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A cluster randomised controlled trial of a multi-component intervention to support the implementation of policies and practices that promote healthier environments at junior sports clubs: study protocol

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Keywords: sporting clubs, randomised controlled trial, implementation, prevention, risk factors

Abstract

Introduction: A large proportion of children and adolescents participate in organised sport, making community sports clubs a promising setting to support healthy behaviours. To date however, there have been few interventions conducted in junior sports clubs that have targeted health promoting practices. The primary aim of this pilot study is to assess the potential effectiveness of an intervention to implement health promoting policies and practices in junior sporting clubs targeting alcohol and tobacco practices, healthy food and beverage availability, and physical activity via participation in sport. A secondary outcome is to assess the impact of such strategies on child exposure to alcohol and tobacco use at the club, purchasing behaviours by/for children at the club canteen, and child sports participation opportunities.

Methods and analysis: The study will employ a cluster randomised controlled trial design and be conducted in metropolitan and regional areas of two Australian states. Randomisation will occur at the level of the football league. Community football clubs with over 40 junior players (players under 18 years) within each league will be eligible to participate. The intervention will be developed based on frameworks that consider the social, cultural and environmental factors that influence health behaviours. Intervention clubs will be supported to implement 16 practices targeting alcohol management, tobacco use, nutrition practices, new player recruitment activity, equal participation for players, and the development of policies to support these practices. Trained research staff will collect outcome data via telephone interviews at baseline and follow-up. Interviews will be conducted with both club representatives and parents of junior players.

Ethics and dissemination: The study has been approved by the University of Newcastle Human Research Ethics Committee (H-2013-0429). The results of the study will be disseminated via peer-reviewed publications and presentations at conferences.

Trial registration number: Australian New Zealand Clinical Trials Registry ACTRN12617001044314.

Strengths and limitations of this study

- An independent statistician will randomly allocate football leagues to experimental groups using a computer-generated sequence.
- Post-intervention data will be collected by telephone interviewers who are blind to the experimental group allocation of parents of junior players.
- The intervention design will be guided by the socio-ecological framework and will focus on modifying the social, cultural and physical environments of sporting clubs.
- Experts including drug and alcohol researchers, health promotion practitioners, and behavioural and implementation scientists will develop the intervention content.
- Strategies recommended in the NSW Health Capacity Building Framework will be used to support the implementation of the intervention by sporting clubs.

Introduction

Chronic diseases, including cardiovascular disease, cancer, respiratory disease and diabetes account for more than 80% of deaths globally each year.[1] Modifiable risk factors such as tobacco use, alcohol consumption, physical inactivity and an unhealthy diet are significant contributors to the development of chronic disease.[2] Worldwide in 2010 it was estimated that, 22% of the population aged 15 years and older were current smokers,[3] the prevalence of heavy episodic drinking in the past 30 days for people aged 15 years and older was 16%,[1] and 23% of adults aged 18 years and over were insufficiently physically active, having less than 150 minutes of moderate-intensity physical activity per week.[1] In Australia the prevalence of smoking and heavy episodic drinking was slightly less, with 17% of the population aged 15 years and older being current smokers,[3] and 10% of people aged 15 years and older reporting heavy episodic drinking in the past 30 days.[1] However, almost a quarter (24%) of Australian adults aged 18 years and over were insufficiently physically active,[1] and in 2011-12 only 6% of Australian adults aged 18 years and over reported that they met the recommended daily servings of fruit and vegetables.[4]

Numerous studies have reported that health behaviours established in childhood and adolescence often track into adulthood. First experiences with alcohol generally occur during adolescence,[5] and early onset of drinking has been associated with alcohol dependence in adulthood.[6] Similarly, the uptake of tobacco smoking often begins in adolescence,[7] and commencing smoking at a young age has been linked to heavier smoking in adulthood and greater difficulty quitting.[8] Other studies have found that certain aspects of dietary intake in childhood, such as the consumption of fruit and vegetables, are significant determinants of dietary intake in adulthood,[9] and that levels of physical activity (or inactivity) in childhood remain relatively constant across the lifespan.[10] Given these findings, interventions to

improve health risk behaviours in childhood have been recommended to avert future chronic disease burden.

Effective child health behaviour interventions have previously been conducted in settings such as child care centres[11] and primary and secondary schools.[12 13] Recently, community sports clubs have also received recognition as a promising setting to implement health promoting interventions.[14-16] A significant number of individuals participate in organised sport, meaning sports clubs provide access to a large proportion of the population. For example, it is estimated that 270 million people worldwide actively participate in football (soccer) alone.[17] In the United Kingdom, 27% of children aged 5-15 years were reported to participate in organised sport outside of school hours in 2011-2012.[18] This proportion is roughly doubled in Australia, where 60 % of all children aged 5-14 years were reported to participate in at least one organised sport activity outside of school hours in 2011-2012.[19]

Despite the potential to mitigate health risk behaviours for children in the sports club setting, this potential is not yet being realised. Studies from Australia have reported that the implementation of alcohol harm reduction policies and practices by community sports clubs is sub-optimal.[16 20] Additionally, a report by Kelly and colleagues[21] found that 30% of regional sporting associations did not have written policies on smoke-free facilities. Sporting clubs are also not supportive of healthy eating, with studies suggesting club kiosks or canteens primarily sell energy dense, nutrient poor foods and beverages.[22 23] In a study where sporting club representatives were asked about products available at the club canteen it was reported that: 99% of clubs sold sweetened drinks;[23] 94% sold confectionary;[23] 99% sold salty snacks;[23] and 93% sold pastries.[23]

Not surprisingly, alcohol, smoking, and poor nutrition were identified as priority areas for health promotion in children's community sporting clubs by 26 health promotion, nutrition, physical activity and sport management/delivery professionals.[24] Recommendations by this expert group included: having responsible alcohol practices and restricting the sale and consumption of alcohol during children's sporting activities; having smoke-free club environments; increasing the availability of healthy foods and beverages at club canteens; and restricting unhealthy food and beverage company sponsorship.[24] Other aspects of the sporting club environment may impact a child's willingness to be physical active and participate in sport. For example, poor sideline and spectator behaviour from parents has been suggested to reduce child enjoyment.[25]

Few trials have sought to improve the environments of sporting clubs so that they are more supportive of healthy behaviours.[15] In senior clubs (for players 18 years and older), randomised trials have reported improvements in the implementation of alcohol management practices, and healthy food provision[20 26] with implementation support. However, to our knowledge no randomised trials have previously been conducted in junior sporting clubs (for players under 18 years) that investigate the impact of strategies to support the implementation of health promotion initiatives targeting multiple risk behaviours.

Methods and analysis

Study aim

The aim of this pilot study is to assess the potential effectiveness of an intervention to implement health promoting policies and practices in junior sporting clubs targeting alcohol and tobacco practices, healthy food and beverage availability, and physical activity via participation in sport. A secondary outcome is to assess the impact of such strategies on child

