Evaluation of an injury prevention programme (Prep-to-Play) in women and girls playing Australian Football: design of a pragmatic, type III, hybrid implementation-effectiveness, stepped-wedge, cluster randomised controlled trial

Brooke E Patterson,1,2 Alex Donaldson,2,3 Sallie M Cowan,2,3 Matthew G King,1,4 Christian G Barton,1,4 Steven M McPhail,5,6 Martin Hagglund,7,8 Nicole M White,2,3 Natasha A Lannin,9 Michael Makdissi,10,11 Adam G Culvenor,10,11 Andrea B Mosler,10,11 Andrea M Bruder,10,11 Jessica Choong,11 Nicole Livingstone,12 Rachel K Elliott,12 Anja Nikolic,13 Jane Fitzpatrick,14,15 Jamie Crain,16 Melissa J Haberfield,1,2 Eliza A Roughhead,1 Elizabeth Birch,1 Sarah J Lampard,1 Christian Bonello,1 Karina L Chilman,1 Kay M Crossley1

ABSTRACT

Introduction Due to the increase in participation and risk of anterior cruciate ligament (ACL) injuries and concussion in women’s Australian Football, an injury prevention programme (Prep-to-Play) was codesigned with consumers (eg, coaches, players) and stakeholders (eg, the Australian Football League). The impact of supported and unsupported interventions on the use of Prep-to-Play (primary aim) and injury rates (secondary aim) will be evaluated in women and girls playing community Australian Football.

Methods and analysis This stepped-wedge, cluster randomised controlled trial will include ≥140 teams from U16, U18 or senior women’s competitions. All 10 geographically separated clusters (each containing ≥14 teams) will start in the control (unsupported) phase and be randomised to one of five dates (sequential transition to the intervention (supported Prep-to-Play)) during the 2021 or 2022 season to sequentially transition to the intervention (supported Prep-to-Play), until all teams receive the intervention. Prep-to-Play includes four elements: a neuromuscular training warm-up, contact-focussed football skills (eg, tackling), strength exercises and education (eg, technique cues). When transitioning to supported interventions, study physiotherapists will deliver a workshop to coaches and player leaders on how to use Prep-to-Play, attend team training at least two times and provide ongoing support. In the unsupported phase, team will continue usual routines and may freely access available Prep-to-Play resources online.

STRENGTHS AND LIMITATIONS OF THIS STUDY

Prep to Play is a sport-specific injury prevention programme codesigned with consumers and stakeholders for women and girls playing community Australian Football.

The two-season stepped-wedge cluster design allows all participating teams to receive supported intervention by the end of the trial.

Football-specific skill is a novel, important component of the programme, in the context of most women and girls having limited previous participation in the sport.

Team recruitment and/or outcome reporting may be impacted by reduced sport participation and increased volunteer burden following the COVID-19 pandemic.

Injury incidence will be reported at team level due to the difficulty of collecting individual-level training exposure identified during piloting and consumer consultation.

To cite: Patterson BE, Donaldson A, Cowan SM, et al. Evaluation of an injury prevention programme (Prep-to-Play) in women and girls playing Australian Football: design of a pragmatic, type III, hybrid implementation-effectiveness, stepped-wedge, cluster randomised controlled trial. BMJ Open 2022;12:e062483. doi:10.1136/bmjopen-2022-062483

© Author(s) (or their employer(s)) 2022. Re-use permitted under CC BY-NC. No commercial re-use. See rights and permissions. Published by BMJ.

For numbered affiliations see end of article.

Correspondence to Dr Brooke E Patterson; B.Patterson@latrobe.edu.au
Secondary outcomes: injuries will be reported by the team sports trainer and/or players. Injury definition: any injury occurring during a football match or training that results in: (1) being unable to return to the field of play for that match or (2) missing ≥ one match. Outcomes in the supported and unsupported phases will be compared using a generalised linear mixed model adjusting for clustering and time. Due to the type III hybrid implementation-effectiveness design, the study is powered to detect a improvement in use of Prep-to-Play and a reduction in ACL injuries.

**Methods and Analysis**

**Study design**

This protocol adheres to the Standard Protocol Items Recommendations for Interventional Trials guidelines (online supplemental file 1). The trial was prospectively registered (https://clinicaltrials.gov/) and the interventions will occur in 2021 and 2022. The study is a pragmatic type III hybrid implementation-effectiveness stepped-wedge, cluster randomised controlled trial that will adhere to the Consolidated Standards of Reporting Trials guidelines for stepped wedge cluster trials.

The stepped wedge cluster design is a unidirectional cross-over design, where all clusters start in the control (unsupported intervention), and sequentially transition into the supported intervention, until all clusters have received the intervention (figure 1). The hybrid type III implementation-effectiveness design is an emerging concept used by other musculoskeletal trials, whereby an implementation strategy is tested while gathering effectiveness outcomes.
Randomisation and blinding

The study includes 10 clusters, each consisting of ≥14 teams in a similar geographic location. Following recruitment, each cluster is randomly allocated to one of the five sequences (two clusters per sequence) for time of crossover from the control to supported intervention (figure 1). The randomisation sequence for all teams was determined prior to the start of the 2021 season using a computer-generated list of random numbers (1 to 10, for each of the 10 clusters) provided by a statistician (without any restriction, stratification or blocking). The different phases are: (1) Tcontrol: unsupported intervention, (2) Ttransition: beginning at time of intervention workshop delivery and ending at time of first support visit, (3) Tsupported: supported intervention, beginning after first support visit and ending at completion of season 2022 (figure 1).

In Ttransition, a cluster is not considered to be in the control or supported group—implementation and injury data will be collected but not included in the primary analysis, as per recommendations for stepped-wedge designs. In figure 1, each square represents a cluster period, which contains ≥14 weekly team periods. As each cluster period contains ≥14 teams, there are ≥1792 and ≥1708 team periods for Tcontrol and Tsupported, respectively. Outcome data will be collected in each weekly team period and used to compare the primary outcome (Prep-to-Play use) and secondary outcome (injury rates) in the Tcontrol and Tsupported phases. The roles, qualifications, blinding, training and support of the primary outcome reporters (team designates and independent observers), secondary outcome reporters (sports trainers), programme trainers (physiotherapists) and programme deliverers (coaches) are outlined in table 1.

Recruitment

Recruitment (primary outcome—use of Prep-to-Play)

All teams in U16, U18 or senior women’s community leagues in metropolitan (n=9 leagues) and regional Victoria (n=7 leagues) in Australia, were invited to participate before the 2021 season (figure 2). Teams received invitation emails from their league. Coaches, club presidents or team managers responded to the invitation and were included if: (1) their team competed in an organised senior (excluding masters) or junior (U16, U17, U18 or Youth) league; (2) their team trained at least once per week and (3) the coach consented for the team to participate. Coach consent included willingness to complete a baseline survey (online supplemental file 2), assign outcome reporters (team designates and sports trainers) and to be supported to implement Prep-to-Play in 2021 and/or 2022. Team recruitment continued until each geographical cluster had ≥14 teams. Once a team is recruited, all players participate in the intervention as directed by their coach.

Recruitment (secondary outcomes—injured body regions)

In addition, all consenting coaches distributed the link to the player (parents/guardians for players aged <16 years) in their teams, inviting players to complete an online consent form and baseline survey (online supplemental file 2). Players consented to be contacted by the research team to provide further information about knee or head injuries sustained during the football season. Sports trainers reported injuries by body region (eg, knee, head, ankle, shoulder), but only players with a head or knee injury were contacted by the research team.

