

BMJ Open 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, Alex Donaldson ², Sallie M Cowan ¹, Matthew G King ¹, Christian G Barton ¹, Steven M McPhail,^{3,4} Martin Hagglund ⁵, Nicole M White ³, Natasha A Lannin ⁶, Ilana N Ackerman ^{7,8}, Michelle M Dowsey ⁹, Karla Hemming ¹⁰, Michael Makdissi ¹, Adam G Culvenor ¹, Andrea B Mosler ¹, Andrea M Bruder ¹, Jessica Choong,¹¹ Nicole Livingstone,¹² Rachel K Elliott,¹² Anja Nikolic,¹³ Jane Fitzpatrick ^{14,15}, Jamie Crain,¹⁶ Melissa J Haberfield ¹, Eliza A Roughead,¹ Elizabeth Birch,¹ Sarah J Lampard,¹ Christian Bonello,¹ Karina L Chilman,¹ Kay M Crossley ¹

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For numbered affiliations see end of article.

Correspondence to

Dr Brooke E Patterson;
B.Patterson@latrobe.edu.au

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 (or 'wedges') 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.

(eg, posters and videos about the four elements), but without additional face-to-face support. Outcomes will be evaluated throughout the 2021 and 2022 seasons (~14 weeks per season). Primary outcome: use of Prep-to-Play will be reported via a team designate (weekly) and an independent observer (five visits over the two seasons) and defined as the team completing 75% of the programme, two-thirds (67%) of the time.

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 \geq 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.

Ethics and dissemination La Trobe University Ethics Committee (HREC 20488) approved. Coaches provided informed consent to receive the supported intervention and players provided consent to be contacted if they sustained a head or knee injury. Results will be disseminated through partner organisations, peer-reviewed publications and scientific conferences.

Trial registration number NCT04856241.

INTRODUCTION

Women's participation in all football codes is rapidly increasing at all levels, including in Australian Football.¹ The benefits of playing any football code are offset by the heightened risk of sustaining an anterior cruciate ligament (ACL) injury (~2–5 times higher)^{2–3} or a concussion^{4–5} (~2 times higher) for women than men. In elite Australian Football, sex differences in ACL injury risk are 5–7 times higher than other team ball sports worldwide,⁶ and likely to be similarly high in community players. Preventing serious knee (ie, ACL) injuries and concussions is a priority in Australian Football^{7–8}—especially due to the associated low return to sport rates and risk of persistent symptoms and poor quality of life in other sports.^{9–12} An ACL injury increases the risk of post-traumatic osteoarthritis and total knee replacement at a young age,^{10–13–14} while concussion may result in persistent symptoms,¹⁵ cognitive and motor impairments¹⁶ that can impact school, social and vocational activities. The burden of ACL injury and concussion appears to be greater for women.^{17–18} Developing an effective injury prevention programme that is used consistently and with high fidelity by women's community Australian Football teams is urgently required.

Injury prevention programmes can reduce ACL injury risk by 50% in women playing soccer¹⁹ and concussion in men playing rugby,²⁰ but no tailored programme existed for women's Australian Football. Prep-to-Play PRO (professional) was informed by evidence-based programmes^{19–23} and ACL injury prevention clinical guidelines²⁴ and code-signed with consumers (ie, players, coaches, medical and high performance staff) and industry stakeholders. It was implemented in the elite programme (AFLW—2018),^{25–27} and then adapted for community football (Prep-to-Play) (2019).²⁸ Prep-to-Play is publicly available online via an Australian Football League (AFL) coach development platform (<https://coach.afl/female-football>). Prep-to-Play consists of: (1) a neuromuscular training warm-up; (2) football skills; (3) strength exercises and (4) education. The warm-up and strength exercises are similar to existing programmes shown to reduce women's ACL

injuries in soccer, handball and basketball.²⁹ The football skills include unique Australian Football activities (eg, tackling) and aim to reduce the risk of ACL injuries and concussion. Sport-specific skills and education can enhance programme uptake³⁰ potentially reducing concussion,^{20–31} particularly where participation is new for women and girls.