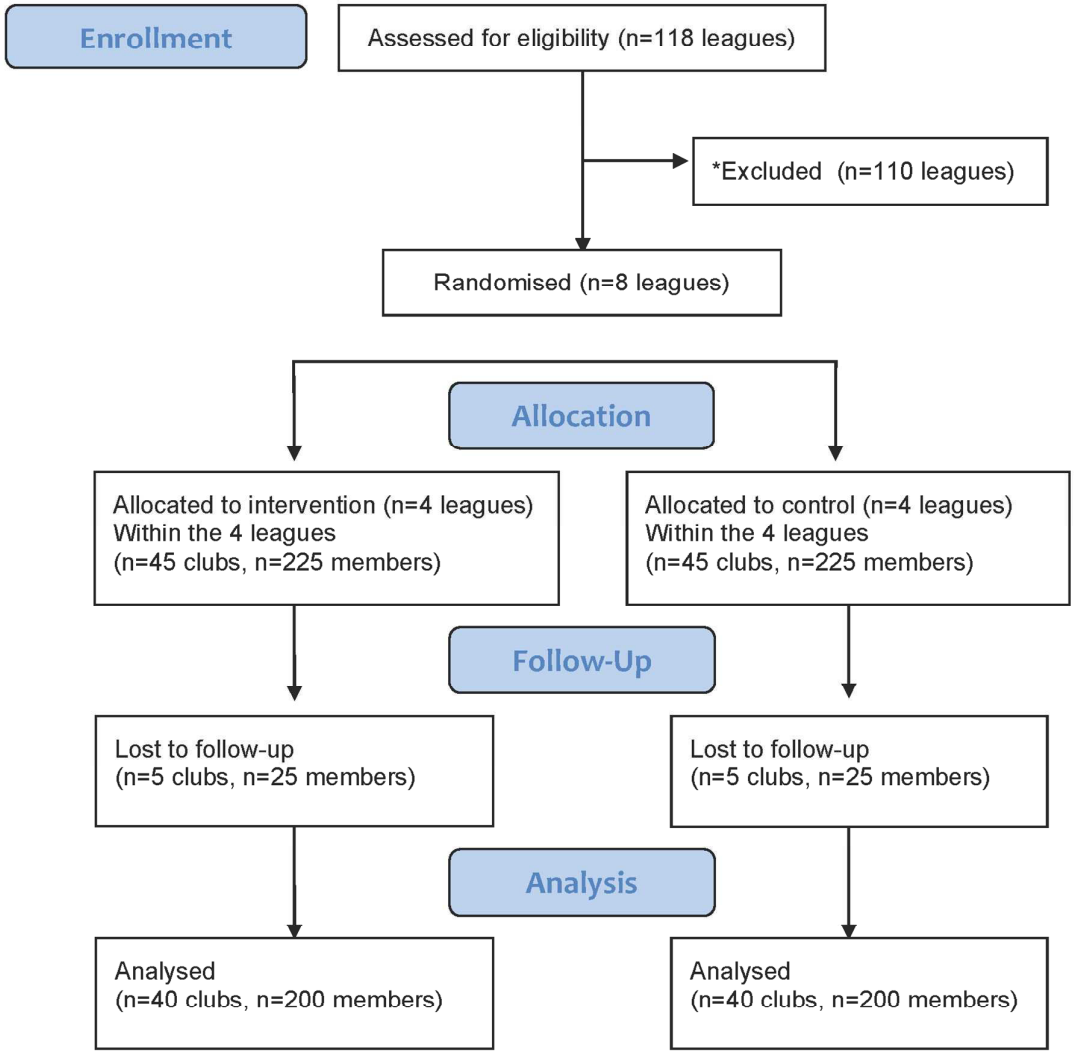
exposure to alcohol and tobacco use at the club, purchasing behaviours by/for children at the club canteen, and child sports participation opportunities.

Study design

As a pilot, and to inform future work in the field, the study will utilise an effectiveness-implementation hybrid design.[27] This will entail collecting information regarding strategies to improve the implementation of health promoting practices and policies, as well as data about the effects of the intervention on health behaviour.[27] The study will employ a cohort, cluster randomised controlled trial design for evaluation. The unit of randomisation will be the football League to which clubs belong (see Figure 1). A six month intervention over one winter sporting season will be implemented, with outcome data collected immediately following the intervention period.

Research setting

The trial will be conducted across the states of Victoria and New South Wales (NSW) Australia, and will encompass metropolitan and regional areas. The predominant code of football in NSW is Rugby League, which is played internationally in over 117 countries.[28] The predominant code of football in Victoria is Australian Rules (AFL), with approximately 35 countries in the world playing AFL at an amateur level.[29]



*Note –It is likely that the majority of leagues will be ineligible as most will not have ≥10 junior clubs who already meet Level 3 accreditation with the *Good Sports* program.

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

Participants and research eligibility

Football Leagues

All Australian Football Leagues in Victoria, and all Rugby and Country Rugby Leagues in NSW will be assessed for eligibility. Some clubs within these leagues will already be part of a sporting club alcohol harm reduction program called *Good Sports*.[30] The *Good Sports* program supports sporting clubs to implement alcohol management practices using a three-level accreditation process.[30]

AFL, Rugby and Country Rugby Leagues will be eligible to participate in the study if they: are a community-level (non-professional) league; are not currently involved in any other research trial; have ≥10 junior clubs who already meet Level 3 accreditation with the *Good Sports* program. The league is required to have ≥10 junior clubs who already meet Level 3 accreditation with the *Good Sports* program to ensure clubs in the trial are starting with a similar baseline attainment of alcohol management strategies.

Junior Football Clubs

Junior football clubs within participating leagues will be invited to participate. To be eligible clubs must have > 40 players. For the data collection component of the trial, one representative from each eligible junior club (e.g. president, secretary, committee member), who is aged 18 years or older and can speak sufficient English will be eligible to participate in a telephone interview.

Parents of Junior Players

Parents of junior players at the club will be able to participate in a telephone interview if they: are aged 18 years or older and speak sufficient English. Information collected from

parents of junior players will be included as a proxy for their child, given the young age of some junior players, and the likelihood that child exposure to many of the risk factors at the club (alcohol, tobacco, unhealthy food and beverages) will be dependent on their parent's behaviour.

Recruitment procedures

Football Leagues

Leagues which meet the eligibility criteria will be identified from the list of all AFLs in Victoria, and all Rugby and Country Rugby Leagues in NSW. A member of the research team will then arrange to attend a brief meeting with representatives of each eligible league to inform them about the research trial and verbally invite their participation. Following this meeting, formal information statements and consent forms will be emailed to the league representatives to obtain their written consent to participate.

Junior Football Clubs

Once a league has consented to participate, members of the research team will arrange to make a brief presentation at the next league meeting where representatives of all affiliated clubs will be present. The presentation will aim to inform clubs of the research trial and highlight the league's endorsement of club participation. Following the meeting, a nominated club representative (e.g. club president or secretary) will be emailed an information statement inviting participation in the study and a consent form. After the email has been sent, up to three follow-up calls will be made to confirm the clubs eligibility and to ascertain interest in participating in the study. In the event that a club representative does not recall receiving an invitation email, contact details will be clarified and a second copy of the information statement will be emailed.

The representative, who provides consent for their club to participate in the study, will also be asked if they (or another committee member) can be contacted to participate in a telephone interview. The contact details of the nominated representative will then be recorded by the research staff and passed on to the interviewers.

Parents of Junior Players

As part of the club recruitment process, electronic information statements for parents of junior players will be included as an attachment in the club's invitation email. Club representatives will be asked to distribute either electronic or hard copies of the information statements to the parents of junior players. Parents who are willing to participate in a telephone interview will be asked to provide consent for the club representative to forward their name and telephone contact details to the research team. The research team will then pass these contact details on to the telephone interviewers who will confirm the parent's eligibility and obtain verbal consent to participate in the study at the time of the telephone interview.

In order to maximise research participation by both club representatives and parents, the research team will utilise strategies such as pre-notification of the study, invitation and consent via direct phone contact, and multiple contact attempts.[31]

Random allocation and blinding

Eligible leagues will be identified and randomly allocated to either the intervention group (multi-component, risk factor prevention) or control group (no contact group) following baseline data collection. Leagues will be matched on code (AFL or Rugby) and jurisdiction

(Victoria or NSW) and randomly allocated to an experimental condition in a 1:1 ratio. The randomisation sequence will be computer generated by an independent statistician. This block randomisation of clubs to either the intervention or control condition will occur post-baseline data collection (i.e. once the telephone interviews for all club representatives and parents of junior players have been completed). Telephone interviewers collecting the post-intervention data will not be members of the research team. Due to the nature of the intervention, club representatives will not be blind to their club's experimental group allocation. Interviewers will also be aware of the experimental group allocation of clubs, as representatives from intervention clubs will be asked to answer an additional set of survey items regarding the intervention process. However, for the telephone interview with parents, interviewers will not know whether participants are from intervention or control clubs.

Intervention

Intervention development

The intervention has been developed by an expert advisory group consisting of experienced drug and alcohol researchers, health promotion practitioners, and behavioural and implementation scientists. It is based on a socio-ecological framework focusing on modifying the social, cultural and physical environments of sporting organisations so that they are more supportive of making healthy choices.[32] Specifically the intervention will focus on the implementation of 16 policies and practices (listed in Table 1) to reduce child exposure to alcohol and tobacco use at the club, to improve the availability and promotion of healthy food and drinks at the club, and to support child participation in sport. The policies and practices are consistent with: 1) relevant legislation (e.g. alcohol management and smoke free legislation); 2) evidence which suggests such policies or practices may be associated with improved health behaviors;[33] 3) previous health promotion initiatives in this setting[16 20 26]

conducted by the research team, and 4) recommendations following consultation with sporting clubs and content experts.

Table 1. List of the 16 policies and practices to be implemented by clubs in the intervention group.

