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A cluster randomised controlled trial of a comprehensive accreditation intervention to reduce alcohol consumption at community sports clubs: study protocol

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ABSTRACT

Introduction: Excessive alcohol consumption is responsible for considerable harm from chronic disease and injury. Within most developed countries, members of sporting clubs consume alcohol at levels above that of communities generally. Despite the potential benefits of interventions to address alcohol consumption in sporting clubs, there have been no randomised controlled trials to test the effectiveness of these interventions. The aim of this study is to examine the effectiveness of a comprehensive accreditation intervention with community football clubs (Rugby League, Rugby Union, soccer/association football and Australian Rules football) in reducing excessive alcohol consumption by club members.

Methods and analysis: The study will be conducted in New South Wales, Australia, and employ a cluster randomised controlled trial design. Half of the football clubs recruited to the trial will be randomised to receive an intervention implemented over two and a half winter sporting seasons. The intervention is based on social ecology theory and is comprehensive in nature, containing multiple elements designed to decrease the supply of alcohol to intoxicated members, cease the provision of cheap and free alcohol, increase the availability and cost-attractiveness of non-alcoholic and low-alcoholic beverages, remove high alcohol drinks and cease drinking games. The intervention utilises a three-tiered accreditation framework designed to motivate intervention implementation. Football clubs in the control group will receive printed materials on topics unrelated to alcohol. Outcome data will be collected pre- and postintervention through cross-sectional telephone surveys of club members. The primary outcome measure will be alcohol consumption by club members at the club, assessed using a graduated frequency index and a seven day diary.

Ethics and dissemination: The study was approved by The University of Newcastle Human Research Ethics Committee (reference: H-2008-0432). Study findings will be disseminated widely through peer-reviewed publications and conference presentations.

ARTICLE SUMMARY

Article focus

- This article describes the protocol for a cluster randomised controlled trial of an intervention to reduce alcohol consumption at community sports clubs.

Key messages

- Excessive alcohol consumption is particularly prevalent among people involved in sports, particularly team and contact sports.
- There are currently no existing controlled trials testing the effectiveness of interventions to reduce excessive alcohol consumption in the sporting club setting.
- The findings from this study will provide a basis for further research and potentially important findings for both policy makers and those implementing health promotion programmes in sporting clubs.

Strengths and limitations of this study

- The study has a strong design incorporating random allocation, blinding of data collection staff and the use of dual, validated outcome measures.
- The intervention is multifaceted and comprehensive, based on a strong theoretical framework (social ecology) and past research evidence.

Trial registration number: Australian New Zealand Clinical Trials Registry: ACTRN12609000224224.

INTRODUCTION

Alcohol consumption is causally linked with more than 60 types of injury and chronic disease,[1 2] contributing to 3.2% of deaths and 4.0% of disability-adjusted life years

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worldwide.[2] In 2007, 20% of Australian adults reported regular consumption of alcohol at risky levels (seven drinks for males; five drinks for females).[3] Excessive alcohol consumption appears to be particularly prevalent among young, male sportspeople,[4–6] and those involved in team and contact sports, such as Rugby League, Rugby Union, soccer/association football and Australian Rules football (AFL).[4 7]

Interventions implemented in community sports clubs represent one potential means of reducing excessive alcohol consumption by members of sporting clubs generally, and football clubs in particular. Twenty-eight per cent of Australians aged 15 years and over report participating in organised sports, and 44% report attending at least one sporting match each year.[8] Over one million (1.26 million; 7.4%) report participating in some form of football.[9] Despite the potential of interventions in community sporting clubs to reduce alcohol related harms, the only relevant systematic review that has been conducted[10] failed to identify any randomised intervention trials targeting alcohol use in this setting.

METHODS AND ANALYSIS

Study aim

The aim of this study is to examine the effectiveness of a comprehensive accreditation intervention with community football clubs (Rugby League, Rugby Union, soccer/association football and AFL) in reducing excessive alcohol consumption by club members.