Injury prevention programme implementation in real-world sports settings is typically low,^{32–33} and using theoretical frameworks to inform programme design and delivery is an emerging concept in sports injury prevention.^{34–35} Programme codesign with end users (eg, coaches) and key stakeholders (eg, the AFL) should facilitate acceptable and context-specific intervention strategies,^{30–36} which may enhance programme uptake. Social or behavioural science-informed strategies^{34–37} may enhance programme uptake, leading to greater 'real-world' injury reduction rates.^{38–40} Addressing barriers and drivers of programme implementation across multiple socioecological levels (eg, the coach, players, parents, club and organisational administrators) is vital to design a programme and delivery strategy that facilitates behaviour change and sustainability beyond the research project.^{41–43}

The primary aim of this stepped-wedge, cluster randomised controlled trial is to compare the use of Prep-to-Play in women's and girls' community Australian Football teams between those receiving supported (intervention) and unsupported (control) implementation strategies. The secondary aim is to evaluate if supported intervention can reduce ACL and concussion injury rates compared with the unsupported intervention. We hypothesise that supported intervention will result in greater use of Prep-to-Play as well as a greater subsequent reduction in ACL and concussion injury rates compared with unsupported intervention.

METHODS AND ANALYSIS

Study design

This protocol adheres to the Standard Protocol Items Recommendations for Interventional Trials guidelines⁴⁴ (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.⁴⁵ 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.^{46–47}

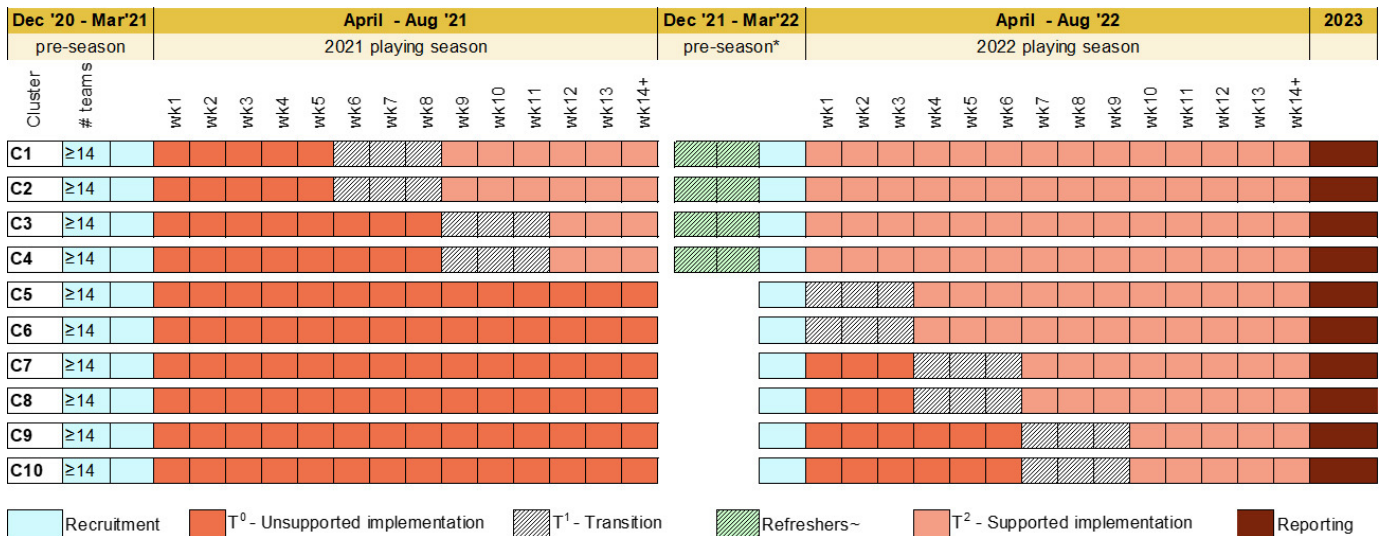


Figure 1 Stepped-wedge cluster randomisation and intervention plan. *New players and coaches will be recruited in pre-season 2022.+Some teams may have >14 weeks per season due to varying lengths in competitions and/or finals series. ~Refresher workshops to support teams in clusters 1–4 to continue using Prep-to-Play will be offered. C, cluster; wk, week of the season, wk1, round 1 of the playing season.

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) T^{control}: unsupported intervention, (2) T^{transition}: beginning at time of intervention workshop delivery and ending at time of first support visit, (3) T^{supported}: supported intervention, beginning after first support visit and ending at completion of season 2022 (figure 1).

