Randomised controlled trial of a web-based programme in sustaining best practice alcohol management practices at community sports clubs: a study protocol

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BMJ Open  Randomised controlled trial of a web-based programme in sustaining best practice alcohol management practices at community sports clubs: a study protocol

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ABSTRACT

Introduction Community-based interventions have been found to effectively increase the implementation of alcohol management practices and reduce excessive alcohol use and alcohol-related harm at sports clubs. However, once implementation support ceases there may be a reduction in such intervention effects. Thus, ongoing contribution to improving the health of the community is diminished; sustaining practice implementation is a key determinant to address this. One possible solution to the strategic and logistical challenges of sustainability involves the use of the web. The primary aim of this study is to assess the effectiveness of a web-based programme in sustaining the implementation of alcohol management practices by community football clubs. The secondary aim is to assess the effectiveness of the programme in preventing excessive alcohol consumption and alcohol-related harm among members of community football clubs.

Methods and analysis The study will employ a repeat randomised controlled trial design and be conducted in regional and metropolitan areas within two states of Australia. Community level football clubs who are currently accredited with an existing alcohol management programme (‘Good Sports’) and implementing at least 10 of the 13 core alcohol management practices (eg, not serving alcohol to <18-year-olds) required by the programme will be recruited and randomised to either a web-based sustainability programme or a ‘minimal contact’ programme. The primary outcome measures are the proportion of football clubs implementing ≥10 of the 13 required alcohol management practices and the mean number of those practices being implemented at 3-year follow-up. Secondary outcomes include: the proportion of club members who report risky drinking at their club, the Alcohol Use Disorder Identification Test (AUDIT) score and mean AUDIT score of club members. Outcome data will be collected via observation at the club during a 1-day visit to a home game, conducted by trained research assistants at baseline and follow-up.

Strengths and limitations of this study

- The study has a strong design incorporating random allocation, blinding of research personnel undertaking data collection and the use of objective outcome measures.
- The intervention is a multifaceted novel design, based on theoretical frameworks and evidence from past research in this area.
- The study will be conducted with community football clubs only, therefore the generalisation of outcomes from this study will be uncertain for other sporting codes and community settings generally.

Ethics and dissemination The study was approved by The University of Newcastle Human Research Ethics Committee (reference: H-2013-0429). Study findings will be disseminated widely through peer-reviewed publications and conference presentations.

Trial registration number ACTRN12614000746639; Pre-results.

INTRODUCTION

Excessive use of alcohol is responsible for more than 3 million deaths and over 200 varieties of disease and injuries worldwide each year.1 One population group that has been identified as consuming excessive amounts of alcohol are those involved with organised sport (both players and supporters), including those at the non-elite/community level.2–7 Young men, particularly those involved in contact team sports, have been reported to have a high prevalence of excessive alcohol consumption.3 5 8 Additionally, when compared with people not associated with sport, a greater prevalence of alcohol-related harm has been reported among players and spectators of a range of sports,
alcohol management practices. Given this, a study will be conducted with the primary aim of assessing the effectiveness of a web-based programme in sustaining the implementation of best practice alcohol management practices by community football clubs. The secondary aim is to assess the effectiveness of the programme in preventing excessive alcohol consumption and alcohol-related harm among members of community football clubs.

**METHODS AND ANALYSIS**

**Study design**

The study will employ a repeat cross-sectional randomised controlled trial design (see figure 1). Clubs will either be randomised into a ‘web-based sustainability program’ or an ‘ethical minimal contact’ control group.

**Research setting**

The research will occur in Australia, in regional areas of the state of New South Wales (NSW) and throughout metropolitan and regional areas of the state of Victoria.

**Participants and research eligibility**

**Football clubs**

Non-elite, community-level clubs that currently hold the highest level of accreditation in an alcohol harm-reduction programme (‘Good Sports’) will be recruited to participate in the trial. Sporting clubs interested in becoming involved in the Good Sports programme, a free nationwide programme, register their details and are required to implement alcohol management practices of increasing comprehensiveness across three levels of accreditation. Level 3 is the highest level of accreditation with the programme. There are currently approximately 2600 level 3 Good Sports clubs in Australia. All clubs participating in this trial will have been involved with the Good Sports programme for a minimum of 5 years to progress to the highest level (level 3) of accreditation.