Study design

The study will be a repeat cross-sectional, parallel group cluster randomised controlled trial (see figure 1). A cluster design will be employed as the intervention is implemented at the level of the football club, and the main outcome measures are related to alcohol consumption within this setting. Football clubs will be randomised to either a control or intervention group. Primary trial outcomes will be assessed through cross-sectional surveys of club members, pre- and post-intervention. Repeat cross-sectional designs have been recommended for trials seeking to assess changes within defined populations and settings (in the case of this study, alcohol consumption among members of sports clubs),[11] and in which loss to follow-up of individual participants is likely to be high.[12] Such designs have been utilised in other public-health randomised trials, particularly in workplaces.[13 14]

Research setting

The research will occur within the Hunter, New England and Sydney regions of New South Wales, Australia. The study area includes major city, inner regional and rural communities that account for approximately 75% of the state population (New South Wales) and 25% of Australia's overall population.[15]

Participants and research eligibility

Football clubs

Football clubs will be eligible to participate in the study if they satisfy the following criteria:

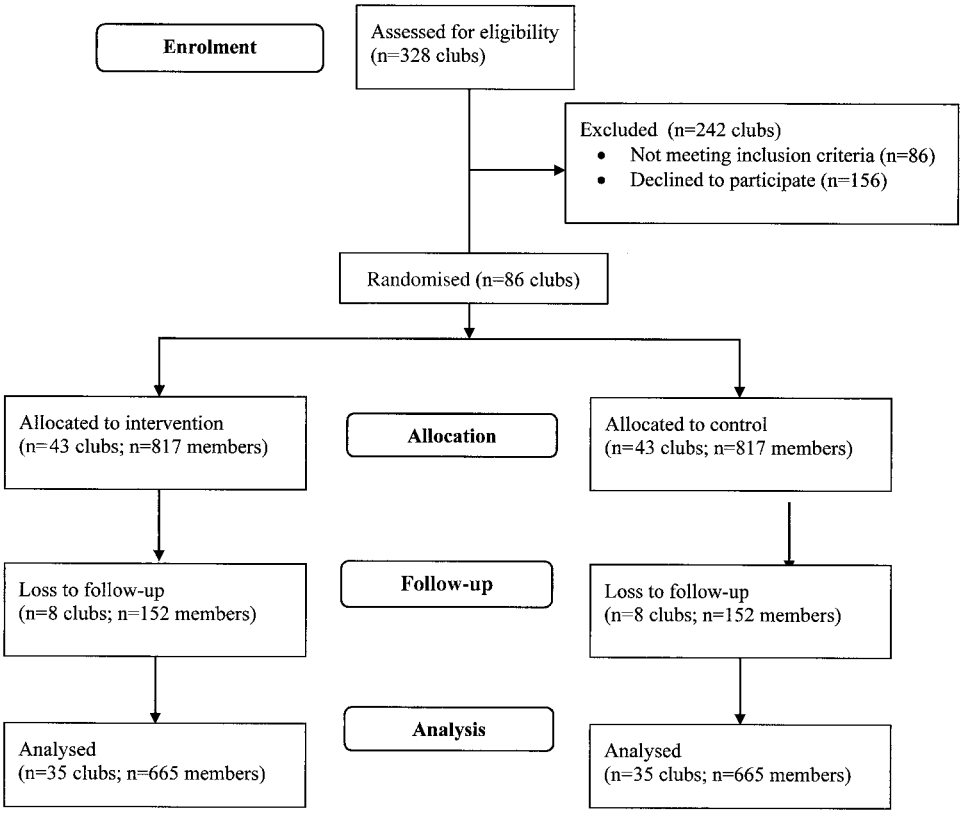


Figure 1 Consort flow chart estimating the progress of participants through the trial.

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- are a community-level, non-professional senior football club;
- are an AFL, soccer (association football), rugby union or rugby league football club;
- have >40 members;
- sell alcohol at their sporting fixture.

The football codes to be included in the study (Rugby League, Rugby Union, soccer/association football and AFL) are all team-based ball sports predominantly involving male players, which are played at the community and professional level in Australia and internationally.[16] Clubs that hold a registered club or hotel liquor licence will be excluded, as the intervention is not suited to the different operational characteristics of such venues.

Football club members

Club members will be eligible to be surveyed if they are at least 18 years of age, speak English and are current members of the club (players, committee members, spectators/fans or coaches).