1) Alcohol is not available or consumed during junior competition
2) Alcohol is not available or consumed at junior events or presentations
3) Alcohol is not present in the change rooms when players under 18 years are present
4) Alcohol manufacturers, wholesalers, retailers or other businesses whose core function is to sell alcohol are not promoted or advertised by the club on any junior apparel
5) Alcohol is not used for prizes, rewards or for fundraising
6) The club is compliant with the relevant state tobacco legislation
7) The club promotes all junior events as smoke free
8) Water is promoted as the drink of choice for junior players
9) Multiple healthy food and beverage (e.g. fruit, vegetables and non-sugar sweetened drink) options are available at the canteen or barbeque
10) The purchase of healthy choices at the canteen or barbeque are promoted by ensuring healthy food and beverage options are displayed prominently
11) The club encourages parents to provide healthy snacks (e.g. fruit and water) for junior players
12) The club conducts at least one recruitment activity prior to the beginning of the winter sporting season to attract new junior players and retain current players
13) The club has a Participation policy that it communicates to members, coaches, officials and volunteers to ensure junior players are provided with equal opportunities for participation at both training and during games
14) The club has a Code of Conduct policy which it communicates to all members, and ensures member agreement is recorded
15) The club has a Spectator Behaviour policy that is promoted and clearly visible at the club
16) The club has a written Good Sports Junior policy, which outlines the club's practices with regards to alcohol consumption, tobacco use, healthy eating and physical activity at junior competitions and events

Implementation support strategies.

The research team will support clubs to implement the 16 intervention components using strategies recommended in the NSW Health Capacity Building Framework.[34] The framework has been previously used by the research team to improve the implementation of healthy eating and alcohol management practices in senior sporting clubs. The framework identifies key action areas including: Organisational Development; Workforce Development; and

Resource Allocation. Specific strategies within these action areas have been selected to address identified barriers to the implementation of health promotion interventions by community sporting clubs[35 36] and are summarised in in Table 2.

Intervention delivery

The intervention will consist of face-to-face, web- and phone-based support to assist junior sporting clubs to implement health promoting practices. Implementation support will be provided over one winter sports season in Australia, which usually runs for 6 months (March to August). Implementation support staff will be based at the Alcohol and Drug Foundation. Support staff will not be required to have any particular tertiary qualifications, however they will have experience in previous Good Sports Service Delivery. Support staff will offer assistance to intervention clubs by contacting them three times by email and three times by phone throughout the intervention period, with the mode of contact alternating each month. The first phone contact will last for approximately 30 minutes and will focus on reviewing the clubs current practices, which support staff will record using an online customer relationship management (CRM) system. The CRM system will then generate action plans that will help clubs to identify the practices they need to implement. Resources (see table 2) will be sent to clubs after the first telephone contact. The remaining two phone calls will check on the clubs progress in implementing the identified practices and will last for around 10-15 minutes. The three email contacts from support staff will identify practices that clubs might like to focus on in the coming month. Support staff will encourage club representatives to provide evidence of the implementation of the intervention strategies via the upload of policies, photos, and copies of emails to club members onto the online CRM system. In addition to the six contacts initiated by support staff, automated theme-based emails will also be sent to clubs monthly throughout the sporting season. These emails will each contain

content relevant to the five themes of: 1) conduct; 2) healthy eating; 3) alcohol; 4) smoking; and 5) member conduct. For example, the automated alcohol themed email will emphasise the importance of changing the club's culture around alcohol for junior members and include some key messages for the club to share on their social media pages. The messages will be included at the end of the email so clubs can copy these messages directly onto their social media pages (e.g. Facebook, Instagram, Twitter). Key messages for the alcohol email will include short sentences about the potential risks and harms of alcohol consumption, and the importance of role-modeling for junior players.

Table 2. Intervention implementation support strategies

Organisational Development	
Management support	Research staff will be allocated time to speak to club representatives about the research study at a Football League meeting, which all clubs attend. Football Leagues will endorse the intervention to their clubs via email and encourage their clubs participation and progress through the program.
Policies and procedures	Club representatives will be provided with hardcopy and electronic templates to assist clubs develop health promotion policies. Examples of recruitment strategies that can be used to attract new junior players to the club, and retain current players, will also be supplied.
Recognition and reward systems	Clubs will be provided with ongoing recognition of progress (e.g. upon completion of an action item, at monthly contacts) to promote sustained engagement. Progress will be recognised and rewarded with a certificate of accreditation. A digital asset pack (copy and paste templates for the club's social media pages and website) will be provided to clubs when they have achieved accreditation. Clubs will also be provided with a 'case study template' that they can provide to their local media outlet, which will showcase their participation in the program.
Information systems	A customer relationship management (CRM) system will allow research staff to monitor the progress of each club towards achieving the intervention criteria and provide real time feedback. Clubs will be provided with tailored action plans generated by the CRM system.
Systems and prompts	Electronic reminders (e.g. emails) will be used to prompt the implementation of pre-specified health promotion practices.
Informal culture	Clubs will be encouraged to select rounds of the junior competition, or a junior event, to focus on promoting the intervention informally (i.e. the alcohol awareness round, or the healthy juniors round).
Workforce Development	
External courses	Clubs will be provided with an alcohol management toolkit to increase awareness of alcohol legislation and best practice strategies to manage alcohol in their setting.
Resource allocation	
Human resources	Research staff will be allocated to help clubs implement the intervention. These research staff will also monitor and provide feedback on the implementation of practices. Assistance will be provided via regular phone and email contact with individual club representatives (once per month) during the winter season to maintain support.
Physical resources	A comprehensive kit of hard copy resources will be provided to clubs upon commencement of participation. The kit will include: posters promoting alcohol free junior competitions; alcohol free change room signs; a list of alternate prizes to alcohol for fundraisers, raffles or gifts to coaches; smoke-free posters; a canteen whiteboard to promote healthy food and beverage options prominently; a safe food handling poster; letter templates for clubs to send to parents to encourage them to provide healthy snacks for juniors; a playing environment sign with the Good Sports code of conduct prominently displayed, and other similar signs, posters and letter templates. Additionally, electronic versions of resources will be provided to junior clubs throughout winter season via email, including the policy templates, posters and signage. Links to industry experts (i.e. healthy food and beverage suppliers) will be provided to clubs, and a lead sporting person for each participating football code (AFL or Rugby League) will endorse the intervention through hard-copy and digital (e.g. video) resources. The Alcohol and Drug Foundation will develop all toolkits and resources for use in the intervention.

Control group clubs

Control clubs will not be offered any implementation support or resources by the research team throughout the intervention period. There may be instances where control clubs pro-actively contact the Alcohol and Drug Foundation seeking support regarding an area targeted by the intervention. Any support provided to clubs following such requests will be documented and reported.

Trial outcomes

Primary outcome

The primary trial outcome will be the mean number of policies and practices (out of 16) implemented by junior sporting clubs. The number of policies and practices that each junior sporting club has implemented will be reported by the junior club representative during a telephone interview, designed by the research team for the study.

Secondary outcomes

Secondary outcomes will be the proportion of clubs who implement each of the following policies and practices. This will be assessed as the proportion of junior club representatives who report via telephone interview that, in the past season:

1) alcohol was not available or consumed during junior competition;

2) alcohol was not available or consumed at junior events or presentations;

3) alcohol was not present in the change rooms when under 18 players were present;

4) alcohol manufacturers, wholesalers, retailers or other businesses whose core function is to sell alcohol were not promoted or advertised by the club on any junior apparel;

5) alcohol was not used for prizes, rewards or for fundraising;

6) the club was compliant with the relevant state tobacco legislation;

7) the club promoted all junior events as smoke free;

8) water was promoted as the drink of choice for junior players;

9) multiple healthy food and beverage options (e.g. fruit, vegetables and non-sugar sweetened drink) were available at the canteen or barbeque;

10) the purchase of healthy choices at the canteen or barbeque was promoted by ensuring healthy food and beverage options were displayed prominently;

11) the club encouraged parents to provide healthy snacks (e.g. fruit and water) for junior players

12) the club conducted at least one recruitment activity prior to the beginning of the winter sporting season to attract new junior players and retain current players;

13) the club has a Participation policy that it communicated to members, coaches, officials and volunteers to ensure junior players were provided with equal opportunities for participation at both training and during games;

14) the club has a Code of Conduct policy which it communicated to all members, and ensured member agreement was recorded;

15) the club has a Spectator Behaviour policy that was promoted and clearly visible at the club;

16) the club has a written Good Sports Junior policy, which outlines the club's practices with regards to alcohol consumption, tobacco use, healthy eating and physical activity at junior competitions and events.