In T^{transition}, 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.⁴⁸ 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 T^{control} and T^{supported}, 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 T^{control} and T^{supported} 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

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

Personnel (role)	Qualifications	Blinded	Training and support
Physiotherapists train coaches to use Prep to Play	≥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 in women's football, focused on ACL injuries and concussion; (ii) demonstration/videos of Prep-to-Play, (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 T ^{transition}	3-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) 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 T ^{transition}	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 and all activities have a prescribed dosage (sets and repetitions). Online materials instruct coaches to deliver all warm-up activities before every team training and match. The football skill component includes three Australian Football-specific contact-focussed drills: tackling, ground balls and aerial contests (online supplemental file 4). A drill library (posters and videos) was codeveloped 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 guidelines²⁴ and efficacious programmes in female soccer,¹⁹ male rugby²¹ and male Australian Football.^{20 21} Consumer input and the 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.^{25–27} 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

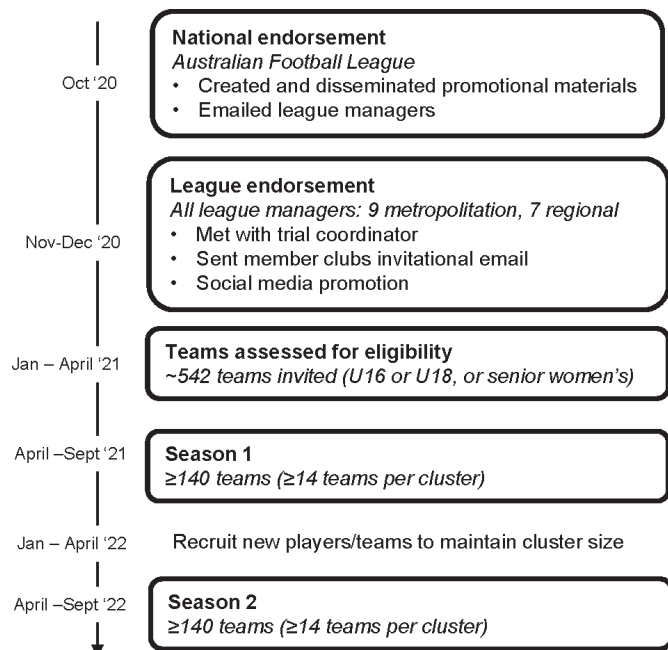


Figure 2 Team recruitment process.

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 process³⁷ 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)^{25–27} 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.²⁸ Feedback from Prep-to-Play early adopters (coach interviews/focus groups—2019²⁸) and the Implementation Drivers framework^{42 49} informed programme modifications and supported intervention activities.

Table 2 Supported intervention implementation drivers

Driver	Examples of supported intervention activities
Competency	<ul style="list-style-type: none"> ▶ 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	<ul style="list-style-type: none"> ▶ 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	<ul style="list-style-type: none"> ▶ 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.

The Implementation Drivers framework^{42 49} 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 drivers²⁸ (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 model⁵⁰ and adult learning theories⁵¹ 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)

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 prior ACL injury. 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 $T^{\text{transition}}$ ([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 $T^{\text{supported}}$ 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 $T^{\text{supported}}$ 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 T^{control}) to completion (end of $T^{\text{supported}}$) ([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-5⁵² (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

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)				X		X

*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 T⁰ unsupported phase and ≥2 observations in T² supported phase.
 Euro-QoL-5D-5L, European Quality of Life Five Dimensions Five Levels Questionnaire.

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: ≥ one in T^{control} and ≥two in T^{supported}. Programme adherence is typically a secondary outcome in other injury prevention trials, and programme

Table 4 Team designate report card—mock entry*

	Training	Game
Neuromuscular training warm-up		
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.

deliverers (eg, coaches) report adherence,^{20 23 53–55} often retrospectively.^{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).^{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 REDcap⁵⁷ 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 codesigned with the observers, and similar to a trial in male community

Box 1 Operational definitions for injury reporting**Reportable injury**

⇒ All body areas except head: an injury that occurred during a scheduled football match or training session, causing the player to leave the field and not return, or miss at least one match.

⇒ Head injury: as any injury to the head region occurring during a football match or training, regardless of time loss

ACL injury: acute knee injury, where a ruptured ACL is confirmed by clinical examination, with or without MRI or surgery

Concussion: direct or indirect impact to the head resulting in loss of consciousness and/or any of the following clinical symptoms (memory loss, headache, dizziness, confusion, nausea, difficulty concentrating, feeling like being in a fog, balance problems, slowed reactions, feeling not quite right).