Recruitment procedures

Football clubs

All clubs within the study area will be approached for eligibility assessment and subsequently invited to participate in the study if eligible. To generate a population of clubs in the study region, lists of community football clubs and contact persons will be obtained from relevant local councils and the peak association for each football code. These lists will be supplemented with clubs identified through telephone directories and web searches.

Procedures for recruiting clubs to the study will be based on strategies previously found to maximise research participation, including prenotification of the study and opportunity to participate, direct telephone contact with participants to invite participation, multiple contact attempts, access to research staff for further clarification regarding participation and the use of dedicated research staff to manage the recruitment process.[17–19] Specifically, a club contact person (club president or other nominated contact such as a club secretary) from each eligible club will be sent a letter inviting their club to participate in the study. Two weeks following the distribution of letters, the contacts of all identified clubs will be telephoned to confirm eligibility based on the above-mentioned criteria and to assess interest in participating in the study. If club representatives do not recall receiving the information letter, address details will be clarified, and additional information letters will be sent. Follow-up phone calls will be made until the club representative is able to make an informed decision regarding their club's participation in the trial. It is envisaged that in some cases this decision will need to be made in consultation with the club's management committee. Research staff will attend such meetings if required. Following the completion of this process, all consenting clubs will be sent a confirmation letter thanking them for agreeing to participate in the trial. All recruitment procedures will be managed by a dedicated member of the research team.

Football club members

Recruitment strategies of club members will also be based on strategies found to maximise research participation.[17–19] Study information sheets and consent forms will be printed on institutional letterheads and distributed by clubs representatives to the 25 members of the club with the most recent birthday. Members who agree to participate in the study will be asked to advise the club representative of their consent to do so. This quasi-randomised sampling procedure will be used to reduce selection bias and provide a representative sample of club members.[20 21]

To maximise response rates, club representatives will be asked to make follow-up contact with selected members to ask if they consent to participate in the study and to forward the names and contact details of consenting members to the study team.[18 19] Each participating club will be provided with hard copies and electronic copies of the information and invitation letters to give to their members, as well as a $250 payment to compensate for the club's involvement in the recruitment of members.[19] Club representatives will provide the telephone details of consenting members to the project team.

All of the club members who have consented to participate in the study will be telephoned by the research team to formally confirm eligibility and participation in the study.

Intervention

Intervention development

The intervention is modelled on social ecology theory, which recognises the role of the physical, social and cultural environment in health behaviour and emphasises the importance of multiple levels of human interaction, including that of groups and organisations.[22 23] As such, the intervention is focused on sporting clubs as an environment in which excessive alcohol consumption can occur, seeking to reduce the likelihood of excessive alcohol consumption through modifying club responsible service of alcohol and management practices and social situations encouraging excessive alcohol consumption.

The intervention is based on an existing sporting club alcohol accreditation programme.[24] The feasibility of the programme has been previously demonstrated by Duff and Munro[24] and Munro,[25] who reported that the programme was successfully implemented by over 500 clubs across the state of Victoria, Australia. More recently, unpublished data have suggested an inverse association between participation in the programme and prevalence of risky drinking (Rowland, Allen and Toumbourou, 2011) and drink driving among club members (Rowland, Toumbourou and Allen, 2011). Specifically, clubs not participating in the programme were found to have significantly greater levels of risky

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drinking among club members compared with clubs accredited with the programme (at Level 2 and Level 3).

Based on such formative research and parallel evidence from interventions targeting excessive alcohol consumption in other licensed premises such as hotels,[26–32] an expert advisory group consisting of experienced alcohol researchers, health promotion practitioners and programme staff developed the intervention to be tested in this study.