To address turnover in 2022, we will recruit new teams and players to maintain the minimum cluster size...
have a prescribed dosage (sets and repetitions). Online interventions (figure 2) offer variety and/or progression, and all activities include how and when to use Prep-to-Play. Education topics included education clinical guidelines and efficacious programmes in female soccer, male rugby and male Australian Football.

Table 1 Overview of outcome reporters, programme deliverers, research team roles and training

| Personnel (role)          | Qualifications                  | Blinded | Training and support                                                                 |
|---------------------------|--------------------------------|---------|---------------------------------------------------------------------------------------|
| Physiotherapists          | ≥5 years clinical experience    | No      | Pre-workshop webinar: 20 min related to development of Prep-to-Play and study design  |
|                           |                                |         | 6-hour training workshop: (i) presentation about injury prevention women’s football focused on ACL injuries and concussion; (ii) demonstration/videos of Prep-to-Play by the physiotherapist; (iii) self-practice delivering the programme; (iv) discussion about optimising the learning environment for coaches, facilitated by an AFL coach learning manager, and a professor in sport coaching; and (v) how to conduct the support visits and solutions for common barriers to Prep-to-Play use. Online digital toolbox: materials required for the coach workshop (eg, slide deck with speaker notes), research articles and webinars related to the study and injury prevention in football. Ongoing support: drop-in sessions and 1:1 phone calls with research team. Learnings from delivered workshops will be shared by their peers/research team via a weekly email. |
| Coaches deliver Prep to Play to the team | Level 1 coach accreditation | To sequence until 4 weeks prior to Ttransition | 3-hour training workshop: (i) demonstration/videos of Prep-to-Play by the physiotherapist; (ii) self-practice delivering the programme; (iii) action planning, discuss support visits, and perceived barriers to programme use and potential solutions. Resources to their players, and set expectations (ie, who will be leading and when). Support visits: two visits from physiotherapist to provide feedback and support coaches/players. Online digital toolbox: coach and player manuals, posters, videos. Ongoing support: monthly online drop-in, refresher workshops, can call physiotherapist. |
| Team designates report training and game activities | Team manager/trainer, player | Until 4 weeks prior to Ttransition | Training webinar: 30 min delivered by research team on how to record the training/game activities in the Smartabase App. Ongoing support: training manuals, webinars, online-drop in, weekly SMS reminders (every training and game day) |
| Prep-to Play observers report training and game activities | Health science student independent to the team | Blinded to sequence and allocation | Training webinar: 60 min delivered by research team during the 2021/22 pre-seasons: how to observe a training/game (eg, identifying activities, not to approach team staff) and record activities. Ongoing support: training manuals, webinars, call research team. |
| Team sports trainers report injuries | Basic injury management and first aid training | Blinded to sequence & allocation | Training webinar: 30 min delivered by research team on how to record injuries in the Smartabase App. Ongoing support: training manuals, webinars, online-drop in, weekly SMS reminders (game day and proceeding 2 days) |

ACL, anterior cruciate ligament; AFL, Australian Football League.

and gain consent from new coaches to continue the team’s participation in the study (figure 2). Participant information and consent forms are included in online supplemental file 3.

Interventions
Prep-to-Play consists of: (1) a neuromuscular training warm-up, (2) football skills, (3) strength exercises and (4) education. The warm-up includes eight activities (~10 min). Most warm-up activities have three options to provide variety and/or progression, all activities have a prescribed dosage (sets and repetitions). Online materials instruct coaches to deliver all warm-up activities before every training session. The football skill component includes three Australian Football-specific contact-focused drills: tackling, ground balls and aerial contests (online supplemental file 4). A drill library (posters and videos) was codveloped with the AFL with a focus on safe and effective skill execution. Coaches are instructed to deliver at least one football skill drill per training session, for at least 5 min. Strength training involves three exercises (5–10 min before, during or after every training): (1) lower limb; (2) gluteal and hamstring and (3) core and hip. The strength exercises were informed by ACL injury prevention clinical guidelines and efficacious programmes in female soccer, male rugby and male Australian Football. Consumer input and knowledge of the physical demands of Australian Football informed the inclusion of reverse Nordics (ie, high-speed kicking on the run) and Copenhagen adductor exercise (ie, high volume of change of direction, ground balls, kicking). Each strength exercise has three progression options and prescribed dosage. Education is integral to the Prep-to-Play programme. Education topics covered in the programme manuals, posters and/or videos include how and when to use Prep-to-Play, the rationale for included activities, potential programme benefits, technique cues, activity progression and feedback.
Open access

principles and general player well-being principles (eg, sleep, menstrual/female health, hydration). A full description of Prep-to-Play is in online supplemental file 4.

Control intervention (unsupported Prep-to-Play)
The control intervention is unsupported Prep-to-Play. Coaches are instructed to train and play as usual throughout the season. Coaches can, but are not prompted to, independently access the Prep-to-Play resources on the CoachAFL website. The Prep-to-Play resources were promoted by the AFL (independent and prior to the study) via email to all registered coaches nationwide, discussed at national coaching forums (2019 and 2020) and promoted to leagues since 2019. The online resources in the unsupported and supported arms are identical.

Supported intervention
Developing the supported intervention
A generalised intervention development process was used to develop the Prep-to-Play-supported intervention, incorporating codesign and the use of social behavioural theoretical frameworks. Codesign was used to develop the Prep-to-Play PRO program (2018) and adapt the programme for community football (February 2019); with expert and community coaches, coach educators, AFL health and safety managers, clinical and research injury prevention experts. Feedback from Prep-to-Play early adopters (coach interviews/focus groups—2019) and the Implementation Drivers framework points to three key themes that could enhance Prep-to-Play use: (1) increasing end-user competency, (2) aligning with organisational systems and processes and (3) developing leadership drivers (table 2). All themes included an element of ‘shared responsibility’ across socioecological levels, including the individual (coach), interpersonal (eg, player, other officials), organisational (club, league, the AFL), community (eg, local injury prevention experts) and policy (eg, recognition by the AFL). The supported intervention materials and activities were then developed. The ‘Capabilities, Opportunities, Motivation and Behaviour’ theoretical model guided the development of training materials and activities, with the aim to facilitate behaviour change (ie, use of Prep-to-Play). The AFL coaching department and coach learning managers provided feedback on the physiotherapist training workshop, and the coach workshops were piloted in March 2021 (n=10 coaches, n=3 players, n=1 AFL coach educator).

Table 2 Supported intervention implementation drivers

| Driver | Examples of supported intervention activities |
|--------|-----------------------------------------------|
| Competency | ► Experienced physiotherapists trained by experts to train coaches to deliver Prep-to-Play.  
  ► Coaches complete supervised self-practice of Prep-to-Play delivery.  
  ► Support visits to coaches to provide feedback and improve confidence and competence in delivering.  
  ► Refresher workshops cater for coach and player turnover. |
| Organisational | ► Coach education integrated into the club for all stakeholders (eg, players, parents, administrators) who share the responsibility and promote programme uptake.  
  ► Alignment with existing organisational systems: resources accessed via CoachAFL.  
  ► Alignment with community organisations: physiotherapists are local to the area to optimise the feasibility of ongoing support. |
| Leadership | ► Coaching, Health and Safety teams at the AFL co-design and delivery.  
  ► Coaches provided with organisational recognition (professional development certificate) from the AFL.  
  ► Programme ambassadors feature in programme materials and promotional materials.  
  ► Stakeholder organisations support and engagement: all coaches, players, and support staff receive project merchandise (eg, shirts, beanies, drink bottles). |

AFL, Australian Football League.

Figure 2
Team recruitment process.
to refine the training activities, format and learning outcomes.