Return to participation: the player will be defined as injured until they have returned to match play

Severity of injury:

⇒ Mild injury—absence for ≤1 match.

⇒ Moderate injury—absence from two or three matches.

⇒ Severe injury—absence from ≥4 matches.

Multiple injury definition

⇒ Index injury—the first recorded injury for specific body location within the study period.

⇒ Recurrent injury—an injury recorded to the same body location as the index injury.

⇒ Subsequent injury—an injury that occurred following the index injury, but to a different body location.

Exposure

⇒ Number of match and training hours per team, per week.

Australian football with high inter-rater reliability.⁵⁸ 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.⁵⁹ 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 (\pm 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 T^{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)^{25 27 28} 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 tool⁶⁰ for binary outcomes, based on a linear mixed model specification for stepped wedge designs.⁶¹ 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).⁶² 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.⁶³

The estimated weekly proportion of teams using Prep-to-Play in the unsupported phase is 0.09 (9%), based on published data.⁶⁴ 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^{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 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^{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, a 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 analysed 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^{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 designand 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

Table 5 Examples of potential bias and strategies to minimise bias

Type of bias	Example	Strategies to minimise bias
Selection		
Volunteer	Volunteer coaches more likely to adhere	<ul style="list-style-type: none"> ▶ 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 of Prep to Play, trainers report no injuries)	<ul style="list-style-type: none"> ▶ 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 $T_{\text{transition}}$
Non-respondent	Incomplete outcome reports may reflect teams not using Prep to Play/ have no injuries	<ul style="list-style-type: none"> ▶ 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)
Recall	Team designates or sports trainers may forget training activities and injuries	<ul style="list-style-type: none"> ▶ SMS reminders (team designates: every training and game; trainers: game day and preceding 2 days). Research team: follow-up calls for missing reports
Intervention		
Contamination	Teams in T^{control} may start using Prep-to-Play independently	<ul style="list-style-type: none"> ▶ 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 from teams that play each other
Timing	Intervention timing (eg, round 1 vs round 8) differs between clusters and may influence programme uptake	<ul style="list-style-type: none"> ▶ 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	<ul style="list-style-type: none"> ▶ 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	<ul style="list-style-type: none"> ▶ 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	<ul style="list-style-type: none"> ▶ 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	<ul style="list-style-type: none"> ▶ 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	<ul style="list-style-type: none"> ▶ Data collection for all teams will commence at the beginning of T^{control} period ▶ Additional analyses will explore the effect of season/year

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

project reports, and a lay summary will be available for study participants.

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 trial⁴⁸—it was important to the partner organisations to deliver an evidence-informed programme to their stakeholders in a equitable and timely manner.⁴⁸

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.^{46–47} 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^{19–21–23} and need to focus on adherence in sports injury prevention.^{40–65} 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 collection 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.⁶⁶ 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 procedures 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 coach and player turnover, and evaluating how the intervention will develop over time.⁴⁸ 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.^{20–31}

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

¹⁶Sports Medicine Australia, Albert Park, Victoria, Australia

Twitter Brooke E Patterson @Knee_Howells, Alex Donaldson @AlexDonaldson13, Sallie M Cowan @PhysioHill, Matthew G King @matmgking1, Christian G Barton @drchrisbarton, Martin Hagglund @MHgglund, Natasha A Lannin @A-4195-2013, Ilana N Ackerman @IlanaAckerman, Adam G Culvenor @agculvenor, Andrea B Mosler @AndreaBMosler, Andrea M Bruder @AndreaBruder, Nicole Livingstone @NicLiv, Melissa J Haberfield @melhabphysio, Sarah J Lampard @slampard8, Christian Bonello @c2bonello and Kay M Crossley @kaymrossley

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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, 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.

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ORCID iDs

Brooke E Patterson <http://orcid.org/0000-0002-6570-5429>
 Alex Donaldson <http://orcid.org/0000-0003-4764-2361>
 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/0000-0002-6028-1612>
 Michelle M Dowsey <http://orcid.org/0000-0002-9708-5308>
 Karla Hemming <http://orcid.org/0000-0002-2226-6550>
 Michael Makdissi <http://orcid.org/0000-0003-0334-7133>
 Adam G Culvenor <http://orcid.org/0000-0001-9491-0264>
 Andrea B Mosler <http://orcid.org/0000-0001-7353-2583>
 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>

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