Intervention content

The intervention will apply social ecology theory by targeting the physical availability of alcohol through: restrictions on the types of alcoholic beverages sold (no ready to drink products above 5% alcohol/volume, no shots and no double nips of alcohol); mandatory inclusion of relatively inexpensive low-alcohol and non-alcohol beverages (priced lower than full strength alcohol options),[29] prohibiting the sale of alcohol to intoxicated persons; and prohibiting the sale of alcohol by bar servers who have been consuming alcohol. The intervention will also include environmental supports including signage on liquor laws and standard drink measures, and the provision of free water and substantial food when alcohol is sold. The presence of the licensee will be required at all times alcohol is sold. The intervention will target the social and cultural environment of the football club by: prohibiting drinking games and promotions including cheap or discounted drinks,[28] alcohol-only awards or prizes[27] and all-you-can-drink functions; introducing a club-based alcohol policy; and routine patrolling of sporting club grounds to monitor and inform spectators of expectations regarding alcohol use and consumption at the venue. The comprehensive, multicomponent intervention utilises a three-tiered accreditation framework designed to motivate intervention implementation. Box 1 describes the intervention components by accreditation level.

Box 1 Intervention strategies by accreditation level

Level 1 accreditation
- Alcohol management action plan developed
- Club has a current liquor licence
- Required liquor licence signage is clearly displayed at the alcohol point-of-sale location
- Alcohol is only served during times specified on the liquor licence and within the designated licensed area of the club
- Licensee (or nominated person) is always present when alcohol is served
- Tap water is provided free of charge
- People aged under 18 years do not serve alcohol
- Identification checks are conducted on people who appear to be under the age of 25 years, and people aged under 18 years are not served alcohol
- All entrances to the club are monitored by staff/volunteers, and intoxicated people are not permitted to enter the premises
- Intoxicated people are not served alcohol and are not permitted to remain on the premises
- Alcohol sold at the club is only consumed at the club
- All bar servers have undertaken an accredited responsible service of alcohol (RSA) training course
- The club maintains an RSA training register
- Names of all staff who have been trained in RSA are displayed on a sign near the bar
- Alcoholic drinks are only served in standard drink measures
- Club maintains an up-to-date incident register

Level 2 accreditation
- Bar servers do not consume alcohol while on duty
- Substantial food is provided when alcohol is served
- At least four non-alcoholic and one low-alcoholic drink options are available
- Non-alcoholic and low-alcoholic drink options are at least 10% cheaper than full strength alcoholic drinks
- Club does not serve 'shots' of alcohol or double-nips of alcohol
- Club does not sell ready-to-drink products over 5% alcohol/volume
- Club does not conduct drinking games/promotions that can encourage excessive drinking

Level 3 accreditation
- Club attempts to source additional non-alcohol related sponsorship
- Club has a written alcohol-management policy
- Alcohol-management policy provided to members and staff/volunteers

Intervention delivery

Intervention delivery will occur over two and a half successive winter sports seasons. Participating sports clubs will be encouraged to implement the strategies in accordance with three successive levels of accreditation (see box 1). Complete intervention implementation, consistent with level 3 criteria, is expected by the end of the two-and-a-half-year intervention period.

Intervention implementation strategies

The New South Wales Health Capacity Building Framework will provide a framework for strategies to support the implementation of the intervention by sporting clubs.[33] This framework acknowledges the importance of the following aspects in supporting change within organisations: organisational development; workforce development; resource allocation; and leadership. Such intervention-implementation strategies have been effective in enhancing intervention fidelity in a number of public-health intervention trials.[34 35] These strategies are detailed in box 2.

Intervention quality assurance

The following quality-assurance processes will be implemented: appointment of club support staff who satisfy standard selection criteria; training sessions with all club support staff; fortnightly meetings between the research

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Box 2 Intervention-implementation strategies

Organisational development

Recognition and reward
Club practices will be recognised and rewarded through the three-level accreditation framework. A certificate of accreditation and merchandise (eg, bar mats, posters) will be provided at each level of accreditation to recognise and provide reward for intervention implementation. Three times during the intervention period, promotion of the accreditation status of all clubs will be undertaken via a programme newsletter, allowing for peer recognition.

Performance audit and feedback
Observational audits of clubs during busy football matches will be conducted at each level of accreditation by research staff whom are otherwise independent of intervention implementation. A formal written feedback report outlining the audit results and suggested strategies to improve intervention implementation will be provided to the club. A research team member will verbally discuss the report with the club.

