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Original article

Scientific evidence is just the starting point: A generalizable process for developing sports injury prevention interventions

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Abstract

Background: The 2 most cited sports injury prevention research frameworks incorporate intervention development, yet little guidance is available in the sports science literature on how to undertake this complex process. This paper presents a generalizable process for developing implementable sports injury prevention interventions, including a case study applying the process to develop a lower limb injury prevention exercise training program (FootyFirst) for community Australian football.

Methods: The intervention development process is underpinned by 2 complementary premises: (1) that evidence-based practice integrates the best available scientific evidence with practitioner expertise and end user values and (2) that research evidence alone is insufficient to develop implementable interventions.

Results: The generalizable 6-step intervention development process involves (1) compiling research evidence, clinical experience, and knowledge of the implementation context; (2) consulting with experts; (3) engaging with end users; (4) testing the intervention; (5) using theory; and (6) obtaining feedback from early implementers. Following each step, intervention content and presentation should be revised to ensure that the final intervention includes evidence-informed content that is likely to be adopted, properly implemented, and sustained over time by the targeted intervention deliverers. For FootyFirst, this process involved establishing a multidisciplinary intervention development group, conducting 2 targeted literature reviews, undertaking an online expert consensus process, conducting focus groups with program end users, testing the program multiple times in different contexts, and obtaining feedback from early implementers of the program.

Conclusion: This systematic yet pragmatic and iterative intervention development process is potentially applicable to any injury prevention topic across all sports settings and levels. It will guide researchers wishing to undertake intervention development.

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Keywords: Australian football; Implementation; Intervention development; Lower limb injuries; Research-to-practice; Sports injury prevention; Translation

1. Introduction

Evidence-based sports injury prevention interventions are not well implemented in real-world settings,^{1–3} often because the interventions are not directly relevant to specific implementation contexts.^{4,5} Interventions should be informed by research evidence and be widely adopted, properly implemented, and sustained over time.^{4,6}

Both the Translating Research into Injury Prevention Practice framework⁴ and the Sequence of Prevention of Sports Injuries model⁷ require practitioners and researchers to identify potential injury prevention solutions and develop appropriate prevention measures guided by high-quality epidemiologic and etiologic studies. Most research remains in the early stages of these models and frameworks,^{8,9} and this limits the potential for injuries to be prevented. In practice, preventive measures are often based on anecdotal experience or current practice,⁴ and the scientific literature rarely provides insights into the complex process of intervention development in real-world settings.¹⁰ Although systematic reviews and meta-analyses can identify promising interventions,

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their conclusions are rarely directly applicable to specific real-world settings, and translation into effective practice is challenging.¹¹

Australian football (AF) is a popular sport at the community level in Australia. It is a dynamic sport that incorporates running, rapid acceleration and deceleration, changing direction, jumping and landing, full body contact including tackling and bumping, and kicking and marking (catching) a ball. As in many other sports, preventing lower limb injuries (LLIs) is a priority in community AF.¹² Although several evidence-based LLI prevention programs exist,^{13–15} how they were developed is largely unreported, and only 1 targeting selected LLIs is specific to community AF.¹⁶ For example, the only published information available on the development of the well-known and widely used Fédération Internationale de Football Association (FIFA) “FIFA 11+” program states that it was developed by an expert group, and tested by 1 club, before it was implemented in trials.¹⁷

This paper presents a generalizable process for developing evidence-informed sports injury prevention interventions that need to be widely and sustainably implemented in real-world settings. An example application of the process is provided based on the development of an exercise training program (called FootyFirst) to prevent LLIs in community AF. This paper serves as a guide to researchers wishing to progress their research through the intervention development process.

2. Methods

Two complementary ideas underpin the process described in this paper: (1) evidence-based practice integrates the best available scientific evidence with practitioner expertise and end user values,¹⁸ and (2) research evidence alone is insufficient to develop implementable interventions.² This process addresses the criticism that evidence-based practice devalues practitioner expertise, ignores community values, and promotes a “one-size-fits-all” approach.¹⁹ It also acknowledges that unless intervention design

considers the implementation context, the end user’s perspectives, and long-term sustainability, injury prevention programs are unlikely to be widely used and will therefore have limited impact.^{4,5}

Three methods underpinned the application of the intervention development process to FootyFirst: (1) literature search to identify published research evidence, (2) use of clinical expertise and expert opinion via a Delphi process, and (3) focus groups to identify end user preferences, capacities, and values (Table 1). The specific methods used to establish LLIs as a priority,¹² compile and assess the quality of exercise protocols aimed at reducing LLIs in similar sports,²⁰ and achieve expert consensus on the contents of FootyFirst²¹ are described elsewhere. Federation University Australia (E13-004) Human Research Ethics Committee approved the study protocol.