Football clubs will be eligible to participate in the study if they: have held the highest level of accreditation (level 3) within the Good Sports programme for a minimum of 12 months; adhere to the alcohol management practices required of level 3 Good Sports clubs; are a non-elite community-level football club; are an Australian Football League, Rugby League, Rugby Union or Soccer club; hold a current valid liquor licence; currently sell alcohol; have at least one senior (over 18s) team; and report having access to the internet.

The football codes that are eligible to participate in this study are among the most popular organised sports in Australia and people involved with these sports as players or spectators have been identified as particularly at risk of alcohol-related harm relative to other sporting codes.

**Football club members**

Club members will be eligible to participate in the study if they are: current members/affiliates of a participating club (including players, committee members, regular
spectators/fans and coaches), at least 18 years of age and speak English.

**Recruitment procedures**

**Football clubs**

A list of level 3 Good Sports football clubs within the study areas will be generated by the research team from programme records. A club representative (eg, club president, vice president or secretary) from eligible clubs will be sent a study information sheet inviting the club to participate in the study. Two weeks after sending the letter, club representatives will be contacted via telephone to screen the club for eligibility based on the above criteria and assess interest in study participation. If club representatives do not recall receiving the study information sheet, contact details will be confirmed and an additional information sheet will be sent to them either via email or postal mail. Follow-up phone calls will occur until club representatives are able to make informed decisions about their club’s participation in the study. It is envisaged that some clubs may require this decision to be taken to the club management committee. If club representatives are not able to be contacted, alternative contacts will be sought via programme databases, relevant football code association websites and other publicly available forums. Consenting clubs will be asked to complete and sign a consent form and return it to the research team. All recruitment procedures will be managed by a dedicated member of the research team.

**Football club members**

At baseline and follow-up a separate independent sample of club members (players, committee members, regular spectators/fans and coaches) will be recruited at club grounds during a senior home game using a pilot-tested, standardised recruitment protocol which will detail specified locations for recruitment within the club grounds (ie, club bar or canteen). A random number sequence will be generated by a computer program and integrated into the data collection tool. The random number sequence will dictate the order in which members at the grounds are to be approached by the research assistants. These randomly selected members will then be screened for eligibility, and those who are eligible will be provided with a study information sheet and invited to participate in the study. Eligible and consenting club members will be asked to provide their contact details to the research staff. This recruitment process will continue until a maximum of 20 members’ contact details are collected at each club/game. The 20 club members who agreed to provide contact details will receive a phone call from the research team formally

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**Figure 1** Consort flow chart estimating the possible progress of participants through the trial from enrolment to final analysis.
inviting them to participate in the study. This process will occur until five members from each participating club have been enrolled into the study.

For recruitment of both clubs and members, strategies previously found to maximise research participation will be used, including prenotification of the study and opportunity to participate, direct telephone contact with participants to invite participation, multiple contact attempts, access to research staff for further clarification regarding participation and the use of dedicated, specifically trained research staff to undertake the recruitment process. Such recruitment strategies have been previously used successfully by the research team.26–28

**RANDOM ALLOCATION OF SPORTS CLUBS**

Clubs will be randomly allocated (after baseline data collection) in a 1:1 ratio to either the intervention or control group by a statistician independent to the research team using a computerised random number function. The randomisation procedure will be stratified by sports code. Research conducted by the research team14 and others29 has previously demonstrated an association between this factor and secondary outcomes related to excessive alcohol consumption and alcohol-related harm. Additionally, due to operational differences between football clubs, the randomisation procedure will also be stratified by state (NSW or Victoria).

**BLINDING**

Research assistants conducting the field observations for the outcome measures will be blind to group allocation and not be involved in any other aspect of the trial. Effectiveness of research personnel blinding will be tested by asking research assistants to nominate group allocation of clubs following collection of postintervention data. Additionally, the analysis of primary trial outcomes will be undertaken by a statistician who will be blind to study group allocation through use of and dummy variable for allocation. Due to the difficulty in blinding clubs to group allocation, this will be an open trial with club representatives being told of the treatment status of their club following pretest data collection.