Workforce development
Club staff will be trained in elements of the accreditation programme to facilitate club implementation of the intervention. Training will include government-accredited RSA training conducted by accredited training organisations. This package is a mandatory state-wide standard training package for all people serving alcohol. This includes training in: standard drink measures; checking identification; assessing intoxication and taking appropriate actions to cease service of alcohol to intoxicated persons and have them leave the licensed area; and required liquor licensing signage.

Resource allocation

Financial resources
All intervention clubs will be provided with $500 seed funding in each of the two intervention sporting seasons for expenditure on intervention-related products. Suggestions will be provided to the clubs on appropriate ways to spend funds.

Human resources
Each club will be allocated a club support officer who will assist the club in implementing required intervention strategies. Assistance will be in the form of face-to-face meetings with the club committee and face-to-face and phone/email contact with individual club representatives.

Physical resources
All clubs will receive a comprehensive hardcopy resource kit and electronic versions of resources to support implementation of required intervention strategies. These resources will include: templates for development of alcohol-management policies and required signage, and information on how to contact relevant food and beverage suppliers.

Leadership

Champion/peer opinion leaders
Endorsement will be sought from the sporting association for each participating football code. Letters of endorsement and encouragement will be sent from these associations to clubs as they progress through the accreditation programme.

Management support
The management committee of each club will be briefed on the programme at the start of the season and their support gained. Regular updates will be provided to management to maintain support for intervention implementation.

team and club support staff; maintenance of meeting logs by club support staff, which will be used to record all of their contact with their allocated clubs; standard club activity reporting sheets for club support staff to record intervention criteria implemented with each club; provision of standardised resources (clubs kits, presentation templates, etc) to club support staff for provision to clubs; and observational audits of clubs at each accreditation level to assess the quality of implementation of intervention criteria.

Control group clubs
During the intervention period, the control group will receive printed resources on topics unrelated to the trial outcomes such as illicit drug use.

Data collection procedures

Outcome data
At pre- and post-test, computer-assisted telephone surveys[36] will be conducted with members from clubs in intervention and control groups to assess alcohol consumption at the club. Survey questions will be developed based on validated measures of alcohol consumption[3 37 38] and will be pilot-tested. Data from telephone interviews with club members will be automatically transferred into a computerised data set and directly exported into data-analysis software. Any open fields will be coded by a trained member of the study team and checked by a second member of the team. Final outcome data will be collected by the end of 2012.

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Intervention implementation data

Data on intervention implementation will be collected via computer-assisted telephone surveys[36] of club members and club representatives (club president or other nominee) to assess the prevalence of intervention-related club policies and practices. Survey items will be developed by an expert advisory group of health-promotion practitioners and alcohol researchers, and will be pilot-tested before use in the study. Data from telephone interviews with club members will be automatically transferred into a computerised data set and directly exported into data-analysis software. Any open fields will be coded by a trained member of the study team and checked by a second member of the team.

Observational audits will be conducted at clubs during football matches as a secondary measure of intervention implementation, which will allow measurement triangulation.[39] Each audit will be conducted by two independent observers, and clubs will not be advised of the day that observations will be conducted. At least three audits per club will be conducted over the course of the study, with at least one per intervention accreditation level.

Data from telephone interviews with club members will be automatically transferred into a computerised data set and directly exported into data-analysis software. Any open fields will be coded by a trained member of the study team and checked by a second member of the team.

Process data

Measurement of intervention inputs and processes will be undertaken through the analysis of routine project-management records, including meeting logs, club activity reporting sheets and observational audit reports. Programme acceptability will be measured through items contained in a telephone survey conducted postintervention with representatives of clubs in the intervention group. Such items will be based on previous assessments of acceptability of public-health interventions[40 41] and will be piloted before use.

Club characteristic data

During surveys with club representatives, questions will be asked to assess club characteristics, such as football code, number of players and teams, club revenue and geographical location. Testing and piloting of these questions will be undertaken as described above.