Other secondary outcomes will be child exposure alcohol and tobacco, child healthy food and drink purchases, opportunities for physical activity (equal participation), and provision of a safe playing environment (code of conduct). This will be assessed as the proportion of

parents of junior players at the club who report via telephone interview that, in the past season:

1) they have not consumed alcohol at the club during junior matches or events;

2) they have not smoked tobacco at the club during junior matches or events;

3) they have signed the club's Code of Conduct policy;.

4) the club encouraged them to bring healthy snacks for junior players by providing them with information about healthy snacks and the club's policy about healthy snacks;

5) a healthy food item was usually purchased from the club canteen by/for their child;

6) a healthy beverage was usually purchased from the club canteen by/for their child;

7) their child spent as much time involved in training and on the field during games as other children in their team.

Opportunities for regular physical activity for children will also be assessed by measuring the number of junior players (under 18 years) registered to play at each club. This information is held by the leagues the clubs belong to, therefore research staff will request this de-identified data from the leagues directly.

Data collection procedures

Primary outcome

Primary outcome data will be collected via computer-assisted telephone interviews (CATIs) with club representatives at baseline (July-September 2016) and post-intervention (August-September 2017). The club representative CATIs will take approximately 30 minutes to complete. Given that sporting club committee membership often changes from year to year, the club representative who completes the CATI at baseline may not be the same person who completes the CATI post-intervention.

Secondary outcomes

Secondary outcome data will be collected via the CATI with club representatives (described above) and the CATI with parents of junior players, at baseline and post-intervention. The CATI of parents of junior players will take approximately 40 minutes to complete, and the same cohort of parents will complete the survey at baseline and post-intervention.

Demographic characteristics

Items in the club representative CATI will capture data on the club (e.g. football code, number of players/teams, and geographic location) as well as the demographic characteristics of the club representatives (e.g. gender, age, role at the club, education level). Items in the parent CATI will capture the demographic characteristics of parents of junior players (e.g. gender, age, education level, socio-economic status).

Data management

Data collected from the telephone interviews will be transferred automatically into a computerised data set. Data sets will then be directly exported into data-analysis software. A trained member of the research team will code any open data fields, and these will be cross checked by a second research team member. Analyses of the trial data will be the responsibility of a statistician independent to the research team. As per human research ethics requirements, all data will be stored securely and will only be accessed by members of the research team and the appointed statistician. Identifying participant details will be stored separately from their telephone survey responses, and all analyses will be performed using de-identified datasets.

Sample size and power calculations

A sample size of 40 clubs per group at follow-up will enable the detection of a difference of 63% of a SD (or 0.63 units of z-score) between groups in all continuous outcomes, as reported by the club representative. Allowing for approximately 10% of clubs to be lost to follow-up, 45 clubs per group from 4 leagues (a total of 90 clubs from 8 leagues) will be recruited at baseline.

A sample size of 200 parents per group from 80 clubs at follow-up, with an intra-class correlation of ICC=0.05, will yield an effective sample size of 139 parents per group (assuming an 80% response rate). 139 parents per group will enable the detection of a reasonable detectable difference in behaviour across secondary outcomes including: a 15% increase in healthy food purchases by/for children (from 20% to 35%) and a 17% increase in healthy drink purchases by/for children (from 50% to 67%).

Statistical analysis

Descriptive statistics will be used to describe the demographic characteristics of participating clubs and club representatives, as well as the mean number of practices and policies implemented by the club.

Primary outcome

For the primary outcome, a linear regression model will be implemented under an intention to treat approach to compare group differences on the mean number of practices and policies at follow-up, adjusting for baseline values. Sub-group analyses will be conducted by introducing group by sub-group interaction terms into the linear model for: football code

(AFL vs Rugby League), and geographic location (metropolitan vs regional) using the Australian Standard Geographic Classification System[37] based on the club's postcode. All analyses will be conducted using SAS (V9.3 or later).

Secondary outcomes

Generalised linear mixed model analysis will be used to examine between group differences to account for potential clustering effect. The models will be implemented under an intention to treat approach, adjusting for baseline values. The alpha value for significance testing will be 0.05.

Research trial coordination

The research team will oversee the conduct of the trial in accordance with the protocol. Data management and analyses will be conducted by a statistician who is independent of the project team and the trial implementation.

Trial discontinuation or modification

Trial discontinuation or modification will only occur if an adverse event could result in unintended harm to the trial participants, as determined by the University of Newcastle's Human Research Ethics Committee. If any such trial modification is deemed necessary by the ethics committee, changes to the protocol will be updated on the trial registration held by the Australian New Zealand Clinical Trials Registry. These changes will also be communicated in any publications reporting the outcomes of the trial.

Ethics and dissemination

This trial has been approved by the University of Newcastle Human Research Ethics Committee (H-2013-0429) and registered with the Australian New Zealand Clinical Trials Registry ACTRN12617001044314. Study findings will be disseminated widely through peer-reviewed publications and conference presentations.

Discussion

A large proportion of children and adolescents participate in organised sport, and their parents attend as spectators, making junior sporting clubs a promising setting to support healthy behaviours for all family members. This will be the first intervention to focus on modifying the social, cultural, physical and environmental aspects of junior sporting clubs to support health-promoting behaviours. The study has been designed to allow random allocation of football leagues using a computer-generated sequence. Interviewers collecting the post-intervention data will be blind to the experimental group allocation of parents of junior players. Strategies to support clubs implement the intervention practices follow those recommended by the NSW Health Capacity Building Framework.[34] Results from this study will inform policy makers and those providing health-promoting interventions with valuable information regarding the best way to support junior sporting clubs provide a healthier environment for their members.

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Authors contributions

SM, SS, MK, AM, DB, JW and LW contributed to the conception of the project and intervention content. SM, SS, TCM, JD, NZ, SG, JYO and LW contributed to the study design, intervention development and evaluation methods. All authors drafted, critically reviewed and edited the final manuscript. All authors approved the version to be published and are responsible for its accuracy.

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Competing interests statement

All authors declare that they have no competing interests.

SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents*

Section/item	Item No	Description	Addressed on page number
Administrative information			
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	1
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry	4
	2b	All items from the World Health Organization Trial Registration Data Set	ANZCTR meets this criteria
Protocol version	3	Date and version identifier	n/a
Funding	4	Sources and types of financial, material, and other support	28
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors	1, 28
	5b	Name and contact information for the trial sponsor	n/a
	5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	n/a
	5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	n/a

Introduction			
Background and rationale	6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	4-6
	6b	Explanation for choice of comparators	n/a
Objectives	7	Specific objectives or hypotheses	6
Trial design	8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory)	7
Methods: Participants, interventions, and outcomes			
Study setting	9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained	7
Eligibility criteria	10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	9
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	12-17
	11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease)	22
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)	16
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	n/a
Outcomes	12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	17-19
Participant timeline	13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	14-15,19

Sample size	14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	21
Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size	11
Methods: Assignment of interventions (for controlled trials)			
Allocation:			
Sequence generation	16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	11-12
Allocation concealment mechanism	16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	11-12
Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	10-11
Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	11-12
	17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	n/a
Methods: Data collection, management, and analysis			
Data collection methods	18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	19-20
	18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	n/a

Data management	19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	20
Statistical methods	20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	21-22
	20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	21-22
	20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	21
Methods: Monitoring			
Data monitoring	21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	22
	21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	22
Harms	22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	22
Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	22
Ethics and dissemination			
Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval	23
Protocol amendments	25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators)	22

Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	10-11
	26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	n/a
Confidentiality	27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	20
Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site	28
Access to data	29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	20
Ancillary and post-trial care	30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	n/a
Dissemination policy	31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	23
	31b	Authorship eligibility guidelines and any intended use of professional writers	n/a
	31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	n/a
Appendices			
Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates	n/a
Biological specimens	33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	n/a

*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items. Amendments to the protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT Group under the Creative Commons "Attribution-NonCommercial-NoDerivs 3.0 Unported" license.

BMJ Open

A cluster randomised controlled trial of a multi-component intervention to support the implementation of policies and practices that promote healthier environments at junior sports clubs: study protocol

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A cluster randomised controlled trial of a multi-component intervention to support the implementation of policies and practices that promote healthier environments at junior sports clubs: study protocol

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Keywords: sporting clubs, randomised controlled trial, implementation, prevention, risk factors

Abstract

Introduction: A large proportion of children and adolescents participate in organised sport, making community sports clubs a promising setting to support healthy behaviours. To date however, there have been few interventions conducted in junior sports clubs that have targeted health promoting practices. The primary aim of this pilot study is to assess the potential effectiveness of an intervention to implement health promoting policies and practices in junior sporting clubs targeting alcohol and tobacco practices, healthy food and beverage availability, and physical activity via participation in sport. A secondary outcome is to assess the impact of such strategies on child exposure to alcohol and tobacco use at the club, purchasing behaviours by/for children at the club canteen, and child sports participation opportunities.