**INTERVENTION**

**Alcohol management practices**

Intervention clubs will be supported to maintain the implementation of the alcohol management practices outlined in box via a web-based programme. Each intervention club will be assigned a unique identifier so the research team can track their progress through, and engagement with the programme. The alcohol management practices are consistent with legislation and guidelines regarding the sale and supply of alcohol in licensed premises30–32 and have been found to be associated with lower levels of alcohol consumption in licensed premises, broadly,33 34 and community sports clubs, specifically.35–37

**Web-based sustainability programme**

A web-based approach was selected given the capacity for web-based support to be: (1) efficiently delivered to a large number of sports clubs located in a wide geographic area; (2) maintained and updated centrally at relatively low cost; (3) tailored to the needs of individual clubs. Such computer-based interventions have been used to improve and sustain the health-promoting practices of organisations generally.38 Preliminary unpublished data (2014) collected by the research team suggest that a web-based intervention will be acceptable to sports club representatives as they reported a high level of use of computers and web-based programmes (n=202), 81% reported that club representative tasks were mainly undertaken on computer-based programmes, 62% reported using a web-based programme for the majority of club tasks and 99% indicated that they had a website or social media page.

An expert advisory group consisting of community sports club representatives, health promotion practitioners and experts in community organisational change and reducing alcohol-related harm associated with licensed premises will develop the programme based on theory39 40 and evidence.13 The advisory group will continue to meet via the telephone and face-to-face and undertake programme testing to develop the web-based programme. The web-based programme will only be available to those clubs allocated to the intervention group of the trial, this is not a publicly available web site. It can only be accessed by a personalised login number.

**Conceptual model and strategies**

A frequently identified limitation of sustainability research has been the lack of conceptual models to guide intervention development.18 41 To address this, the web-based sustainability programme will be developed based on the

**Box Alcohol management practices**

<table>
<thead>
<tr>
<th>Practice</th>
<th>Reference</th>
</tr>
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<tbody>
<tr>
<td>Substantial food provided when alcohol sold.36</td>
<td></td>
</tr>
<tr>
<td>Non-alcoholic drinks 10% cheaper than full-strength alcoholic drinks.32–34</td>
<td></td>
</tr>
<tr>
<td>Drunk/intoxicated people not allowed to enter club.35 36 57</td>
<td></td>
</tr>
<tr>
<td>Low-alcoholic drinks 10% cheaper than full-strength alcoholic drinks.32 53 58–60</td>
<td></td>
</tr>
<tr>
<td>Four non-alcoholic options available for purchase.32 53 61</td>
<td></td>
</tr>
<tr>
<td>People under 18 years of age do not serve alcohol.35 36 57</td>
<td></td>
</tr>
<tr>
<td>Drunk/intoxicated people not served alcohol.35 36 57</td>
<td></td>
</tr>
<tr>
<td>Drunk/intoxicated people not permitted to remain on club premises.57</td>
<td></td>
</tr>
<tr>
<td>Free water provided when alcohol sold.33</td>
<td></td>
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<tr>
<td>Staff do not consume alcohol while on duty.35 36</td>
<td></td>
</tr>
<tr>
<td>One low-alcoholic drink option available.32 53 61</td>
<td></td>
</tr>
<tr>
<td>Licensing signs visible at all bars.35 61</td>
<td></td>
</tr>
<tr>
<td>No drink promotions undertaken at the club (happy hour, all-you-can-drink functions, alcohol-only awards and prizes, cheap drinks, drinking games, drinking vouchers/cards).32 35 36 58 62 63</td>
<td></td>
</tr>
</tbody>
</table>
Sustainability Framework,39 which identifies the following domains as being important in sustaining the delivery of programme practices:

- Environmental: having a supportive internal and external climate.
- Organisational capacity: having internal support and resources needed to effectively manage the programme.
- Programme adaptation: taking actions that adapt the programme to ensure its ongoing effectiveness.
- Communications: having strategic communication with stakeholders and the public about the programme.
- Strategic planning: using processes that guide the programme’s directions, goals and strategies.
- Programme evaluation: assessing the programme to inform planning and document results.
- Partnership: having connections between the programme and its stakeholders.
- Funding stability: having a consistent financial base for the programme.

Additionally, as the programme will be web based, the Persuasive Systems Design framework40 will be used to ensure programme usability. This framework recognises the importance of the following elements that are relevant to the proposed programme:

- Reduction: system reduces complex behaviour into simple tasks.
- Tunnelling: using the system to guide users through a process or experience provides opportunities to persuade along the way.
- Tailoring: information tailored to the potential needs, interests, personality, usage context or other factors relevant to a user group.
- Personalisation: personalised content.
- Self-monitoring: keeps track of one’s own performance or status, supports the user in achieving goals.
- Simulation: provides simulations, links between cause and effect.
- Praise: make users more open to persuasion.
- Rewards: reward targeted behaviour.
- Reminders: remind users of the targeted behaviour.
- Suggestion: offering fitting suggestion for persuasion.