3. Results

The intervention development process can be encapsulated in 6 steps (Fig. 1). The application of these steps and the outcomes of each step when developing FootyFirst are summarized in Fig. 2 and Table 2.

As recommended in Translating Research into Injury Prevention Practice Stage 3,⁴ a multidisciplinary FootyFirst Development Group (FFDG) was established, consisting of 2 sports physiotherapists (authors JC and BJB), 1 biomechanist (author DGL), 1 sports scientist (author WY), and their research teams. Alongside their clinical and research experience, the FFDG had considerable exercise and rehabilitation experience in community and elite sport as well as involvement in previous community AF LLI prevention research.¹⁶

3.1. Step 1: use the research evidence and clinical experience

This initial step is necessary to maximize the likelihood that the developed intervention will “work” by ensuring firm

Table 1
Summary of the primary methods used to develop FootyFirst.

Evidence-based practice element	Aims	Contribution to the development of FootyFirst
Compilation and quality assessment of research evidence	To ensure that the best available research evidence relevant to the specific problem was identified and applied in the development of the intervention	<ul style="list-style-type: none"> • Compilation of published and previously unpublished community AF injury data (Fig. 1, Step 1)¹² • Review of the scientific literature to systematically evaluate the evidence about the benefits of lower limb injury prevention protocols aimed at reducing the most common, severe lower limb injuries in community AF (Fig. 1, Step 1).²⁰
Incorporation of clinical expertise and practitioner knowledge and views	To fill in the gaps where there was limited information in the literature or where no successful intervention for a specific injury was identified To fit the available evidence to the specific circumstances, populations, and needs	<ul style="list-style-type: none"> • Application of health promotion, implementation science, physiotherapy, biomechanical, and sports science clinical and research expertise to develop the exercise training program (Fig. 1, Step 1) • Delphi consultation to achieve expert consensus on the specific content of the exercise training program (Step 2)²¹
Consideration of end user preference, capacity, and values	To ensure that the intervention is appropriate for, and reflects the capacity of the implementation context	<ul style="list-style-type: none"> • Focus groups, following standard focus group methods,³⁴ with community AF senior coaches, strength and conditioning/fitness/high-performance coaches, players, sports trainers, and administrators (Fig. 1, Step 3) • Testing of the exercise training program with delivery agent representatives and conducting a “train-the-trainer” session (Fig. 1, Step 4) • Evaluation of the program against the attributes of innovations from the diffusion of innovations theory (Fig. 1, Step 5)²⁵ • Feedback from early implementers on the content and presentation of the program (Fig. 1, Step 6)

Abbreviation: AF = Australian football.