The supported intervention is underpinned by a ‘train-the-trainer’ model and is designed to increase use of Prep-to-Play compared with the control intervention via four key activities: (1) the research team train and support physiotherapists to teach coaches to use Prep-to-Play, (2) physiotherapists train coaches, player leaders and relevant team members to use Prep-to-Play, (3) physiotherapists provide two support visits to each team, (4) physiotherapists provide ongoing support for the teams.

**Training and support for physiotherapists**

Approximately, 60 physiotherapists will be recruited and trained to train the coaches of their allocated teams to use Prep-to-Play. Preference will be given to physiotherapists with >5 years clinical experience and postgraduate musculoskeletal or sports qualifications. Each physiotherapist will be allocated between two and five teams geographically close to their workplace to optimise feasibility and sustainability. All recruited physiotherapists will attend a 6-hour training workshop before they train their allocated teams. The face-to-face workshop will be led by authors BEP, SMC and KLC—all physiotherapists with clinical expertise and a PhD in knee injuries. BEP also has lived experience as a previous AFLW player, current AFLW coach and a PhD in knee injuries. The content of the physiotherapists’ workshop and ongoing support is outlined in table 1. The 6-hour training workshop (and associated supports) will be repeated in 2022 to train and support the physiotherapists allocated to teams randomised to receive the supported intervention in 2022. Physiotherapists will be provided with project merchandise and will be reimbursed for their time to attend training and deliver the workshop and support visits at standard professional rates.

**Training and support of study coaches/teams**

**Coach/team workshops**

Prep-to-Play physiotherapists will deliver a 3-hour workshop to coaches and other key team personnel at the start of Ttransition (figure 1). Coaches will be encouraged to invite influential team members who could facilitate programme use and/or delivery (eg, assistant coaches, captains, player leaders and team/club officials). The content of the workshop and ongoing support is outlined in table 1. Coach and player manuals, club posters and links to access Prep-to-Play videos for each programme component (online supplemental file 4) will be distributed at the workshop and housed on an online digital toolbox. Coaches will be trained to select appropriate options for warm-up and strength activities (A, B or C), and football drills for their players. Workshop participants will be shown a video about duty of care and the importance of developing football contact skills, featuring programme ambassadors, and be directed to the football skills drill library (online supplemental file 4). Coaches will be taught to educate their players about the programme rationale and to provide the manual and links to online resources.

**Coach/team support visits**

Physiotherapists will attend two football training sessions for each allocated team — the first within 3 weeks and the second within 6 weeks of the team’s workshop. Physiotherapists will provide real-time feedback and support to coaches and players to address technical Prep-to-Play implementation challenges (eg, motivating players, identifying missing components and/or poor technique) and other barriers (eg, lack of support from players or club administration). After each support visit, physiotherapists will complete an online survey about missing/modified/difficult Prep-to-Play elements, who leads the programme, and the type of support provided.

**Ongoing coach/team support**

Coaches will be encouraged to liaise with their Prep-to-Play physiotherapist if they require additional support to implement Prep-to-Play. Optional monthly online drop-in sessions (‘coaches shed’) with their peers/research team will be offered during the Tsupported phase. After the second support visit, physiotherapists will indicate any additional support required to implement Prep-to-Play. Refresher workshops (online and/or in-person) will be offered in the 2022 preseason (for teams who received supported implementation in 2021) to address staff and player turn-over, re-engage clubs and enhance programme maintenance. A third support visit, refresher workshops, or a phone call will be considered if needed in the Tsupported phase (could be in 2021 or 2022) (online supplemental file 5).

**Outcomes**

Primary and secondary outcomes will be measured during the 2021 and 2022 seasons in all participants, weekly from baseline (start of Tcontrol) to completion (end of Tsupported) (table 3).

**Player and coach characteristics (baseline survey)**

Player characteristic questions included: age, residential postcode, occupation, employment status, education level, physical characteristics (limb dominance, height, body mass), injury and medical history, football/sport experience, playing position, women’s health (menstrual, hormonal therapy/contraception, pregnancy/breastfeeding, breast injury history) and the Euro-QoL-5D-5L (registration number: 44931). Coach characteristic questions included: age, gender identity, residential postcode, employment status, education level, playing/coaching experience and current injury prevention programme use. New players and coaches in 2022 will complete the baseline survey at the beginning of the 2022 season. The coach and
player baseline surveys are in online supplemental file 2.

Use of Prep-to-Play (primary outcome)
Successful use of Prep-to-Play at training is defined as the team completing 9 of the 12 (75%) Prep-to-Play components—consisting of ≥6 of 8 warm-up exercises, ≥2 of 3 strength exercises and ≥1 football skill-based drill. Successful completion at games is defined as the team completing ≥6 of 8 (75%) warm-up exercises. A team will be categorised as ‘using Prep-to-Play’ (yes/no) during each weekly team period if they complete 75% of the programme components (as above) two-thirds of the time (ie, denominator is all training sessions and/or games during the weekly team period).

Each team will appoint a ‘team designate’ to record activities completed by the team at each training session and game via the Smartabase Athlete App or website (Fusion Sport, Brisbane, Australia) (table 4). The research team will train team designates before each season in recording training/game activities. The activities are not considered ‘Prep-to-Play’ activities, as data collection starts before transition to the supported intervention.

Independent Prep-to-Play observers (health science students blinded to the randomisation sequence and allocation) will make five unannounced and anonymous visits to each team to observe the use of Prep-to-Play at training/games: ≥1 observation in T<sub>0</sub> unsupported phase and ≥2 observations in T<sub>2</sub> supported phase.

Table 3 Overview of outcomes and timing

|                      | 2021 season |          | 2022 season |          |
|----------------------|-------------|----------|-------------|----------|
|                      | Pre         | During   | End         | Pre      | During | End |
| Enrolment            |             |          |             |          |        |
| Coach consent and baseline |             |          |             |          |        |
| Demographic characteristics | X       |          | X*          |          |        |
| Football experience  | X           |          | X*          |          |        |
| Player consent and baseline |             |          |             |          |        |
| Demographic characteristics | X       |          | X*          |          |        |
| Football experience  | X           |          | X*          |          |        |
| Injury and medical history | X         |          | X*          |          |        |
| Other sporting history | X           |          | X*          |          |        |
| Women’s health†      | X           |          | X*          |          |        |
| Anthropometrics      | X           |          | X*          |          |        |
| Euro-QoL-5D-5L       | X           |          | X*          |          |        |
| Interventions        |             |          |             |          |        |
| Clusters 1–4 supported implementation | X |          |             |          |        |
| Clusters 5–10 supported implementation |          | X |          |          |        |
| Outcomes             |             |          |             |          |        |
| Primary outcome - use of Prep-to-Play |             |          |             |          |        |
| Team designate (weekly) | X       |          | X           |          |        |
| Independent observer  | X‡          |          | X‡          |          |        |
| Secondary outcomes   |             |          |             |          |        |
| Sports trainer (weekly) | X           |          | X           |          |        |
| Direct from player (weekly) | X          |          | X           |          |        |
| Match and training exposure | X         |          | X           |          |        |
| Healthcare costs     |             |          |             |          |        |
| Direct from player: phone call (head/knee) | X       |          | X           |          |        |
| Direct from player: survey (all other injuries) |          |        |             |          |        |

*New coaches and players will complete the same consent form and baseline survey in 2022.
†Optional questions regarding menstrual health, use of hormonal therapy/contraception, pregnancy/breastfeeding status, breast injury history.
‡Completed five times throughout 2021 and 2022 seasons: ≥1 observation in T<sub>0</sub> unsupported phase and ≥2 observations in T<sub>2</sub> supported phase.