The use of such frameworks in the design of practice change initiatives, particularly those operating at multiple levels of complex systems, has been suggested to be important in facilitating effective practice change.42

The programme will include the following functions:

1. Annual online assessment. At the start of each year (sporting season), the club president or a nominated representative from each intervention club (eg, club secretary) will complete an online monitoring assessment. The monitoring assessment will require the club representative to complete a series of questions regarding their club’s alcohol management practices (box). The completion of the monitoring report will highlight any practices that clubs are not undertaking.

2. Action plan. An action plan, individualised for each club, will be generated from the identified incomplete alcohol management practices from the monitoring report. It will contain specific information about such practices, such as why the practice is important, if it is required by legislation and steps to effectively implement the practice.

3. Tools and resources. From the action plan, clubs will be guided to practise specific tools and resources to support clubs in implementing identified incomplete alcohol management practices. All intervention clubs will have access to all tools and resources via the online intervention programme.

Programme implementation strategies

The programme will be designed to include implementation strategies (table 1) that address common impediments to organisations sustaining new initiatives or innovations and impediments that are particularly relevant to the volunteer community sport club setting such as high staff turnover, limited resources, lack of time and competing demands.43–45

Table 1 outlines the programme implementation strategies mapped against the domains of the Sustainability Framework and the Persuasive Systems Design framework.

Programme delivery

Programme delivery will occur over three successive Australian winter sporting seasons (April to September 2015–2017). Participating intervention clubs will receive contact from a member of the programme team a maximum of four times via telephone and a maximum of four times via email during each intervention season. Programme implementation completion will occur at the end of the 3-year intervention period with clubs having completed three rounds of annual online assessments and action planning.

Programme quality assurance

User acceptance testing will be undertaken with a sample of representatives from community sporting clubs. Web-based programme testing will occur, with feedback being integrated into the final version of the programme. Ongoing quality assurance checks will be undertaken as clubs engage with the web-based programme. Research staff will perform annual checks on all links to external sites within the intervention site to ensure they remain current, and club logins will be monitored to ensure no barriers to intervention access, such as site blocking or browser issues.

CONTROL GROUP CLUBS

Control group clubs will not have access to the web-based programme or any of the intervention programme resources. Control group clubs will receive minimal
programme support throughout the intervention period. This will entail one phone contact occasion initiated by the research team during the 3-year intervention period. Additionally, the research team will provide reactive support, on an as-needs basis in instances where a club seeks support about an alcohol-related incident or concern. The research team will assess each support request to ensure group contamination does not occur and record any additional contact made with clubs.

### MEASURES

**Primary outcomes**

1. The proportion of clubs implementing ≥10 of the 13 required alcohol management practices (box) at follow-up.
2. The mean number of alcohol management practices being implemented at follow-up.

Such implementation is consistent with research that recognises that the implementation of multiple strategies