Overall data management

Data management will be primarily the responsibility of a Hunter New England Population Health statistician, otherwise independent of the research team and trial activities. Management of trial data will be in accordance with a data-management protocol, which has been developed and approved by the Project Advisory Group. This protocol details requirements regarding data entry, data cleaning, data backup, secure storage and transport, and analysis. As a requirement of ethics approval granted by The University of Newcastle Human Research Ethics Committee (HREC), all data collected for the trial will be securely stored, accessible only to primary researchers and statisticians through the allocation of access rights. Confidential participant data including contact details (eg, phone numbers) will be stored in a secure data set that is not linked to survey response data sets. An independent statistician will be the only person with access to confidential participant data.

Measures

Primary outcome measure: alcohol consumption behaviour at the club

Alcohol consumption of club members at the club will be assessed using a graduated frequency index[3 37] and a 7-day diary.[38] Using the graduated frequency index, members will be asked how often they have consumed: 20 or more; 11–19; 7–10; 5–6; 3–4; and 1–2 standard drinks of alcohol at their club over the past 3 months. They will be asked to report whether the frequency of this consumption was: everyday; 5–6 days a week; 3–4 days a week; 1–2 days a week; 2–3 days a month; about 1 day a month; less often; or never. Consumption of five or more drinks about 1 day a month or more often will be used to define risky drinking that places members at risk of immediate harm.[42] Using the 7-day diary, members will be asked how many standard drinks of alcohol they consumed at their club each day for the last 7 days. The average number of drinks consumed by club members at the club during a weekend day (Saturday or Sunday) will be calculated. These dual primary outcome measures will be used to account for limitations inherent in each measure.[37 43 44]

Intervention-implementation measures

Intervention-implementation measures will be based on the accreditation criteria and include: the club's liquor licence status (yes/no) and type[45]; existence of a written alcohol-management policy (yes/no); alcohol-related sponsorship of the club (yes/no); sponsorship through free/discounted alcohol (yes/no); proportion of staff trained in responsible service of alcohol (all/most/some/none); how often staff consume alcohol on duty (never/rarely/sometimes/usually/always); availability of non-alcoholic and low-alcoholic drinks (yes/no); relative pricing of low-alcohol and full-strength alcohol drinks (low-alcohol more expensive/priced the same/full-strength alcohol more expensive); availability of substantial food when alcohol is sold (snacks/light meals/full meals); existence of alcohol promotions: happy hour, all you can drink, discounted drinks, alcohol awards/prizes and drinking vouchers (all yes/no); and how often alcohol is served to intoxicated people at the club and how often intoxicated people are admitted to the club (never/rarely/sometimes/frequently/always).

Process measures

Programme acceptability will be measured through a series of question regarding the acceptability of intervention content (box 1) and intervention-implementation

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strategies (box 2), with participants asked to respond to statements on a four-point Likert scale ranging from 'strongly agree' to 'strongly disagree.'

Measures of club characteristics

The following data will be collected about participating sporting clubs: club size (number of players and members), football code and postcode of sporting club.

Sample size and power calculations

Data previously collected indicate that the average number of drinks consumed by members of a sporting club on a weekend day is 4.7 (SD: 4.2), and the prevalence of at-risk alcohol consumption is approximately 27%. Based on these figures and allowing for intraclass correlations of 0.08 and 0.18, respectively, 35 clubs per experimental group and 19 members per club will provide the study with 80% power to detect a 13% difference in the prevalence of at-risk consumption, and 35 clubs per experimental group and seven members per club will provide the study with 80% power to detect a difference of 1.3 standard drinks in the average number of drinks consumed by members at the club on a weekend day.

Random allocation and blinding

Following the completion of pre test data collection from all club members, football clubs will be randomly allocated to intervention or control groups using simple randomisation in a 1:1 ratio. Allocation will be undertaken centrally by an independent statistician using a computerised random number generator in Microsoft Excel. The statistician involved in this randomisation procedure will neither have access to club pre test data nor be involved in intervention implementation or post-test data collection. The random allocation of clubs will be stratified by football code and geographic area, as evidence suggests that alcohol consumption of club members is associated with these characteristics.[3 46] Interview staff involved in collecting survey data postintervention will be blind to the treatment status of the club and not involved in any other aspect of the trial. To assess the effectiveness of blinding, interview staff will be asked to nominate the group allocation of participants following collection of post-intervention data. Owing to the difficulty in blinding clubs to group allocation, this will be an open trial with club representatives told of the treatment status of their club following pretest data collection.