Euro-QoL-5D-5L, European Quality of Life Five Dimensions Five Levels Questionnaire.
Observers use an online REDcap\textsuperscript{57} form to record additional details related to exercise fidelity including: (1) type of activity (ie, option A, B or C), (2) dosage (number of repetitions/sets) and (3) who led the activities (eg, coach, player). The reporting form was co-designed with the observers, and similar to a trial in male community coach, player). The reporting form was co-designed with the observers, and similar to a trial in male community deliverers (eg, coaches) report adherence,\textsuperscript{20 23 53–55} often retrospectively.\textsuperscript{23 53} Given the primary outcome of this study is programme use, the real-time independent observations and the weekly team designate reports provide a rigorous evaluation of adherence. Five visits per team by independent observers exceed those of previous trials (n=1–2 visits).\textsuperscript{22 56} The primary analysis will use the team designate data. The independent observations will be used to ensure the team designate reports are an accurate representation of programme use.

Observers use an online REDcap\textsuperscript{57} form to record additional details related to exercise fidelity including: (1) type of activity (ie, option A, B or C), (2) dosage (number of repetitions/sets) and (3) who led the activities (eg, coach, player). The reporting form was co-designed with the observers, and similar to a trial in male community coach, player). The reporting form was co-designed with the observers, and similar to a trial in male community délégués (coachs) report adherence,\textsuperscript{20 23 53–55} often retrospectively.\textsuperscript{23 53} Given the primary outcome of this study is programme use, the real-time independent observations and the weekly team designate reports provide a rigorous evaluation of adherence. Five visits per team by independent observers exceed those of previous trials (n=1–2 visits).\textsuperscript{22 56} The primary analysis will use the team designate data. The independent observations will be used to ensure the team designate reports are an accurate representation of programme use.

Observers use an online REDcap\textsuperscript{57} form to record additional details related to exercise fidelity including: (1) type of activity (ie, option A, B or C), (2) dosage (number of repetitions/sets) and (3) who led the activities (eg, coach, player). The reporting form was co-designed with the observers, and similar to a trial in male community

### Table 4  Team designate report card—mock entry*

| Neuromuscular training warm-up | Training | Game |
|--------------------------------|----------|------|
| Did the team perform these activities? | ✓ | ✓ |
| Jogging | ✓ | ✓ |
| Static stretching | ✓ | ✓ |
| Dynamic stretching | ✓ | ✓ |
| Side-stepping/grapevine | ✓ | ✓ |
| High knees or butt kicks | ✓ | ✓ |
| Deceleration | | |
| Change of direction | ✓ | |
| Landing | ✓ | |
| Landing with contact | | |
| Sprinting | ✓ | ✓ |
| Contact (bumping/wrestling) | ✓ | |
| Balancing on one leg | | |

| Strength exercises | | |
| Did the team perform these activities? | | |
| Lower limb strength | ✓ | NA |
| Hamstring/gluteal strength | NA | |
| Upper body strength | ✓ | NA |
| Calf strength | NA | |
| Core/adductor strength | NA | |

| Football skills | | |
| Did the team perform these activities? | | |
| Tackling | NA | |
| Ground balls | ✓ | NA |
| Aerial (marking or spoiling) | NA | |
| Handballing | ✓ | NA |
| Kicking | ✓ | NA |

*An option is given if no training/game. SMS reminders are sent each training and match day. All teams in the study trained either once or twice per week.

Australie football with high inter-rater reliability.\textsuperscript{28} The observers were primarily physiotherapy students or physiotherapists, who underwent training with the research team via a 30 min module and a 2-hour webinar, including practice observations.

#### Injury rates (secondary outcome)

Injury data will be collected via two methods: (1) sports trainer and (2) direct from player. An injury (excluding head) will be defined as any injury occurring during a football match or training resulting in a player: (1) being unable to return to the field of play for that match or (2) missing at least one match. A head injury will be defined as any injury to the head region occurring during a football match or training, regardless of time loss. Sports trainers and players will be trained by the research team (webinars, phone calls, instruction manuals) to report via the Smartabase App or website all injuries complying with the definition (online supplemental file 6). Player name, date of injury and body location (eg, knee, ankle, head) of the injured area from a body chart will be recorded. Publicly available match-day team lists, in conjunction with the sports trainer report, will be used to calculate injury severity (match time loss). Each week, sports trainers will report a ‘current injury list’ of players who are unable to play due to an ongoing football-related injury. Operational definitions for injury reporting are described in box 1 and comply with international rater reliability.\textsuperscript{28} The observers were primarily physiotherapy students or physiotherapists, who underwent training with the research team via a 30 min module and a 2-hour webinar, including practice observations.

#### Injury rates (secondary outcome)

Injury data will be collected via two methods: (1) sports trainer and (2) direct from player. An injury (excluding head) will be defined as any injury occurring during a football match or training resulting in a player: (1) being unable to return to the field of play for that match or (2) missing at least one match. A head injury will be defined as any injury to the head region occurring during a football match or training, regardless of time loss. Sports trainers and players will be trained by the research team (webinars, phone calls, instruction manuals) to report via the Smartabase App or website all injuries complying with the definition (online supplemental file 6). Player name, date of injury and body location (eg, knee, ankle, head) of the injured area from a body chart will be recorded. Publicly available match-day team lists, in conjunction with the sports trainer report, will be used to calculate injury severity (match time loss). Each week, sports trainers will report a ‘current injury list’ of players who are unable to play due to an ongoing football-related injury. Operational definitions for injury reporting are described in box 1 and comply with international
reporting standards for sports injuries. All injury types (index, recurrent and subsequent) will be included in the team injury count.

The primary injuries of interest are ACL injury and concussion. Once notified of a knee or head injury, a registered practicing physiotherapist on the research team will contact players to determine if an injury diagnosis was confirmed by a healthcare professional (ie, physician for concussion, physician or physiotherapist for ACL injuries). If not, a player with a suspected ACL injury or concussion (based on a standardised subjective clinical assessment) will be referred for medical assessment (±imaging) to confirm injury diagnosis at no cost to the player. Additional information will be collected (phone call to player from research team) about the knee/head injury: (1) mode of onset (acute, repetitive, mixed acute/repetitive), (2) mechanism (direct, indirect, non-contact) and sport-specific situation (eg, landing from a mark), (3) multiple injury definition (index, recurrent, subsequent), (4) section of the game/training the injury occurred.

Team designates, sports trainers and independent observers are provided with a small remuneration and project merchandise with the aim to maximise engagement and response rates.

Weekly team match exposure will be estimated from the number of matches played, multiplied by the number of players in each match (publically available registry), and the match length (junior: 1 hour, senior: 1.5 hours). Weekly team training exposure will be estimated using the number and duration of football training sessions completed (reported by team designates), multiplied by the average number of players at training (reported by independent observers on five occasions). The injury incidence rate will be expressed as the number of injuries (eg, ACL, concussion) per weekly team period, adjusted for team-level exposure as an offset.

Healthcare resource use and costs (tertiary outcomes)
Healthcare resource use for players sustaining a knee or head injury will be obtained by a research officer by telephone. This will include asking questions about types of healthcare resources accessed (eg, physiotherapy clinic appointments) as well as the quantity of those services accessed in natural units that can be valued (eg, number of appointments). For all other injuries, players will complete an end of season online survey to capture individual healthcare resource use and costs associated with football-related injuries. Healthcare resource use will be costed using actual total costs (when known) or market rates in a subsequent trial-based economic evaluation. This may include (but not limited to) hospitalisations (eg, length of stay, type of surgery if any), number of health professional appointments (eg, general practitioner/family physician, medical specialist and allied health), medical imaging, medication use and equipment (eg, for home exercise).