#### Table 1  Intervention implementation strategies and conceptual frameworks

<table>
<thead>
<tr>
<th>Intervention strategy</th>
<th>Description</th>
<th>The Sustainability Framework construct&lt;br&gt;39</th>
<th>Persuasive Systems Design framework construct&lt;br&gt;40</th>
</tr>
</thead>
<tbody>
<tr>
<td>Club champion</td>
<td>Club champions will hold a role on the club executive (president, vice president, treasurer, secretary). Club champions will be the club representative who will primarily engage with the web-based programme on behalf of the club to complete the annual online assessment and action plan.</td>
<td>Environmental support</td>
<td>Organisational capacity</td>
</tr>
<tr>
<td>Executive support</td>
<td>The club's alcohol management policy will be reaffirmed each year at the club's committee meetings by all executive members. Results from the club's annual online assessment and action plan will be automatically emailed to all club executive members.</td>
<td>Environmental support</td>
<td>Organisational capacity, strategic planning</td>
</tr>
<tr>
<td>Targeting interactive intervention</td>
<td>A tailored action plan will be automatically developed based on responses from the annual online assessment. All required actions will have links to appropriate list of options/strategies and resources. Clubs will be able to adjust the suggested completion dates for generated action items (with limits). Clubs will be able to track their own progress by updating the status of action items (not started/in progress/complete).</td>
<td>Programme adaptation</td>
<td>Tunnelling, tailoring/personalisation, self-monitoring</td>
</tr>
<tr>
<td>Tailored feedback</td>
<td>Clubs will receive tailored feedback based on their responses to the annual online assessment and completion of agreed actions. The feedback will occur on the screen of the web-based programme immediately after completing the annual online assessment. Email feedback will also be sent in regard to the annual online assessment responses and action plan items generated.</td>
<td>Programme adaptation</td>
<td>Tunnelling, tailoring/personalisation</td>
</tr>
<tr>
<td>Training and support</td>
<td>An instructional video will be available via the web-based programme for club representatives to use. For any user problems email help options will be available.</td>
<td>Organisational capacity</td>
<td>Ease of use/accessibility</td>
</tr>
<tr>
<td>Tools and resources</td>
<td>Printable instructional materials, sample policies and planning templates will be available via the web-based programme.</td>
<td>Organisational capacity</td>
<td>Tailoring/personalisation</td>
</tr>
<tr>
<td>Systems and prompts</td>
<td>Email reminders will be automatically sent to prompt annual online assessment completion and when action plan items' due dates are approaching or are overdue.</td>
<td>Environmental</td>
<td>Reminders and prompts, tailoring/personalisation</td>
</tr>
<tr>
<td>Communication and marketing</td>
<td>An independent nominee (a community stakeholder) will be sent a letter from the programme informing them of the club's progress.</td>
<td>Communication, partnership</td>
<td>Praise, rewards and recognition</td>
</tr>
<tr>
<td>Recognition and reward</td>
<td>Automatic notification and praise via emails will be sent to club champions and club executives when the annual online assessment and action plan is complete. ‘Good News' stories of clubs progressing through the programme will be positioned on the login screen.</td>
<td>Praise, rewards and recognition</td>
<td></td>
</tr>
</tbody>
</table>
targeting different aspects of alcohol management (availability, promotion and alcohol service) is more successful in harm minimisation than the implementation of individual strategies.32 48

Secondary outcomes
1. The proportion of clubs implementing each of the 13 alcohol management practices.
2. The proportion of club members who report drinking alcohol at risky levels at sporting clubs. This outcome is measured by the graduated frequency index,49 with risky drinking defined as five or more standard drinks of alcohol on one drinking occasion50 at least once a month at the club.
3. The proportion of club members at risk of alcohol-related harm, as measured by a total Alcohol Use Disorder Identification Test (AUDIT) score of ≥8.51
4. The mean AUDIT score of club members.

Process data
Process data measures will be collected for each intervention club and will include: total time to complete annual report and action plan online, number of logins to complete annual report and action plan, number of tools and resources accessed/downloaded and average number of action items generated.

Club characteristics
The following data will be collected on participating sports clubs: number of senior (18 years of age and over) and junior (under 18 years of age) teams and members registered with the club, football code and postcode of sporting club.

DATA COLLECTION PROCEDURES
Primary outcome
Baseline and follow-up data for the primary trial outcome will be collected by covert field observation of club practices by trained research assistants. Direct observation represents the gold standard when measuring complex environments and organisational behaviours.52 Observations will occur during a home game at a participating club ground. Participating clubs will not be aware of the exact day that the observation will occur. Given that many clubs have multiple teams, the observation will occur during the most senior game. Observation staff will be trained by the research team, and will be required to complete examples of alcohol practice observation scenarios to a satisfactory level. Observers will assess each of the alcohol management practices outlined in box during the field observation. Protocols and methods for such observations have been developed and successfully implemented by the research team during more than 200 observations of sports clubs, hotels and nightclubs as part of previous trials.53 54 and pilot testing will be conducted with four clubs prior to commencement of data collection to refine the tool.

Secondary outcome
Secondary data collection will occur via a Computer Assisted Telephone Interview with club members recruited from the field observations at baseline (2015) and follow-up (2017).

Process data
Measures outlined above will be collected via reports generated through the web-based software and Google Analytics. The research team will run reports at the end of the intervention period.