Statistical analysis: primary outcome

SAS (V.9.2 or later) will be used for all statistical analyses. Descriptive statistics will be used to describe the demographic and practice characteristics of intervention and control group clubs and their members and to describe intervention implementation, process and acceptability.

To assess intervention efficacy, generalised estimating equations analysis will be used to examine between-group differences on the primary trial outcomes—using a logistic regression model for the categorical risky drinking outcome and a Poisson regression model for the continuous average number of drinks outcome. The generalised estimating equations analysis will adjust for the correlation of outcomes between individuals within clubs. Additionally, such an analysis will be performed incorporating imputation, whereby pretest member data will be carried forward in instances where post-test data are missing for clubs.

The outcome in the model will be at-risk alcohol consumption or number of drinks consumed over a weekend day. The predictors will include group allocation, an indicator variable for pre- and post-test, and the interaction of group and the indicator variable. The p value from the interaction term will be used to determine if there is any statistically significant difference in the change in the outcome over the treatment period. The α value for significance testing will be 0.05.

As a secondary exploratory analysis, both a per-protocol and subgroup analyses will be performed. A per-protocol analysis will be conducted excluding participants from clubs who had not implemented the intervention as specified in the protocol (did not achieve level 3 accreditation). Subgroup analyses will also be conducted by football-club code and for clubs located in urban (vs non-metropolitan) regions based on the values assigned to the club's postcode according to the Australian Standard Geographic Classification System.[47] Subgroup analyses will be performed to determine if the intervention may be differentially effective based on clubs with these characteristics.

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 of the grant, an employee of The University of Newcastle. The group includes other representatives from The University of Newcastle, as well as Hunter New England Population Health and the Australian Drug Foundation, including investigators on the Australian Research Council grant.

A Project Implementation Team has also been formed to implement the trial in accordance with the trial protocol. This team consists of staff members of The University of Newcastle, Hunter New England Population Health and the Australian Drug Foundation. Project implementation is coordinated from offices of Hunter New England Population Health.

Data management is the responsibility of a Hunter New England Population Health statistician, otherwise independent of the research team and trial activities. Management of trial data is in accordance with a data-management protocol, developed and approved by the Project Advisory Group.

Trial discontinuation or modification

There are no predetermined criteria for discontinuing or modifying the trial. While unintended adverse events to trial participants, researchers or other community

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members are not anticipated, any such events will be forwarded to The University of Newcastle HREC in accordance with the conditions of ethics approval. Should the research team or HREC consider it appropriate, the trial protocol or procedures may be modified to prevent such harm.

Any protocol modification will be communicated through modification of the trial registration listed in the Australian New Zealand Clinical Trials Registry and through publications disseminating trial results.

DISCUSSION

There is a clear absence of research evidence on the effectiveness of interventions to reduce excessive alcohol consumption in the sporting club setting. This will be the first randomised controlled trial to evaluate such an intervention in not just the community football club setting, but any sporting club setting. The study has a strong design that incorporates computerised random allocation, blinding of data-collection staff and the use of dual, validated outcome measures. In addition, the intervention is multifaceted and comprehensive, based on a strong theoretical framework and past research evidence involving both sporting clubs and licensed venues generally. The findings from this study will provide a basis for further research in the field and provide potentially important findings for both policy makers and those providing health-promotion programmes to community sporting groups.

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Competing interests None.

Ethics approval Ethics approval was provided by the University of Newcastle Human Research Ethics Committee on the 29/1/09 (reference: H-2008-0432).

Contributions MK led the development of this manuscript. JHW, LW, BCR, KEG and PM secured the funding for the project and, together with authors JT and MK, devised the research design and measures. JT, MK, LW, BCR, KEG, JHW and JCR were involved in devising the intervention content and intervention implementation strategies, which were based on those established and previously operated by JCR. JT, MK, LW, BCR and KEG were primarily responsible for the development of data-collection tools. LW, BCR, PM and MK were primarily responsible for the sample size and power calculations and development of proposed statistical analyses. All authors either drafted or critically revised the manuscript, and all authors approved the final version of the manuscript.

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