Process evaluation (tertiary outcomes)
In 2022 and 2023, process evaluation will explore factors related to the effectiveness of the supported intervention strategy and the barriers and enablers of key stakeholders across multiple ecological levels. Evaluation of the relationship between coach-related factors (eg, gender, experience, other qualifications) and Prep-to-Play adherence (using the team designate data) and exercise fidelity (ie, activity type and dosage, using the independent observer data) will be conducted. The process evaluation protocol will be published separately.

COVID-related changes and other considerations
Cancelled workshops and support visits (eg, due to COVID-related restrictions or other reasons) will be rescheduled and completed as soon as practical. Affected teams will remain in their allocated sequence, and remain in Transition until the completion of the first support visit.

Patient and public involvement
End users (coaches, players, parents, physiotherapists) and stakeholders (eg, AFL Coaching, AFL Health and Safety, AFL Media) codesigned Prep to Play and the supported implementation strategy (see intervention section) and reviewed the outcome measures. Leading officials, players, coaches and partner organisations supported recruitment via social and mainstream media. End users and key stakeholders (eg, the AFL) will be involved in the dissemination of the study results.

Sample size
Sample size calculations sought to determine the minimum sample required to detect a meaningful change in the primary and secondary outcomes after the supported intervention, due to the hybrid implementation-effectiveness design. The unit of observation for the primary outcome is defined as use of Prep-to-Play (see the Outcomes section) per weekly team period. Sample size calculations were completed using the Shiny CRT online tool for binary outcomes, based on a linear mixed model specification for stepped wedge designs. The study design is defined by 10 clusters (figure 1). Calculations assumed ≥14 teams per cluster; a coefficient of variation equal to 0.65 was applied to account for variation in cluster sizes. A two-period decay correlation structure was assumed, to account for within-period and between-period intracluster correlations (ICC). Base case calculations used a within-period ICC of 0.1 and cluster auto-correlation (CAC) of 0.9 (ref: use reference from grant application). Sensitivity analyses considered ICC values between 0.05 and 0.2 and CAC values between 0.72 and 1. Chosen ICC values were guided by empirical studies for binary process outcomes.

The estimated weekly proportion of teams using Prep-to-Play in the unsupported phase is 0.09 (9%), based on published data. A cluster period size of 14 teams will allow us to detect a change in the primary outcome to at least 0.165 (16.5%) with 88% power at the 5% level of
statistical significance. For the same change in outcome, varying the within-period ICC results in power estimates of 86%–89%. Varying the CAC within the proposed range gives power estimates of 80%–92%.

For the secondary outcome, we determined the minimum sample size per cluster period needed to detect a 50% decrease in ACL injury with at least 90% power as the base case. Weekly data on ACL injury will be collected at the player level but aggregated at a team level (see Outcomes section). Calculations assumed a within-period ICC of 0.01 (range: 0.001–0.05) and a CAC of 0.9 (range: 0.72–1). Further sensitivity analysis considered a range of published estimates for ACL injury incidence per team per season to represent the unsupported phase, from 0.03 (3%) to 0.05 (5%). Assuming an incidence of 3% in the unsupported phase, a minimum sample size of 80 players per cluster period will give 91% power to detect a reduction in ACL incidence to 1.5%. Varying values for CAC and ICC result in estimated power of 88%–93% and 83%–96%, respectively. For an incidence of 5% in the unsupported phase, a minimum sample size of 45 players per cluster period will be required to detect a reduction in outcome to 2.5% with 91% power (CAC range: 90%–92% power; ICC range: 86%–96% power). Based on the number of players within each cluster (figure 2), achieving these minimum sample sizes per cluster period is feasible.

Statistical analysis

Crude rates will be reported for the use of Prep-to-Play (primary outcome), and ACL and concussion injury incidence (secondary outcomes) in the $T_{\text{control}}$ and $T_{\text{supported}}$ phases. During $T_{\text{transition}}$ the team periods will not be included in the primary or secondary analysis. All analyses will be performed according to intention-to-treat and per protocol. All statistical tests will be two sided and a significance level of <0.05 will be used. Instances of missing data will be addressed by multiple imputation by chained equations, assuming it is missing at random. Imputed covariates will be missing player (previous injury, age, playing experience) and coach demographics (age, gender, coaching experience). No imputation of injury or exposure outcomes will occur. Demographic information about the coaches, players and team will be summarised using descriptive statistics.

Primary outcome—use of Prep-to-Play

Prep-to-Play use will be compared between $T_{\text{control}}$ and $T_{\text{supported}}$. The dependent variable is a binary outcome, denoting whether the team met the Prep-to-Play criteria in that weekly period. The binary outcome data will modelled using a generalised linear mixed model (GLMM), with a log or identify link to report relative risks and risk differences (with 95% CI), respectively. The GLMM specification will include a random cluster effect and random cluster by period effect. Period will be modelled as a fixed categorical effect to account for secular trends. The effect of the intervention will be modelled as a binary variable, which will switch from 0 to 1 as a cluster changes over from the unsupported to supported phase. Results for unadjusted (except clustering) and adjusted (by covariates) will be reported. A multivariable and multilevel regression will be performed for the primary outcome, priori adjusting for age group, level of competition and season. Sensitivity analysis will consider a linear intervention effect to account for increasing familiarity with the intervention.

Secondary outcomes—ACL injuries and concussion

Analysis of the secondary outcome will focus on the expected reduction of ACL and concussion injury incidence following-supported implementation. The dependent variable will be the injury incidence rate, defined as the number of reported injuries per weekly team period. Differences in team exposure will be accounted for by including the weekly number of team hours as an offset. Injury data will be anlaysed using a GLMM assuming a Poisson-dependent variable. Results will be reported as a relative risk to summarise the difference between unsupported and supported phases. Remaining model specification will follow a similar approach as per the analysis of the primary outcome.

Additional analysis will compare the injury incidence rates of other body regions (eg, ankle) between $T_{\text{control}}$ and $T_{\text{supported}}$. Additional analysis will evaluate the effect of coach factors (eg, experience, gender) on the primary outcomes (use). The effect of player factors (eg, previous injuries, playing experience, education) and team factors (eg, proportion of new players in 2022, adherence defined as the proportion of total sessions meeting Prep-to-Play use criteria) on secondary outcomes will be evaluated using similar regression-based methods that account for individuals within teams as a nested data structure.

Given the two-season design and nature of community sport, players may join mid-season, players from 2021 may cease participation in 2022, or new players may join study teams in 2022. Therefore, players contributing team-level outcome data may differ in any given week. Player turnover will not influence the primary outcome (use of Prep-to-Play at the team level) as the outcome will be assessed at the team level. New players will also be exposed to the intervention, as they will most likely participate in training activities as directed by their coach. Coach and player turnover will be mitigated by refresher workshops in the 2022 preseason for new coaches and/or teams that received the workshop in 2021 (figure 1). New players may influence the secondary (injury) outcomes (eg, lack of training effect); however, their data will contribute to outcome assessment at the team level and the calculation of team exposure as an offset.