Club characteristic data
The operational characteristics of clubs, demographics and attitudes of sports club representatives will be collected during a telephone survey with the club representative.

DATA MANAGEMENT
Data management will primarily be the responsibility of a statistician, independent of the research team and trial activities. Management of trial data will be in accordance with a data management protocol, which will be developed for approval by the Project Advisory Group. As a requirement of ethics approval, all data collected for the trial will be securely stored, accessible only to primary researchers and statisticians through the allocation of access rights. Confidential participant data including contact details (e.g., phone numbers) will be stored in a secure data set that is not linked to survey response data sets. An independent statistician will be the only person with access to confidential participant data.

SAMPLE SIZE AND POWER CALCULATIONS
Assuming at follow-up that 70% of clubs in the control group have maintained ≥10 of the 13 required alcohol management practices (box) (i.e., the prevalence of adequate practice implementation in the control group falls from 100% at baseline to 70% at follow-up), a sample size of 60 clubs per group will be sufficient to detect an absolute difference of 20% between groups at follow-up (which assumes that the prevalence of clubs in the intervention group that maintain 80% of required practices falls from 100% at baseline to 90% at follow-up) with 80% power and alpha of 0.05.

Statistical analysis
Primary outcome
The primary trial outcomes will be assessed by examining group differences at follow-up in the (1) prevalence of clubs maintaining ≥10 of the 13 required alcohol management and (2) the mean number of practices being implemented by clubs. Analysis will be performed in SAS V.9.3 statistical software and under an intention-to-treat approach. Dichotomous primary outcomes will be assessed using logistic regression models. Continuous primary outcomes will be assessed using linear regression models. All models will be controlled for baseline outcome values. Sensitivity
analysis will be performed to test a range of assumptions for missing data at follow-up as recommended by White et al.\textsuperscript{55} Statistical tests will use an alpha of 0.05.

**Research trial coordination**

The trial will be overseen by a Project Advisory Group, which is chaired by one of the chief investigators of the Australia Research Council grant. The group includes representatives from The University of Newcastle, Hunter New England Population Health, the Alcohol and Drug Foundation and Deakin University.

A project team has also been formed to coordinate the implementation of the trial in accordance with the trial protocol. This team consists of staff members of The University of Newcastle, Hunter New England Population Health and the Alcohol and Drug Foundation. Data management is the responsibility of a Hunter New England Population Health statistician, otherwise independent of the research team and trial activities. Management of trial data is in accordance with a data management protocol, developed and approved by the Project Advisory Group.

**Trial discontinuation or modification**

There are no predetermined criteria for discontinuing or modifying the trial. While unintended adverse events to trial participants, researchers or other community members are not anticipated, any such events will be forwarded to The University of Newcastle Human Research Ethics Committee (HREC) in accordance with the conditions of ethics approval. Should the research team or HREC consider it appropriate, the trial protocol or procedures may be modified to prevent such harm. Any protocol modification will be communicated through modification of the trial registration listed in the Australian New Zealand Clinical Trials Registry and through publications disseminating trial results.

**DISCUSSION**

There is an absence of research evidence with regard to how to sustain alcohol management practices in the sporting club setting. This will be the first randomised controlled trial to measure the effectiveness of a web-based programme in sustaining such practices, in not just the community football club setting but any community setting. The study has a strong design that incorporates computerised random allocation, blinding of data collection personnel and observational data collection methods. In addition, the intervention is based on a strong theoretical framework and research evidence from the sports and other settings. This study will provide clubs in regional and remote geographical locations, who previously had restricted face-to-face programme support, extensive access to web-based support for the implementation of alcohol management practices. The use of such web-based support may be applicable to other community settings which have wide geographical spread of sites, such as schools and childcare centres. The findings from this study will provide a basis for further research in the field and provide potentially important findings on programme sustainability for both policymakers and those providing health promotion programmes to community sporting groups and community organisations more broadly.

**Contributors** TM, LW, MK, JW, JT, KG, BR, SS and RH contributed to the study method design and intervention development. CL, LW, MK, JW and TM contributed to analysis design. TM, LW, MK, JW, JT, KG, BR, SS, RH, TC MH and DB contributed to manuscript development and review.

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**Competing interests** None declared.

**Patient consent** Obtained.

**Ethics approval** The University of Newcastle Human Research Ethics Committee.

**Provenance and peer review** Not commissioned; externally peer reviewed.

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