohol sales to youth: Results of alcohol purchase surveys in 45 Oregon communities. *Prevention Science* 2007;8(2):153-59.
- 26 Maltman K, Douglas L. *Pseudo underage liquor sales [electronic resource] : a research report / prepared for: Office of Liquor, Gaming and Racing by TNS Consultants*. : Pyrmont, N.S.W. :: Publisher, 2007.
- 27 Lang A, Zappelli R. Pseudo Underage Liquor Sales: A Research Report / prepared for: Injury Control Council of Western Australia., 2007.
- 28 Huckle T, Broughton D, Pledger M. *Auckland pseudo patrons survey 2004*: Centre for Social and Health Outcomes Research and Evaluation, 2004.
- 29 Grube JW. Preventing sales of alcohol to minors: Results from a community trial. *Addiction* 1997;92:S251-S60.
- 30 Hawkins JD, Oesterle S, Brown EC, et al. Results of a Type 2 Translational Research Trial to Prevent Adolescent Drug Use and Delinquency: A Test of Communities That Care. *Archives of Pediatric and Adolescent Medicine* 2009;163(9):789-98
- 31 Arthur MW, Hawkins JD, Pollard JA, et al. Measuring Risk and Protective Factors for Use, Delinquency, and Other Adolescent Problem Behaviors The Communities That Care Youth Survey. *Evaluation Review* 2002;26(6):575-601.
- 32 AIHW. *Australian Institute of Health and Welfare: 2007 National Drug Strategy Household Survey*: Australian Institute of Health and Welfare, 2011.





CONSORT 2010 checklist of information to include when reporting a randomised trial\*

Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract			
	1a	Identification as a randomised trial in the title	1
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	2
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale	4
	2b	Specific objectives or hypotheses	11
Methods			
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	5
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	N/A
Participants	4a	Eligibility criteria for participants	7
	4b	Settings and locations where the data were collected	7-8
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	9-11
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	16
	6b	Any changes to trial outcomes after the trial commenced, with reasons	N/A
Sample size	7a	How sample size was determined	16
	7b	When applicable, explanation of any interim analyses and stopping guidelines	N/A
Randomisation:			



Sequence generation	8a	Method used to generate the random allocation sequence	17
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	17
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	N/A
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	N/A
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how	N/A
	11b	If relevant, description of the similarity of interventions	N/A
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	18
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	
<b>Results</b>			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	6 & 16
	13b	For each group, losses and exclusions after randomisation, together with reasons	N/A
Recruitment	14a	Dates defining the periods of recruitment and follow-up	N/A
	14b	Why the trial ended or was stopped	N/A
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	N/A
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	N/A
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	N/A

	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	N/A
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	N/A
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	N/A
<b>Discussion</b>			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	N/A
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	N/A
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	N/A
<b>Other information</b>			
Registration	23	Registration number and name of trial registry	6
Protocol	24	Where the full trial protocol can be accessed, if available	N/A
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	1

\*We strongly recommend reading this statement in conjunction with the CONSORT 2010 Explanation and Elaboration for important clarifications on all the items. If relevant, we also recommend reading CONSORT extensions for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological treatments, herbal interventions, and pragmatic trials. Additional extensions are forthcoming: for those and for up to date references relevant to this checklist, see [www.consort-statement.org](http://www.consort-statement.org).