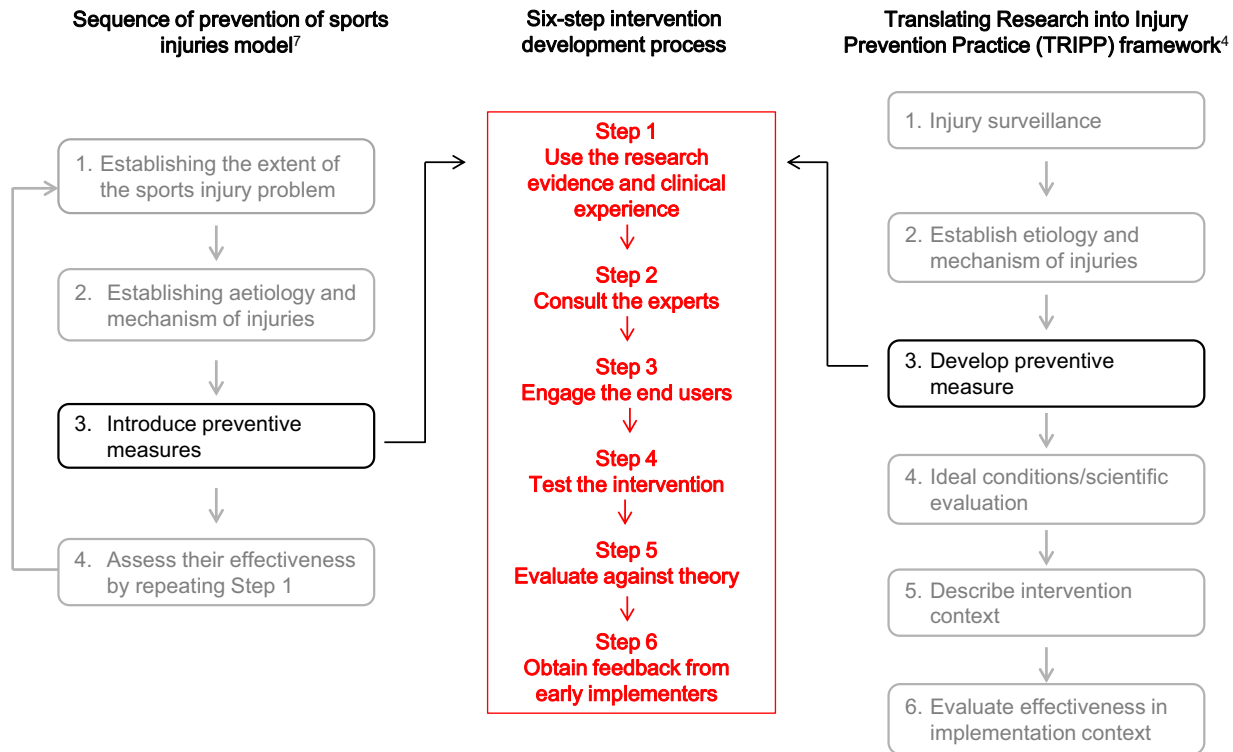


Fig. 1. Six-step intervention development process.

grounding in the available epidemiologic and etiological evidence. To begin the development of FootyFirst, the FFDG systematically evaluated the strength and quality of the evidence on the benefits of exercise protocols with the potential to reduce common community AF LLIs (March to May, 2011).²⁰ In summary, the collated research evidence suggested that an LLI prevention program should include balance and control and eccentric hamstring, plyometric, and strength exercises.²⁰ However, specific details of effective training routines were often unavailable, many studies focused on elite athletes, and there was limited evidence for the prevention of some LLIs.

The FFDG used the synthesized research evidence, their collective clinical and research experience, knowledge of existing LLI prevention protocols and exercise training principles (e.g., progressive overloading, specificity, and regularity), and prior experience with community AF to develop the first draft of FootyFirst. For example, the research evidence on exercises to prevent hamstring injuries was quite conclusive,²⁰ requiring minor modification to suit community AF. Conversely, research evidence was sparse for hip and groin injury prevention, requiring greater reliance on etiologic studies and clinical experience.

3.2. Step 2: consult the experts

This step ensures that the developed intervention is specific to the sport and injury mechanisms of interest. In the case of FootyFirst, the extent to which the information gathered in Step 1 could be translated into the AF context was unknown. Therefore, 55 purposively selected LLI prevention experts working in high-performance AF clubs and other environments were invited to participate in an online consensus-generating approach to critically

assess the content of the first draft of FootyFirst (June to July, 2011).²¹ Three rounds of revisions and consultations went into creating the second draft of FootyFirst, which the FFDG was then confident contained the “right” exercises and progressions. However, whether it “fitted” the community AF context remained unknown.

3.3. Step 3: engage end users

Development of any intervention requires that the proposed strategies and program components are relevant and acceptable to potential program deliverers (e.g., strength and conditioning staff, coaches, *etc.*) and participants (e.g., athletes, players, *etc.*).^{5,6} Two focus groups—one with 3 participants from clubs in a metropolitan region and the other with 12 participants from clubs in a regional league—were conducted (July and August, 2011) to engage potential end users of FootyFirst in determining whether the program was suitable for implementation by community AF coaches. Participants were recruited with the assistance of administrators from the relevant local governing league and included community AF coaches, strength and conditioning/fitness/high-performance staff, sports trainers, administrators, and players. Participants reviewed the expert-agreed version of FootyFirst before discussing its content and presentation, the methods that would be required to support community AF clubs and coaches to implement FootyFirst, and the capacity of end users to deliver or complete FootyFirst.