Methods and analysis: The study will employ a cluster randomised controlled trial design and be conducted in metropolitan and regional areas of two Australian states. Randomisation will occur at the level of the football league. Community football clubs with over 40 junior players (players under 18 years) within each league will be eligible to participate. The intervention will be developed based on frameworks that consider the social, cultural and environmental factors that influence health behaviours. Intervention clubs will be supported to implement 16 practices targeting alcohol management, tobacco use, nutrition practices, new player recruitment activity, equal participation for players, and the development of policies to support these practices. Trained research staff will collect outcome data via telephone interviews at baseline and follow-up. Interviews will be conducted with both club representatives and parents of junior players.

Ethics and dissemination: The study has been approved by the University of Newcastle Human Research Ethics Committee (H-2013-0429). The results of the study will be disseminated via peer-reviewed publications and presentations at conferences.

Trial registration number: Australian New Zealand Clinical Trials Registry ACTRN12617001044314.

Strengths and limitations of this study

- An independent statistician will randomly allocate football leagues to experimental groups using a computer-generated sequence.
- Post-intervention data will be collected by telephone interviewers who are blind to the experimental group allocation of parents of junior players.
- The intervention design will be guided by the socio-ecological framework and will focus on modifying the social, cultural and physical environments of sporting clubs.
- Experts including drug and alcohol researchers, health promotion practitioners, and behavioural and implementation scientists will develop the intervention content.
- Strategies recommended in the NSW Health Capacity Building Framework will be used to support the implementation of the intervention by sporting clubs.

Introduction

Chronic diseases, including cardiovascular disease, cancer, respiratory disease and diabetes account for more than 80% of deaths globally each year.[1] Modifiable risk factors such as tobacco use, alcohol consumption, physical inactivity and an unhealthy diet are significant contributors to the development of chronic disease.[2] Worldwide in 2010 it was estimated that, 22% of the population aged 15 years and older were current smokers,[3] the prevalence of heavy episodic drinking in the past 30 days for people aged 15 years and older was 16%,[1] and 23% of adults aged 18 years and over were insufficiently physically active, having less than 150 minutes of moderate-intensity physical activity per week.[1] In Australia the prevalence of smoking and heavy episodic drinking was slightly less, with 17% of the population aged 15 years and older being current smokers,[3] and 10% of people aged 15 years and older reporting heavy episodic drinking in the past 30 days.[1] However, almost a quarter (24%) of Australian adults aged 18 years and over were insufficiently physically active,[1] and in 2011-12 only 6% of Australian adults aged 18 years and over reported that they met the recommended daily servings of fruit and vegetables.[4]

Numerous studies have reported that health behaviours established in childhood and adolescence often track into adulthood. First experiences with alcohol generally occur during adolescence,[5] and early onset of drinking has been associated with alcohol dependence in adulthood.[6] Similarly, the uptake of tobacco smoking often begins in adolescence,[7] and commencing smoking at a young age has been linked to heavier smoking in adulthood and greater difficulty quitting.[8] Other studies have found that certain aspects of dietary intake in childhood, such as the consumption of fruit and vegetables, are significant determinants of dietary intake in adulthood,[9] and that levels of physical activity (or inactivity) in childhood remain relatively constant across the lifespan.[10] Given these findings, interventions to

improve health risk behaviours in childhood have been recommended to avert future chronic disease burden.

Effective child health behaviour interventions have previously been conducted in settings such as child care centres[11] and primary and secondary schools.[12 13] Recently, community sports clubs have also received recognition as a promising setting to implement health promoting interventions.[14-16] A significant number of individuals participate in organised sport, meaning sports clubs provide access to a large proportion of the population. For example, it is estimated that 270 million people worldwide actively participate in football (soccer) alone.[17] In the United Kingdom, 27% of children aged 5-15 years were reported to participate in organised sport outside of school hours in 2011-2012.[18] This proportion is roughly doubled in Australia, where 60 % of all children aged 5-14 years were reported to participate in at least one organised sport activity outside of school hours in 2011-2012.[19]

Despite the potential to mitigate health risk behaviours for children in the sports club setting, this potential is not yet being realised. Studies from Australia have reported that the implementation of alcohol harm reduction policies and practices by community sports clubs is sub-optimal.[16 20] Additionally, a report by Kelly and colleagues[21] found that 30% of regional sporting associations did not have written policies on smoke-free facilities. Sporting clubs are also not supportive of healthy eating, with studies suggesting club kiosks or canteens primarily sell energy dense, nutrient poor foods and beverages.[22 23] In a study where sporting club representatives were asked about products available at the club canteen it was reported that: 99% of clubs sold sweetened drinks;[23] 94% sold confectionary;[23] 99% sold salty snacks;[23] and 93% sold pastries.[23]

Not surprisingly, alcohol, smoking, and poor nutrition were identified as priority areas for health promotion in children's community sporting clubs by 26 health promotion, nutrition, physical activity and sport management/delivery professionals.[24] Recommendations by this expert group included: having responsible alcohol practices and restricting the sale and consumption of alcohol during children's sporting activities; having smoke-free club environments; increasing the availability of healthy foods and beverages at club canteens; and restricting unhealthy food and beverage company sponsorship.[24] Other aspects of the sporting club environment may impact a child's willingness to be physical active and participate in sport. For example, poor sideline and spectator behaviour from parents has been suggested to reduce child enjoyment.[25]

Few trials have sought to improve the environments of sporting clubs so that they are more supportive of healthy behaviours.[15] In senior clubs (for players 18 years and older), randomised trials have reported improvements in the implementation of alcohol management practices, and healthy food provision[20 26] with implementation support. However, to our knowledge no randomised trials have previously been conducted in junior sporting clubs (for players under 18 years) that investigate the impact of strategies to support the implementation of health promotion initiatives targeting multiple risk behaviours.

Methods and analysis

Study aim

The aim of this pilot study is to assess the potential effectiveness of an intervention to implement health promoting policies and practices in junior sporting clubs targeting alcohol and tobacco practices, healthy food and beverage availability, and physical activity via participation in sport. A secondary outcome is to assess the impact of such strategies on child

exposure to alcohol and tobacco use at the club, purchasing behaviours by/for children at the club canteen, and child sports participation opportunities.

Study design

As a pilot, and to inform future work in the field, the study will utilise an effectiveness-implementation hybrid design.[27] This will entail collecting information regarding strategies to improve the implementation of health promoting practices and policies, as well as data about the effects of the intervention on health behaviour.[27] Hybrid designs have been recommended to facilitate research translation, as they provide policy makers and practitioners with information to assess the merit of an intervention, as well as the mechanisms needed to implement it.[27 28]

The study will employ a cohort, cluster randomised controlled trial (RCT) design for evaluation. Cluster RCT designs are appropriate when interventions are implemented at the level of the organisation and expected to impact groups of people within the organisation (clusters).[29] In the case of this study, junior football clubs are the organisation within which junior players (and their parents) are clustered. The unit of randomisation will be the football League to which junior football clubs belong (see Figure 1). A six month intervention over one winter sporting season will be implemented, with outcome data collected immediately following the intervention period.

Research setting

The trial will be conducted across the states of Victoria and New South Wales (NSW) Australia, and will encompass metropolitan and regional areas. Victoria has a population of around 6.2 million people, with approximately 4.7 million people residing in the greater

metropolitan area of Melbourne, and 1.5 million living in other regional and remote areas of the state.[30] NSW has a population of more than 7.7 million people, with approximately 5 million people living in the greater Sydney metropolitan area, and 2.7 million residing in regional and remote areas.[30] The predominant code of football in NSW is Rugby League, which is played internationally in over 117 countries.[31] The predominant code of football in Victoria is Australian Rules (AFL), with approximately 35 countries in the world playing AFL at an amateur level.[32]

Participants and research eligibility

Football Leagues

All Australian Football Leagues in Victoria, and all Rugby and Country Rugby Leagues in NSW will be assessed for eligibility. Some clubs within these leagues will already be part of a sporting club alcohol harm reduction program called *Good Sports*.[33] The *Good Sports* program supports sporting clubs to implement alcohol management practices using a three-level accreditation process.[33]

AFL, Rugby and Country Rugby Leagues will be eligible to participate in the study if they: are a community-level (non-professional) league; are not currently involved in any other research trial; have ≥10 junior clubs who already meet Level 3 accreditation with the *Good Sports* program. The league is required to have ≥10 junior clubs who already meet Level 3 accreditation with the *Good Sports* program to ensure clubs in the trial are starting with a similar baseline attainment of alcohol management strategies.