Ethics and dissemination

La Trobe University Human Research Ethics Committee (HREC 20488) approved the study. Coaches provided informed consent to receive the supported intervention, and players provided consent to be contacted if
they sustained a head or knee injury. Participants will be informed that if they withdraw from the trial, personal health information already collected will be retained, unless an explicit request to the contrary. Data management procedures and the roles and responsibilities of the authors at the trial management centre (La Trobe University) and advisory group are in online supplemental file 7. Results will be disseminated through partner organisations, peer-reviewed publications and scientific conferences. The partner organisations will be provided with

Table 5

| Type of bias  | Example                                                                 | Strategies to minimise bias                                                                                                                                 |
|--------------|--------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Selection    |                                                                          |                                                                                                                                                            |
| Volunteer    | Volunteer coaches more likely to adhere                                  | ► All U16, U18 and senior women’s teams in Victoria are invited to participate                                                                             |
| Measurement  |                                                                          |                                                                                                                                                            |
| Desirability | Outcome reporters report expected or desired results (eg, team designates report they are using Prep to Play, trainers report no injuries) | ► Non-Prep-to-Play activities (eg, static stretching) added to team designate report.  
► Team designates instructed not to ask the coach about activities  
► Team designates informed that independent observers will attend training  
► Prep-to-Play observers independent to the club and blinded to the randomisation sequence make five unannounced and anonymous visits to each team to validate team designate reports  
► Team designates blinded to randomisation sequence until 4 weeks before Ttransition |
| Non-respondent | Incomplete outcome reports may reflect teams not using Prep to Play/ have no injuries | ► Team designates and sports trainers trained to complete even if nothing to report  
► Engagement activities and incentives to maximise response rate (project merchandise, gift vouchers, free professional development events)  
► SMS reminders (team designates: every training and game; trainers: game day and proceeding 2 days). Research team: follow-up calls for missing reports |
| Recall       | Team designates or sports trainers may forget training activities and injuries |                                                                                                                                                            |
| Intervention |                                                                          |                                                                                                                                                            |
| Contamination | Teams in Tcontrol may start using Prep-to-Play independently             | ► This reflects usual care (control) and we expect some teams will be using Prep-to-Play  
► Each cluster include teams in a unique geographical area to avoid contamination form teams that play each other |
| Timing       | Intervention timing (eg, round 1 vs round 8) differs between clusters and may influence programme uptake | ► Teams educated that injury prevention programmes are effective in-season and the advantage of the staggered study design is that all teams receive the intervention |
| Attrition    | Reduce statistical power, and coaches who withdraw may be non-adherers    | ► Sample size sufficient for 20% drop-out  
► Nature of missing data will be assessed, and appropriate imputation and mixed model used |
| Proficiency  | Quality of supported intervention delivery may differ between physiotherapists | ► Experienced physiotherapists (>5 years), training and ongoing support provided  
► Research team attends every workshop to monitor quality and fidelity of training activities |
| Analysis     |                                                                          |                                                                                                                                                            |
| Confirmation | Outcome data are processed and interpreted in favour of the research hypotheses | ► Authors MK and SL (audit the primary outcome data and determine use of Prep-to-Play in each team period) are blinded to the randomisation sequence and the allocation  
► The statistician will be unblinded to information required to complete the analyses (ie, timing of transition) but blinded to team information (eg, location, name). Teams will be given a unique code. |
| Confounding  | Team/coach/player characteristics may influence Prep-to-Play use and injuries | ► Information on confounding factors related to the team (eg, region), coach (eg, gender), and player (eg, injury history) is collected and incorporated into the statistical models. |
| Chronology   | External trends during 2021 and 2022 (eg, COVID-related training restrictions) may influence outcome reporting and/or participation in the intervention | ► Data collection for all teams will commence at the beginning of Tcontrol period  
► Additional analyses will explore the effect of season/year |
DISCUSSION

This stepped-wedge cluster randomised controlled trial will compare the effect of the supported and unsupported intervention strategies on the use of Prep-to-Play, and injury rates in community women’s Australian Football. As one of the largest implementation trials in sports injury prevention, this study aims to build on existing programmes by using an extensive codesign process, incorporating social behavioural theory to inform the supported intervention, a detailed assessment of implementation outcomes, and an extensive process evaluation. The stepped-wedge design allows all participating teams to receive support during the trial—it was important to the partner organisations to deliver an evidence-informed programme to their stakeholders in an equitable and timely manner.

Like all injury prevention trials, the trial design does not allow coaches and players to remain blinded to their allocation. Teams are informed of the timing of their transition from control to intervention 4 weeks before their workshop. We expect that some teams in the control group may become aware of (and/or start using) Prep-to-Play before their allocated sequence. The risk of selection, measurement, intervention and/or analysis bias will be minimised using a variety of strategies and study design elements (table 5).

The study is powered to detect an increase in use and a reduction in injuries, resulting in a pragmatic hybrid implementation-effectiveness design. Injuries are a secondary outcome due to the: (1) limitations of team-level injury data, 2) potential effects of COVID-related restrictions on football participation and injury rates, 3) known-effectiveness of similar programmes and need to focus on adherence in sports injury prevention. Team-level exposure data may introduce differential measurement bias, if the proportion of players in the team at any given training and/or game more likely to develop an injury, differs between clusters. Similarly, the use of aggregate exposure data assumes complete data collection on player injuries to estimate weekly incidence rates. Team-level exposure data was a pragmatic choice due to the difficulty of accurately collecting individual-level training exposure (identified from previous piloting and codesign with consumers). It was deemed impractical to collect individual exposure from team managers and trainers who are not at present every training, and already experiencing a high level of volunteer burden, heightened by the COVID-19 pandemic burdens. The trial methodology is pragmatic—it uses interventions and assessments designed to continue beyond the project.

This study is strengthened by including multiple age groups (U16, U18, senior women) and geographical locations (metropolitan, regional, rural) in Victoria and testing the implementation model in the largest group of female Australian Football players. If the supported intervention is effective, it will provide a real-world model of how to integrate an injury prevention programme into existing organisational processes that could be scaled-up or tested in other contexts. This trial will boost the capacity, skills and knowledge of physiotherapists to deliver primary prevention interventions in community football in contrast to their traditional injury rehabilitation focus. The two-season design will test the real-world applicability of the implementation model—accommodating date and player turnover, and evaluating how the intervention will develop over time. A novel feature of Prep-to-Play is the inclusion of football-specific skills, which may provide new insights into the potential for sport-specific skills and education to reduce concussion in women’s football.

Author affiliations
1Australian IOC Research Centre, La Trobe University Sport and Exercise Medicine Research Centre, Bundoora, Victoria, Australia
2Centre for Sport and Social Impact, La Trobe University, Melbourne, Victoria, Australia
3Australian Centre for Health Service Innovation, Queensland University of Technology, Brisbane, Queensland, Australia
4Digital Health and Informatics, Metro South Hospital and Health Service, Woolloongabba, Queensland, Australia
5Unit of Physiotherapy, Department of Health, Medicine and Caring Sciences, Linköpings Universitet, Linköping, Östergötland, Sweden
6Department of Neuroscience, Monash University, Clayton, Victoria, Australia
7School of Public Health and Preventive Medicine, Monash University, Clayton, Victoria, Australia
8Monash-Cabrini Department of Musculoskeletal Health and Clinical Epidemiology, Cabrini Health, Malvern, Victoria, Australia
9Department of Surgery, St.Vincent’s Hospital, University of Melbourne, Melbourne, Victoria, Australia
10Institute of Applied Health Research, University of Birmingham, Birmingham, UK
11Medibank Better Health Foundation, Medibank Private, Melbourne, Victoria, Australia
12Australian Football League, Melbourne, Victoria, Australia
13Australian Physiotherapy Association, Hawthorn, Victoria, Australia
14Faculty of Medicine Dentistry and Health Sciences, University of Melbourne, Melbourne, Victoria, Australia
15Australasian College of Sport and Exercise Physicians, Melbourne, Victoria, Australia
16Australasian College of Sport and Exercise Physicians, Melbourne, Victoria, Australia
17Sports Medicine Australia, Albert Park, Victoria, Australia