Focus group findings suggested that there was general support for replacing current warm-up programs with FootyFirst. Minor revisions to the way in which FootyFirst was presented were suggested, and ideas to facilitate its implementation were

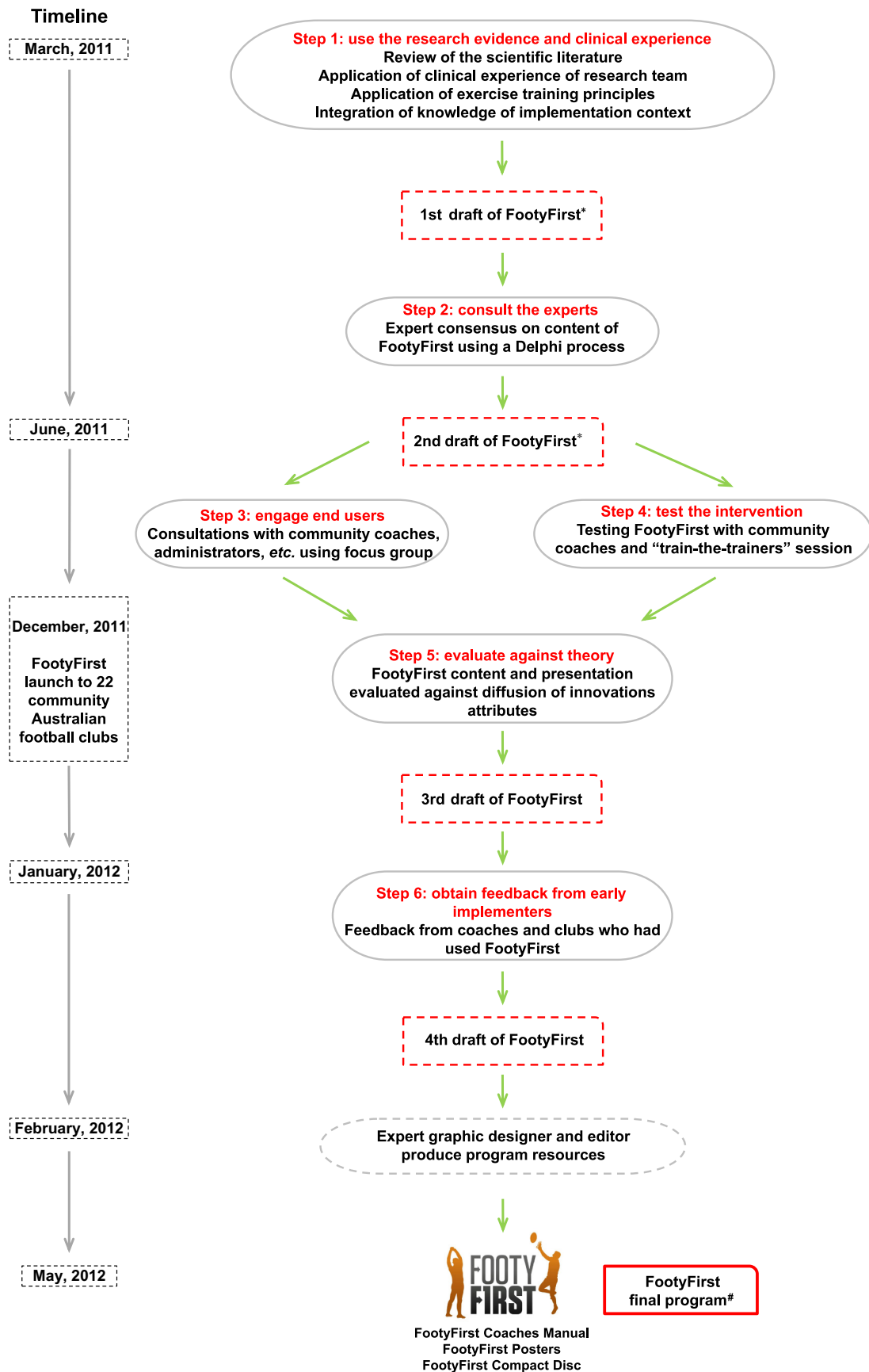


Fig. 2. Application of the 6-step intervention development process to FootyFirst. *Details of these drafts available in Appendix (online). #Available at <https://Footyfirstaustralia.wordpress.com/footyfirst-program>.