Junior Football Clubs

Junior football clubs within participating leagues will be invited to participate. To be eligible clubs must have > 40 players. For the data collection component of the trial, one representative from each eligible junior club (e.g. president, secretary, committee member), who is aged 18 years or older and can speak sufficient English will be eligible to participate in a telephone interview.

Parents of Junior Players

Parents of junior players at the club will be able to participate in a telephone interview if they: are aged 18 years or older and speak sufficient English. Information collected from

parents of junior players will be included as a proxy for their child, given the young age of some junior players, and the likelihood that child exposure to many of the risk factors at the club (alcohol, tobacco, unhealthy food and beverages) will be dependent on their parent's behaviour.

Recruitment procedures

Football Leagues

Leagues which meet the eligibility criteria will be identified from the list of all AFLs in Victoria, and all Rugby and Country Rugby Leagues in NSW. A member of the research team will then arrange to attend a brief meeting with representatives of each eligible league to inform them about the research trial and verbally invite their participation. Following this meeting, formal information statements and consent forms will be emailed to the league representatives to obtain their written consent to participate.

Junior Football Clubs

Once a league has consented to participate, members of the research team will arrange to make a brief presentation at the next league meeting where representatives of all affiliated clubs will be present. The presentation will aim to inform clubs of the research trial and highlight the league's endorsement of club participation. Following the meeting, a nominated club representative (e.g. club president or secretary) will be emailed an information statement inviting participation in the study and a consent form. After the email has been sent, up to three follow-up calls will be made to confirm the clubs eligibility and to ascertain interest in participating in the study. In the event that a club representative does not recall receiving an invitation email, contact details will be clarified and a second copy of the information statement will be emailed.

The representative, who provides consent for their club to participate in the study, will also be asked if they (or another committee member) can be contacted to participate in a telephone interview. The contact details of the nominated representative will then be recorded by the research staff and passed on to the interviewers.

Parents of Junior Players

As part of the club recruitment process, electronic information statements for parents of junior players will be included as an attachment in the club's invitation email. Club representatives will be asked to distribute either electronic or hard copies of the information statements to the parents of junior players. Parents who are willing to participate in a telephone interview will be asked to provide consent for the club representative to forward their name and telephone contact details to the research team. The research team will then pass these contact details on to the telephone interviewers who will confirm the parent's eligibility and obtain verbal consent to participate in the study at the time of the telephone interview.

In order to maximise research participation by both club representatives and parents, the research team will utilise strategies such as pre-notification of the study, invitation and consent via direct phone contact, and multiple contact attempts.[34]

Random allocation and blinding

Eligible leagues will be identified and randomly allocated to either the intervention group (multi-component, risk factor prevention) or control group (no contact group) following baseline data collection. Leagues will be matched on code (AFL or Rugby) and jurisdiction

(Victoria or NSW) and randomly allocated to an experimental condition in a 1:1 ratio. The randomisation sequence will be computer generated by an independent statistician. This block randomisation of clubs to either the intervention or control condition will occur post-baseline data collection (i.e. once the telephone interviews for all club representatives and parents of junior players have been completed). Due to the nature of the intervention, club representatives will not be blind to their club's experimental group allocation.

Telephone interviewers collecting the post-intervention data will not be members of the research team. For questions regarding the trial outcomes, telephone interviewers will be blind to the experimental group allocation of clubs. After the questions related to trial outcomes have been completed, an additional set of questions will appear for intervention clubs. These additional questions will relate to the club's use of implementation support strategies (e.g. use of resources). At this point, the interviewer will become aware of the club's experimental group allocation. For the telephone interview with parents, interviewers will not know whether participants are from intervention or control clubs.

Intervention

Intervention development

The intervention has been developed by an expert advisory group consisting of experienced drug and alcohol researchers, health promotion practitioners, and behavioural and implementation scientists. It is based on a socio-ecological framework focusing on modifying the social, cultural and physical environments of sporting organisations so that they are more supportive of making healthy choices.[35] Specifically the intervention will focus on the implementation of 16 policies and practices (listed in Table 1) to reduce child exposure to alcohol and tobacco use at the club, to improve the availability and promotion of healthy food

and drinks at the club, and to support child participation in sport. The policies and practices are consistent with: 1) relevant legislation (e.g. alcohol management and smoke free legislation); 2) evidence which suggests such policies or practices may be associated with improved health behaviors;[36] 3) previous health promotion initiatives in this setting[16 20 26] conducted by the research team, and 4) recommendations following consultation with sporting clubs and content experts.

Table 1. List of the 16 policies and practices to be implemented by clubs in the intervention group.

1) Alcohol is not available or consumed during junior competition
2) Alcohol is not available or consumed at junior events or presentations
3) Alcohol is not present in the change rooms when players under 18 years are present
4) Alcohol manufacturers, wholesalers, retailers or other businesses whose core function is to sell alcohol are not promoted or advertised by the club on any junior apparel
5) Alcohol is not used for prizes, rewards or for fundraising
6) The club is compliant with the relevant state tobacco legislation
7) The club promotes all junior events as smoke free
8) Water is promoted as the drink of choice for junior players
9) Multiple healthy food and beverage (e.g. fruit, vegetables and non-sugar sweetened drink) options are available at the canteen or barbeque
10) The purchase of healthy choices at the canteen or barbeque are promoted by ensuring healthy food and beverage options are displayed prominently
11) The club encourages parents to provide healthy snacks (e.g. fruit and water) for junior players
12) The club conducts at least one recruitment activity prior to the beginning of the winter sporting season to attract new junior players and retain current players
13) The club has a Participation policy that it communicates to members, coaches, officials and volunteers to ensure junior players are provided with equal opportunities for participation at both training and during games
14) The club has a Code of Conduct policy which it communicates to all members, and ensures member agreement is recorded
15) The club has a Spectator Behaviour policy that is promoted and clearly visible at the club
16) The club has a written Good Sports Junior policy, which outlines the club's practices with regards to alcohol consumption, tobacco use, healthy eating and physical activity at junior competitions and events

Implementation support strategies.

The research team will support clubs to implement the 16 intervention components using strategies recommended in the NSW Health Capacity Building Framework.[37] The framework has been previously used by the research team to improve the implementation of healthy eating and alcohol management practices in senior sporting clubs. The framework identifies key action areas including: Organisational Development; Workforce Development; and Resource Allocation. Specific strategies within these action areas have been selected to address identified barriers to the implementation of health promotion interventions by community sporting clubs[38 39] and are summarised in in Table 2.

Intervention delivery

The intervention will consist of face-to-face, web- and phone-based support to assist junior sporting clubs to implement health promoting practices. Implementation support will be provided over one winter sports season in Australia, which usually runs for 6 months (March to August). Implementation support staff will be based at the Alcohol and Drug Foundation. Support staff will not be required to have any particular tertiary qualifications, however they will have experience in previous Good Sports Service Delivery. Support staff will offer assistance to intervention clubs by contacting them three times by email and three times by phone throughout the intervention period, with the mode of contact alternating each month. The first phone contact will last for approximately 30 minutes and will focus on reviewing the clubs current practices, which support staff will record using an online customer relationship management (CRM) system. The CRM system will then generate action plans that will help clubs to identify the practices they need to implement. Resources (see table 2) will be sent to clubs after the first telephone contact. The remaining two phone calls will check on the clubs progress in implementing the identified practices and will last for around 10-15 minutes. The three email contacts from support staff will identify practices that clubs

might like to focus on in the coming month. Support staff will encourage club representatives to provide evidence of the implementation of the intervention strategies via the upload of policies, photos, and copies of emails to club members onto the online CRM system. In addition to the six contacts initiated by support staff, automated theme-based emails will also be sent to clubs monthly throughout the sporting season. These emails will each contain content relevant to the five themes of: 1) physical activity; 2) healthy eating; 3) alcohol; 4) smoking; and 5) member conduct. For example, the automated alcohol themed email will emphasise the importance of changing the club's culture around alcohol for junior members and include some key messages for the club to share on their social media pages. The messages will be included at the end of the email so clubs can copy these messages directly onto their social media pages (e.g. Facebook, Instagram, Twitter). Key messages for the alcohol email will include short sentences about the potential risks and harms of alcohol consumption, and the importance of role-modeling for junior players.