Twitter Brooke E Patterson @Knee_Howell, Alex Donaldson @AlexDonaldson13, Sallie M Cowan @PhysioHill, Matthew G King @mattmgking1, Christian G Barton @drchrisbarton, Martin Hagglund @Mhagglund, Natasha A Lannin @A-4195-2013, Ilana N Ackerman @IlanaAckerman, Adam G Culveron @aguclveron, Andrea B Mosler @AndreaBMosler, Andrea M Bruder @AndreaBRuder, Nicole Livingstone @NicLiV, Melissa J Haberfield @Melhaberfield, Sarah J Lampard @slampard8, Christian Bonello @cbonello and Kay M Crossley @kaymcrossley

Acknowledgements We thank the AFL Coaching (Julia Lawrence, David Rath, Joshua Atwood, Ricky Coburn), Patrick Clifton (AFL Health and Safety) and the AFL Media department for supporting the development of the Prep-to-Play program content and materials. We thank Zoe Slatter from AFL Victoria, and coaches Jane Lange, Peta Searle, Brett Ratten, Aaron Hamill and the late Danny Frawley for providing expert input to the program content. We thank coach educators Sam McKenzie and Ricky Coburn from the AFL and David Morley from La Trobe University, for contributing to the physiotherapy training. We thank the Northern Knights U18 players, AFL women’s players Isabelle Huntington, Georgia Gee and Ellie Gavalas, and community players Kathleen Roe, Tennille Nash and Ailx Kearney, for assisting to develop the program materials.
Contributors KC, CHB, AD, SMH, MM, NW, MM, KH, IA, NL, and MD obtained funding for the study. JC, NLI, RE, AN, JF, and JCr (from partner organisations) contributed to the intervention design and participant recruitment. All authors contributed substantially to the design of the study, BP, SC, MK, SM, NW and KC prepared the manuscript, and authors AM, AB, AC, M Hab, ER, EB, SL, CBon and Kxh provided input to the final manuscript.

Funding This work is funded by a National Health and Medical Research Council (NHMRC) Partnership Grant (GNT 1193733, 2020-2023). The NHMRC grant includes contributions from partner organisations, including the Australian Football League (AFL), Medibank Better Health Foundation and the Australian Physiotherapy Association (APA) (GNT 1193733, 2020-2023). In-kind support as part of the NHMRC grant (GNT 1193733, 2020-2023) was provided by Sports Medicine Australia (SMA), AFL Victoria and the Australasian College of Sport and Exercise Physicians (ACSEP).

Competing interests MM is employed by the AFL as Chief Medical Officer. The partner organisations assisted with the intervention design (AFL) and participant recruitment (AFL Victoria, Medibank, APA) but will not be involved in collecting, managing, analysing the data or deciding to submit for publication.

Patient and public involvement Patients and/or the public were involved in the design, or conduct, or reporting, or dissemination plans of this research. Refer to the Methods section for further details.

Patient consent for publication Not applicable.

Provenance and peer review Not commissioned; externally peer reviewed.

Supplemental material This content has been supplied by the author(s). It has not been vetted by BMJ Publishing Group Limited (BMJ) and may not have been peer-reviewed. Any opinions or recommendations discussed are solely those of the author(s) and are not endorsed by BMJ. BMJ disclaims all liability and responsibility arising from any reliance placed on the content. Where the content includes any translated material, BMJ does not warrant the accuracy and reliability of the translations (including but not limited to local regulations, clinical guidelines, terminology, drug names and drug dosages), and is not responsible for any errors and/or omissions arising from translation and adaptation or otherwise.

Open access This is an open access article distributed in accordance with the Creative Commons Attribution Non Commercial (CC BY-NC 4.0) license, which permits others to distribute, remix, adapt, build upon this work non-commercially, and license their derivative works on different terms, provided the original work is properly cited, appropriate credit is given, any changes made indicated, and the use is non-commercial. See: http://creativecommons.org/licenses/by-nc/4.0/.

ORCID iDs Brooke E Patterson http://orcid.org/0000-0002-6570-5429 Alex Donaldson http://orcid.org/0000-0002-4764-2361 Sallie M Cowan http://orcid.org/0000-0002-3545-5094 Matthew G King http://orcid.org/0000-0003-0470-5924 Christian G Barton http://orcid.org/0000-0002-3545-5094 Martin Hagglund http://orcid.org/0000-0002-6883-1471 Nicole M White http://orcid.org/0000-0002-9292-0773 Natasha A Lannin http://orcid.org/0000-0002-2066-8345 Ilana N Ackerman http://orcid.org/0000-0002-6026-1612 Michelle M Dowsey http://orcid.org/0000-0002-9708-5308 Karla Hemming http://orcid.org/0000-0002-2226-6550 Michael Makdissi http://orcid.org/0000-0001-0334-7133 Adam G Culvenor http://orcid.org/0000-0001-9491-0264 Andrea B Mosler http://orcid.org/0000-0001-7153-2583 Andrea M Bruder http://orcid.org/0000-0001-5422-5756 Jane Fitzpatrick http://orcid.org/0000-0002-9578-026X Melissa J Haberfield http://orcid.org/0000-0002-6366-0896 Kay M Crossley http://orcid.org/0000-0001-5892-129X