Table 2

The process and outcomes of developing FootyFirst, from the initial exercise selection to the final protocol and resource production.

FootyFirst program version	Key program development processes	Summary of process outcomes and protocol revisions
1st draft	<ul style="list-style-type: none"> Literature review (Fig. 1, Step 1) Clinical research, health promotion, and implementation science experience of project team (Fig. 1, Step 1) Training principles (e.g., progressive overloading, specificity, and regularity) (Fig. 1, Step 1) Knowledge of implementation context (Fig. 1, Step 1) 	Five-level, progressive exercise program developed consisting of brief warm-up and exercises to reduce the risk of groin, hip, hamstring, knee, and ankle injuries among community AF players
2nd draft	<ul style="list-style-type: none"> Expert consultation (Fig. 1, Step 2) 	1st draft revised as follows: <ul style="list-style-type: none"> Instructions for some exercises revised Two exercises removed and 2 exercises added to program The term “core” (muscles) removed and all related exercises referred to as hip strength exercises Order of some exercise changed
3rd draft	<ul style="list-style-type: none"> End user engagement (Fig. 1, Step 3) Exercise program tested for feasibility and acceptability (Fig. 1, Step 4) Program content and presentation evaluated against diffusion of innovations attributes²⁵ (Fig. 1, Step 5) 	2nd draft revised as follows: <ul style="list-style-type: none"> Instructions for some exercises revised Some exercises modified to be more focused on AF and more like usual community AF training, to increase relevance and acceptability “Frequently asked questions” section added to instruction manual Number of repetitions of some exercises reduced Key points for good technique (i.e., high fidelity) added to instruction manual Instructions and photographs on how to identify common faults for most exercises added to instruction manual Justification for each exercise added to instruction manual Exercise added to program
4th draft	<ul style="list-style-type: none"> Feedback from early program implementers (Fig. 1, Step 6) 	3rd draft revised as follows: <ul style="list-style-type: none"> Instructions for some exercises revised Endorsement from the AFL, a high-performance AFL coach, and the AFL Medical Officers Association added
FootyFirst final program	<ul style="list-style-type: none"> Expert graphic designers and editors engaged to produce program resources 	4th draft revised as follows: <ul style="list-style-type: none"> Wording of instructions for some exercises revised to improve clarity for the level of the intended audience Layout and presentation finalized Logo designed and associated color scheme for resources agreed upon Coach’s instruction manual, posters, and compact disk produced

Abbreviations: AF = Australian football; AFL = Australian Football League.

provided. Discussants reported similarities between the warm-up component of FootyFirst and their existing pretraining activities. However, most of the strength and conditioning and neuromuscular training exercises were considered less compatible with existing community AF training. Participants indicated that most clubs had experienced or qualified people to deliver FootyFirst, although help with implementing the program into training sessions was needed. They also advocated for including a rationale for each exercise to help coaches promote FootyFirst to their players. Finally, although they acknowledged and appreciated that FootyFirst was underpinned by scientific evidence, focus group participants suggested that FootyFirst should also be endorsed by respected, high-performance AF coaches and the peak body, the Australian Football League (AFL).

Participants identified other implementation-related issues that needed to be considered when developing FootyFirst, including the following:

- time available to complete the intervention (typically 15–20 min);
- equipment available to implement the intervention in a typical club;

- capacity of community AF players to perform some of the entry-level exercises;
- concern that some exercises might increase the risk of injury and/or muscle soreness; and
- the challenge of implementing a progressive exercise training program with players within a single team/club with varying fitness levels and training commitment.

Consequently, the structure of some FootyFirst exercises was revised to align more closely with typical community AF training activities while maintaining their fidelity from a clinical and biomechanical perspective. The AFL logo, a foreword or introduction from a high-performance AF coach, and a “frequently asked questions” section were also added to the FootyFirst instruction manual.

3.4. Step 4: test the feasibility and acceptability of the intervention

Before assessing intervention efficacy, the feasibility and acceptability of an intervention should be tested to be confident that it can be delivered as intended and that participants can successfully complete all required tasks. In the case of

FootyFirst, the postexpert consultation version of the program (2nd draft in Fig. 2 and Table 2) was tested on several occasions by the FFDG. First, 6 exercise science and physiotherapy students, who were all community-level athletes, were videotaped and photographed performing the exercises correctly and incorrectly (August, 2011). This led to further refinement of some exercise instructions and the addition of photographs and descriptions of common technique faults in the program resources.