Table 2. Intervention implementation support strategies

Organisational Development	
Management support	Research staff will be allocated time to speak to club representatives about the research study at a Football League meeting, which all clubs attend. Football Leagues will endorse the intervention to their clubs via email and encourage their clubs participation and progress through the program.
Policies and procedures	Club representatives will be provided with hardcopy and electronic templates to assist clubs develop health promotion policies. For example, to increase the physical activity of existing members, templates will be supplied to support clubs develop policies regarding equal game time participation for all players. To increase physical activity in the population generally, clubs will be supplied with examples of recruitment strategies that can be used to attract new junior players to the club, as well as retain current players.
Recognition and reward systems	Clubs will be provided with ongoing recognition of progress (e.g. upon completion of an action item, at monthly contacts) to promote sustained engagement. Progress will be recognised and rewarded with a certificate of accreditation. A digital asset pack (copy and paste templates for the club's social media pages and website) will be provided to clubs when they have achieved accreditation. Clubs will also be provided with a 'case study template' that they can provide to their local media outlet, which will showcase their participation in the program.
Information systems	A customer relationship management (CRM) system will allow research staff to monitor the progress of each club towards achieving the intervention criteria and provide real time feedback. Clubs will be provided with tailored action plans generated by the CRM system.
Systems and prompts	Electronic reminders (e.g. emails) will be used to prompt the implementation of pre-specified health promotion practices.
Informal culture	Clubs will be encouraged to select rounds of the junior competition, or a junior event, to focus on promoting the intervention informally (i.e. the alcohol awareness round, or the healthy juniors round).
Workforce Development	
External courses	Clubs will be provided with an alcohol management toolkit to increase awareness of alcohol legislation and best practice strategies to manage alcohol in their setting.
Resource allocation	
Human resources	Research staff will be allocated to help clubs implement the intervention. These research staff will also monitor and provide feedback on the implementation of practices. Assistance will be provided via regular phone and email contact with individual club representatives (once per month) during the winter season to maintain support.
Physical resources	A comprehensive kit of hard copy resources will be provided to clubs upon commencement of participation. The kit will include: posters promoting alcohol free junior competitions; alcohol free change room signs; a list of alternate prizes to alcohol for fundraisers, raffles or gifts to coaches; smoke-free posters; a canteen whiteboard to promote healthy food and beverage options prominently; a safe food handling poster; letter templates for clubs to send to parents to encourage them to provide healthy snacks for juniors; a playing environment sign with the Good Sports code of conduct prominently displayed, and other similar signs, posters and letter templates. Additionally, electronic versions of resources will be provided to junior clubs throughout winter season via email, including the policy templates, posters and signage. Links to industry experts (i.e. healthy food and beverage suppliers) will be provided to clubs, and a lead sporting person for each participating football code (AFL or Rugby League) will endorse the intervention through hard-copy and digital (e.g. video) resources. The Alcohol and Drug Foundation will develop all toolkits and resources for use in the intervention.

Control group clubs

Control clubs will not be offered any implementation support or resources by the research team throughout the intervention period. There may be instances where control clubs pro-actively contact the Alcohol and Drug Foundation seeking support regarding an area targeted by the intervention. Any support provided to clubs following such requests will be documented and reported.

Trial outcomes

Primary outcome

The primary trial outcome will be the change in the mean number of policies and practices (out of 16) implemented by junior sporting clubs. The number of policies and practices that each junior sporting club has implemented will be reported by the junior club representative during a telephone interview, designed by the research team for the study.

Secondary outcomes

Secondary outcomes will be the proportion of clubs who implement each of the following policies and practices. This will be assessed as the proportion of junior club representatives who report via telephone interview that, in the past season:

1) alcohol was not available or consumed during junior competition;

2) alcohol was not available or consumed at junior events or presentations;

3) alcohol was not present in the change rooms when under 18 players were present;

4) alcohol manufacturers, wholesalers, retailers or other businesses whose core function is to sell alcohol were not promoted or advertised by the club on any junior apparel;

5) alcohol was not used for prizes, rewards or for fundraising;

6) the club was compliant with the relevant state tobacco legislation;

7) the club promoted all junior events as smoke free;

8) water was promoted as the drink of choice for junior players;

9) multiple healthy food and beverage options (e.g. fruit, vegetables and non-sugar sweetened drink) were available at the canteen or barbeque;

10) the purchase of healthy choices at the canteen or barbeque was promoted by ensuring healthy food and beverage options were displayed prominently;

11) the club encouraged parents to provide healthy snacks (e.g. fruit and water) for junior players

12) the club conducted at least one recruitment activity prior to the beginning of the winter sporting season to attract new junior players and retain current players;

13) the club has a Participation policy that it communicated to members, coaches, officials and volunteers to ensure junior players were provided with equal opportunities for participation at both training and during games;

14) the club has a Code of Conduct policy which it communicated to all members, and ensured member agreement was recorded;

15) the club has a Spectator Behaviour policy that was promoted and clearly visible at the club;

16) the club has a written Good Sports Junior policy, which outlines the club's practices with regards to alcohol consumption, tobacco use, healthy eating and physical activity at junior competitions and events.

Other secondary outcomes will be child exposure alcohol and tobacco, child healthy food and drink purchases, opportunities for physical activity (equal participation), and provision of a safe playing environment (code of conduct). This will be assessed as the proportion of

parents of junior players at the club who report via telephone interview that, in the past season:

1) they have not consumed alcohol at the club during junior matches or events;

2) they have not smoked tobacco at the club during junior matches or events;

3) they have signed the club's Code of Conduct policy;.

4) the club encouraged them to bring healthy snacks for junior players by providing them with information about healthy snacks and the club's policy about healthy snacks;

5) a healthy food item was usually purchased from the club canteen by/for their child;

6) a healthy beverage was usually purchased from the club canteen by/for their child;

7) their child spent as much time involved in training and on the field during games as other children in their team.

Opportunities for regular physical activity for children will also be assessed by measuring the number of junior players (under 18 years) registered to play at each club. This information is held by the leagues the clubs belong to, therefore research staff will request this de-identified data from the leagues directly.

Syntheses of implementation outcomes

The implementation outcomes assessed in this trial (e.g. the mean number of policies and practices implemented by clubs, and the subsequent behaviour of members) are consistent with those recommended by frameworks such as RE-AIM.[40] The RE-AIM framework is appropriate for evaluating implementation outcomes in the junior sporting club setting, as it is: 1) applicable to community-based and public health research; and 2) incorporates findings at both the individual and organisational level.

Data collection procedures

Primary outcome

Primary outcome data (i.e. the overall number of policies and practices that each junior sporting club has implemented) will be collected via computer-assisted telephone interviews (CATIs) with club representatives at baseline (July-September 2016) and post-intervention (August-November 2017). The club representative CATIs will take approximately 30 minutes to complete. Given that sporting club committee membership often changes from year to year, the club representative who completes the CATI at baseline may not be the same person who completes the CATI post-intervention.

Secondary outcomes

Secondary outcome data will be collected via the CATI with club representatives (described above) and the CATI with parents of junior players, at baseline and post-intervention. For clubs, the secondary data collected will include details regarding the specific policies and practices (out of 16) that each club has implemented. For parents, secondary data collected will include: self-reported behaviour with regard to smoking and alcohol consumption at junior club matches or events; whether or not they signed a Code of Conduct policy; whether or not the club encouraged them to bring healthy snacks for junior players (via information or policies); behaviour regarding healthy food and drink purchases for/or by children at the club canteen; and their perceptions about whether their child spent as much time involved in training and on the field during games as other children in the team (i.e. equal opportunities for child physical activity). The CATI of parents of junior players will take approximately 40 minutes to complete, and the same cohort of parents will complete the survey at baseline and post-intervention.

Demographic characteristics

Items in the club representative CATI will capture data on the club (e.g. football code, number of players/teams, and geographic location) as well as the demographic characteristics of the club representatives (e.g. gender, age, role at the club, education level). Items in the parent CATI will capture the demographic characteristics of parents of junior players (e.g. gender, age, education level, socio-economic status).