REFERENCES
1 Australian Football League. Australian football League (AFL) annual report 2018 Melbourne 2019.
2 Montalvo AM, Schneider DK, Webster KE, et al. Anterior cruciate ligament injury risk in sport: a systematic review and meta-analysis of injury incidence by sex and sport classification. J Athl Train 2019;54:472-82.
3 Montalvo AM, Schneider DK, Silva PL. ‘What’s my risk of sustaining an ACL injury while playing football (soccer)?’ A systematic review with meta-analysis. Br J Sport Med 2018.
4 Prien A, Grafe A, Rössler R, et al. Epidemiology of head injuries focusing on concussions in team contact sports: a systematic review. Sports Med 2018;48:953-69.
5 Abrahams S, Fie SM, Patricios J, et al. Risk factors for sports concussion: an evidence-based systematic review. Br J Sports Med 2014;48:91-7.
6 AFL Doctors Association and AFL Physiotherapists Association. 2020 AFLW injury report. Melbourne, Victoria, Australia: AFL Football Operations Department, 2020.
7 Fortington LV, Finch CF. Priorities for injury prevention in women’s Australian football: a compilation of national data from different sources. BMJ Open Sport Exerc Med 2016;2:e000112.
8 Fortington LV, Donaldson A, Finch CF. Self-reported worst injuries in women’s Australian football identify lower limb injuries as a 2018 prevention priority. BMJ Open Sport Exerc Med 2019;5:e000112.
9 Filbay SR, Ackerman IN, Russell TG. Health-Related QOL after ACLR: a systematic review. Am J Sports Med 2014;42:1247–55.
10 Patterson BE, Culvenor AG, Barton CJ, et al. Patient-Reported outcomes: one to five years after anterior cruciate ligament reconstruction: the effect of combined injury and associations with osteoarthritis features defined on magnetic resonance imaging. Arthritis Care Res 2020;72:412–22.
11 Haider MN, Leddy JJ, Pavlesen S, et al. A systematic review of criteria used to define recovery from sport-related concussion in youth athletes. Br J Sports Med 2018;52:1179–90.
12 Ardern CL, Taylor NF, Feller JA, et al. Fifty-five per cent return to competitive sport following anterior cruciate ligament reconstruction surgery: an updated systematic review and meta-analysis including aspects of physical functioning and contextual factors. Br J Sports Med 2014;48:1543–52.
13 Patterson BE, Culvenor AG, Barton CJ, et al. Worsening knee osteoarthritis features on magnetic resonance imaging 1 to 5 years after anterior cruciate ligament reconstruction. Am J Sports Med 2018;46:2873–83.
14 Ackerman IN, Bohensky MA, Kemp JL, et al. Likelihood of knee replacement surgery up to 15 years after sports injury: a population-level data linkage study. J Sci Med Sport 2019;22:629–34.
15 Makdissi M, Schneider KJ, Feddern-Demont N, et al. Approach to investigation and treatment of persistent symptoms following sport-related concussion: a systematic review. Br J Sports Med 2017;51:958–68.
16 Manley G, Gardner AJ, Schneider KJ, et al. A systematic review of potential long-term effects of sport-related concussion. Br J Sports Med 2017;51:969–77.
17 Ageberg E, Forsblad M, Herbertsson P, et al. Sex differences in patient-reported outcomes after anterior cruciate ligament reconstruction: data from the Swedish knee ligament register. Am J Sports Med 2010;38:1334–42.
18 Merritt VC, Padgett CR, Jak AJ. A systematic review of sex differences in concussion outcome: what do we know? Clin Neuropsychol 2019;33:1016–43.
19 Crossley KM, Patterson BE, Culvenor AG, et al. Making football safer for women: a systematic review and meta-analysis of injury prevention programmes in 11 773 female football (soccer) players. Br J Sports Med 2020;54:1089–98.
20 Hipol MD, Stokes KA, Williams S, et al. Reducing musculoskeletal injury and concussion risk in schoolboy rugby players with a pre-activity movement control exercise programme: a cluster randomised controlled trial. Br J Sports Med 2017;51:1140–6.
21 Finch CF, Twomey DM, Fortington LV, et al. Preventing Australian football injuries with a targeted neuromuscular control exercise programme: comparative injury rates from a training intervention delivered in a clustered randomised controlled trial. Injury Prev 2016;22:123–8.
22 Waldén M, Atroshi I, Magnusson H, et al. Prevention of acute knee injuries in adolescent female football players: cluster randomised controlled trial. BMJ 2012;344:e3042.
23 Akerman I, Waldén M, Sonesson S, et al. Forty-five per cent lower acute injury incidence but no effect on overuse injury prevalence in youth floorball players (aged 12-17 years) who used an injury prevention exercise programme: two-armed parallel-group cluster randomised controlled trial. Br J Sports Med 2020;54:1028–35.
24 Anundale AJH, Bizzini M, Giordano A, et al. Exercise-based knee and anterior cruciate ligament injury prevention. J Orthop Sports Phys Ther 2018;48:A1–42.
25 Bruder AM, Crossley KM, Mosler AB, et al. Co-Creation of a sport-specific anterior cruciate ligament injury risk reduction program for women: a concept mapping approach. J Sci Med Sport 2020;23:353–60.
26 Bruder AM, Crossley KM, Donaldson A, et al. Through the athlete’s lens: a novel study exploring the perspectives and experiences of
pragmatic hybrid effectiveness-implementation type 1 randomised controlled trial. *BMJ Open* 2020;10:e034986.

47 Curran GM, Bauer M, Mittman B, et al. Effectiveness-implementation hybrid designs: combining elements of clinical effectiveness and implementation research to enhance public health impact. *Med Care* 2012;50:217–26.

48 Hemming K, Haines TP, Chilton PJ, et al. The stepped wedge cluster randomised trial: rationale, design, analysis, and reporting. *BMJ* 2015;350:h3391.

49 Fiksen OA, Tjøike KA, Naom SF, et al. Core implementation components. *Res Soc Work Pract* 2009;19:531–40.

50 Michie S, van Stralen MM, West R. The behaviour change wheel: a new method for characterising and designing behaviour change interventions. *Implentment Sci* 2011;6:42.

51 Li, C. Peng W, Zhang F, et al. The effectiveness of blended learning in health professions: systematic review and meta-analysis. *J Med Internet Res* 2016;18:62.

52 Rabin R, de Chorro F. EQ-5D: a measure of health status from the EuroQol group. *Ann Med* 2001;33:337–43.

53 Steffen K, Myklebust G, Clarridge CE, et al. Preventing injuries in female youth football—a cluster-randomized controlled trial. *Scand J Med Sci Sports* 2008;18:605–14.

54 Emery CA, Van Den Berg C, Richmond SA. Implementing a junior high school-based program to reduce sports injuries through neuromuscular training (SPRINT): a cluster randomized controlled trial (RCT). *Br J Sports Med* 2019;bjjports-2019-1.

55 Owoeye OBA, Palacios-Derflinger LM, Emery CA. Prevention of ankle sprain injuries in youth soccer and Basketball. *Clin J Sport Med* 2018;28:325–30.

56 Owoeye OBA, Emery CA, Befus K, et al. How much, how often, how well? Adherence to a neuromuscular training warm-up injury prevention program in youth basketball. *J Sports Sci* 2020;38:2329–37.

57 Bjornsson SA, Crossley KM, Thielke R, et al. Research electronic data capture (REDCap)—A metadata-driven methodology and workflow process for providing translational research informatics support. *J Biomed Inform* 2009;42:377–81.

58 Fortington LV, Donaldson A, Lathlean T, et al. ‘When just doing it’ is not enough: assessing the fidelity of player performance of an injury prevention exercise program. *J Sci Med Sport* 2015;18:272–7.

59 Bahr R, Claesn B, Derman W, et al. International Olympic Committee consensus statement: methods for recording and reporting epidemiological data on injury and illness in sport 2020 (including STROBE extension for sport injury and illness surveillance (STROBE-SIIS)). *Br J Sports Med* 2020;54:372–89.

60 Hemming K, Kasza J, Hooper R, et al. A tutorial on sample size calculation for multiple-period cluster randomized parallel, crossover and stepped-wedge trials using the shiny crt calculator. *Int J Epidemiol* 2020;49:979–95.

61 Hussey MA, Hughes JP. Design and analysis of stepped wedge cluster randomized trials. *Contemp Clin Trials* 2007;28:182–91.

62 Hooper R, Bourke L. Cluster randomised trials with repeated cross sections: alternatives to parallel group designs. *BMJ* 2015;350:h2925.

63 Gulifford MC, Ukoumunne OC, Chinn S. Components of variance and intraclass correlations for the design of community-based surveys and intervention studies: data from the health survey for England 1994. *Am J Epidemiol* 1999;149:876–83.

64 Steffen K, Meeuwisse WH, Romiti M, et al. Evaluation of how different implementation strategies of an injury prevention programme (FIFA 11+) impact team adherence and injury risk in Canadian female youth football players: a cluster-randomised trial. *Br J Sports Med* 2015;49:979–95.

65 Heady RM, Clinkenbeard JS, Clarridge CE, et al. Effectiveness of a cluster-randomised stepped wedge implementation of an injury prevention programme for providing translational research informatics support. *J Biomed Inform* 2009;42:377–81.

66 Hooper R, Bourke L. Cluster randomised trials with repeated cross sections: alternatives to parallel group designs. *BMJ* 2015;350:h2925.

67 Guliford MC, Ukoumunne OC, Chinn S. Components of variance and intraclass correlations for the design of community-based surveys and intervention studies: data from the health survey for England 1994. *Am J Epidemiol* 1999;149:876–83.

68 Steffen K, Meeuwisse WH, Romiti M, et al. Evaluation of how different implementation strategies of an injury prevention programme (FIFA 11+) impact team adherence and injury risk in Canadian female youth football players: a cluster-randomised trial. *Br J Sports Med* 2015;49:979–95.

69 Nielsen RO, Bertelsen ML, Ramskov D, et al. Randomised controlled trials (RCTs) in sports injury research: authors-please report the compliance with the intervention. *Br J Sports Med* 2020;54:51–7.

70 Staley K, Randle E, Donaldson A, et al. Returning to sport after a COVID-19 shutdown: understanding the challenges facing community sport clubs. *Manag Sport Leis* 2021;1:21–21.