Data management

Data collected from the telephone interviews will be transferred automatically into a computerised data set. Data sets will then be directly exported into data-analysis software. A trained member of the research team will code any open data fields, and these will be cross checked by a second research team member. Analyses of the trial data will be the responsibility of a statistician independent to the research team. As per human research ethics requirements, all data will be stored securely and will only be accessed by members of the research team and the appointed statistician. Identifying participant details will be stored separately from their telephone survey responses, and all analyses will be performed using de-identified datasets.

Sample size and power calculations

A sample size of 40 clubs per group at follow-up will enable the detection of a difference of 63% of a SD (or 0.63 units of z-score) between groups for all continuous outcomes reported by the club representative, with 80% power at the 0.05 significance level. Allowing for approximately 10% of clubs to be lost to follow-up, 45 clubs per group from 4 leagues (a total of 90 clubs from 8 leagues) will be recruited at baseline.

A sample size of 200 parents per group from 80 clubs at follow-up, with an intra-class correlation (ICC) of 0.05, will yield an effective sample size of 139 parents per group (assuming an 80% response rate). 139 parents per group will enable the detection of a reasonable difference in behaviour across secondary outcomes (with 80% power at the 0.05 significance level) including: a 15% increase in healthy food purchases by/for children (from 20% to 35%) and a 17% increase in healthy drink purchases by/for children (from 50% to 67%). The ICC of 0.05 is a conservative estimate and is based upon previous ICC's ranging from 0.01-0.05 used by the authors for related studies on alcohol reduction in sporting clubs[41] and healthy product purchasing from primary school canteens.[42]

Statistical analysis

Descriptive statistics will be used to describe the demographic characteristics of participating clubs and club representatives, as well as the mean number of practices and policies implemented by the club.

Primary outcome

For the primary outcome, a linear regression model will be implemented under an intention to treat approach to compare group differences on the mean number of practices and policies at follow-up, adjusting for baseline values. Sub-group analyses will be conducted by introducing group by sub-group interaction terms into the linear model for: football code (AFL vs Rugby League), and geographic location (metropolitan vs regional) using the Australian Standard Geographic Classification System[43] based on the club's postcode. All analyses will be conducted using SAS (V9.3 or later).

Secondary outcomes

Generalised linear mixed model analysis will be used to examine between group differences to account for potential clustering effect. The models will be implemented under an intention to treat approach, adjusting for baseline values. The alpha value for significance testing will be 0.05.

Limitations

There are a number of limitations to the design of this pilot study which should be acknowledged. First, the collection of primary and secondary outcome data via self-report from club representatives presents some risk of social desirability bias. However, previous validation studies conducted by the authors[44 45] suggest that organisational representatives can provide accurate data about their organisation's policies and practices, with high agreement observed between data collected via self-report and data collected via direct observation. Second, interviewers conducting the CATIs with club representatives will not be blind to their experimental group allocation by the end of the interview. However, the additional set of questions regarding implementation strategies will only appear for intervention clubs after all of the questions related to trial outcomes have been completed. Therefore, it is unlikely that this later awareness of group allocation will impact the outcome data collection. Third, there are a large number of secondary outcomes being tested, increasing the risk that a significant difference will be detected by chance (type 1 error). However, trial findings from the secondary outcomes will be used primarily for the purpose of hypotheses generation, and results will be used to refine the intervention for further testing.

Research trial coordination

The research team will oversee the conduct of the trial in accordance with the protocol. Any adverse events will be reported to the University of Newcastle's Human Research Ethics Committee, who will independently monitor the safety of the study. Data management and analyses will be conducted by a statistician who is independent of the project team and the trial implementation.

Trial discontinuation or modification

Trial discontinuation or modification will only occur if an adverse event could result in unintended harm to the trial participants, as determined by the University of Newcastle's Human Research Ethics Committee. If any such trial modification is deemed necessary by the ethics committee, changes to the protocol will be updated on the trial registration held by the Australian New Zealand Clinical Trials Registry. These changes will also be communicated in any publications reporting the outcomes of the trial.

Ethics and dissemination

This trial has been approved by the University of Newcastle Human Research Ethics Committee (H-2013-0429) and registered with the Australian New Zealand Clinical Trials Registry ACTRN12617001044314. Study findings will be disseminated widely through peer-reviewed publications and conference presentations. The Alcohol and Drug Foundation will use the results from this study to improve the design and delivery of the national Good Sports program, funded by the Australian Government Department of Health. The Alcohol and Drug Foundation will also make reports on the findings of the intervention available to their participating partners from government departments in each Australian state and territory.

Discussion

A large proportion of children and adolescents participate in organised sport, and their parents attend as spectators, making junior sporting clubs a promising setting to support healthy behaviours for all family members. This will be the first intervention to focus on modifying the social, cultural, physical and environmental aspects of junior sporting clubs to support health-promoting behaviours. The study has been designed to allow random allocation of football leagues using a computer-generated sequence. Interviewers collecting the post-intervention data will be blind to the experimental group allocation of parents of junior players. Strategies to support clubs implement the intervention practices follow those recommended by the NSW Health Capacity Building Framework.[37] Results from this study will inform policy makers and those providing health-promoting interventions with valuable information regarding the best way to support junior sporting clubs provide a healthier environment for their members.

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Authors contributions

SM, SS, MK, AM, DB, JW and LW contributed to the conception of the project and intervention content. SM, SS, TCM, JD, NZ, SG, JYO and LW contributed to the study design, intervention development and evaluation methods. All authors drafted, critically reviewed and edited the final manuscript. All authors approved the version to be published and are responsible for its accuracy.

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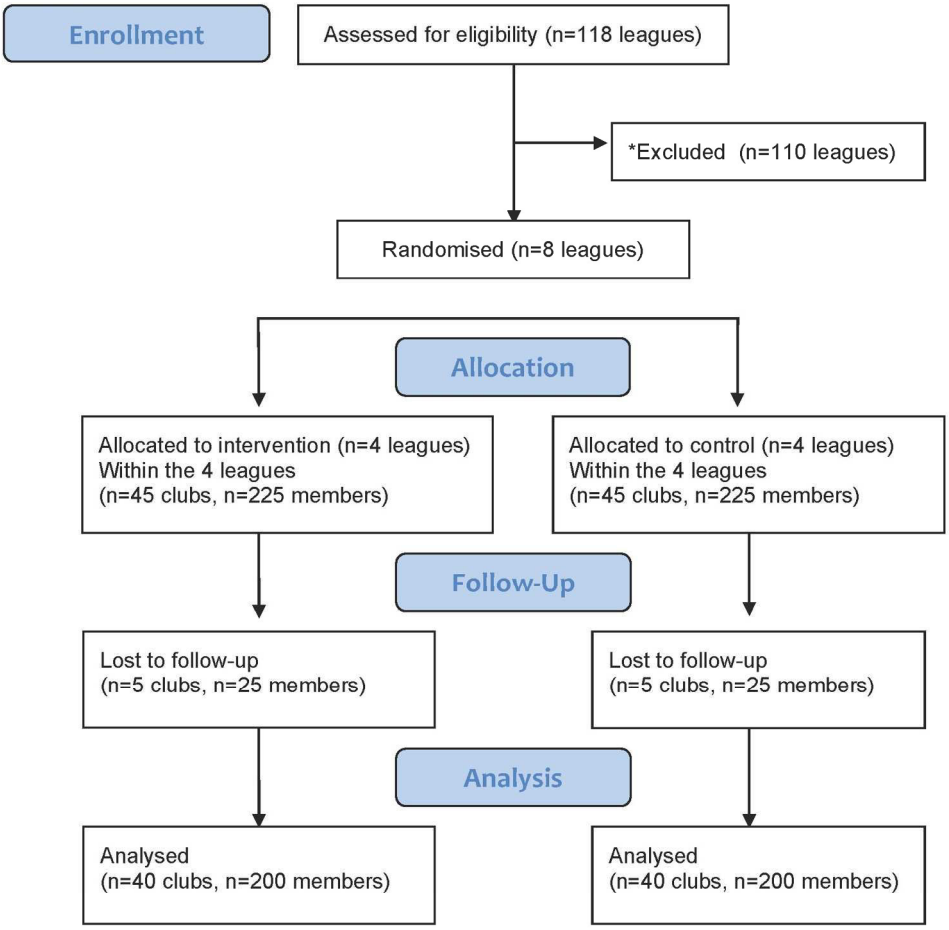
Competing interests statement

All authors declare that they have no competing interests.

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



*Note –It is likely that the majority of leagues will be ineligible as most will not have ≥10 junior clubs who already meet Level 3 accreditation with the *Good Sports* program.

162x182mm (300 x 300 DPI)