The intervention was then tested again. A coach was given the revised FootyFirst instruction manual and observed while delivering the intervention to 2 community AF players (October, 2011). The aim was to determine whether a typical community AF coach who had pre-read the instruction manual could deliver it as intended. The time taken to complete the program was reviewed to ensure compatibility with the time allocated to complete pretraining activities at a typical community AF training session. This test highlighted the need to emphasize proper technique in the instructions, and it showed that additional rest periods were required between repetitions for some exercises. Importantly, it also identified that some exercises needed modifications (e.g., reduction in number of sets or repetitions) to reduce the time taken to complete them. Further minor word changes were also made to improve clarity and assist intervention delivery.

High levels of trainer competency and self-efficacy are acknowledged drivers of implementation success.^{22,23} Therefore, a key strategy for enhancing FootyFirst implementation within targeted community AF clubs was training coaches how to deliver the intervention to players.²⁴ A “train-the-trainer” session was held to explain FootyFirst to a respected, high-profile, high-performance coach affiliated with a community AF club in the targeted region. This coach was observed as he delivered the intervention to 2 community AF players and was provided with feedback (January, 2012). Following the train-the-trainer session, it became apparent that the progression for 1 particular exercise might be too difficult for some community AF players, and a new exercise was added to ensure adequate preparation for the transition between levels. Minor revisions were also made to the instructions and photographs for some exercises.

3.5. Step 5: evaluate against theory

When developing an intervention, one-way to enhance the likelihood of its adoption, implementation, and maintenance by the target audience in the real-world setting is to evaluate it against a relevant theory. To further fit FootyFirst into the community AF context, the research team evaluated the program content and presentation against the *relative advantage*, *compatibility*, and *complexity* attributes of innovations as outlined in the diffusion of innovations theory²⁵ during a structured round-table discussion (December, 2011). The diffusion of innovations theory was selected because it is specifically applicable to the introduction of new ideas into communities²⁶ and is one of the few theories that has been previously applied in sports injury prevention research.^{24,27,28}

Following this discussion, the injury prevention and performance-related advantages of FootyFirst over current warm-up activities were further emphasized in the instruction manual. FootyFirst’s compatibility with the existing values and practices of community AF clubs was also highlighted by explicitly stating that FootyFirst would take <20 min to complete and could replace, rather than be added to, existing warm-up activities. More extensive use of footballs in some exercises was also instituted to enhance compatibility with typical AF game components. FootyFirst was also promoted as a way to align community AF training more closely with training at high-performance AF clubs by adding endorsements from a respected high-performance AF coach and the AFL Medical Officers Association. The complexity of the program was considered by ensuring that all exercises were explained clearly and straightforwardly and by emphasizing that FootyFirst did not require any expensive or sophisticated equipment.

3.6. Step 6: obtain feedback from early implementers

Despite all the effort invested in Steps 1–5, it is not guaranteed that the process will develop a perfect intervention, especially at the first attempt. Therefore, it is useful to ask end users to use the intervention in their settings and obtain feedback from them about the content and presentation before the intervention is formally evaluated. The post-theory-evaluated version of FootyFirst (3rd draft in Fig. 2 and Table 2) was launched and disseminated to 22 community AF clubs affiliated with 1 AF regional league in Victoria, Australia (December, 2011). This provided an opportunity to obtain feedback from early implementers of the program prior to the football season. Eligible clubs and coaches were asked to suggest revisions to the program before final resource production (February, 2012).

No further changes to the program content were suggested, although minor changes were made to the language and presentation where inconsistencies were identified. A professional editor/graphic designer was then engaged to produce the final FootyFirst resources, which were distributed to the 22 targeted clubs (March, 2012). Video footage of the FootyFirst exercises was produced, in partnership with the AFL, and made available to participating clubs in DVD and online formats prior to the 2013 community AF season.²⁹

4. Discussion

Although developing preventive measures is integral to the 2 most widely used sports injury prevention research frameworks,^{4,7} to our knowledge, this is the first detailed description of a process to achieve this. This paper provides a step-by-step generalizable guide on how to develop evidence-informed and context-specific interventions. The guide confirms that intervention development is a complex, iterative process requiring a balancing of evidence and experience.³⁰

Physical training is the second most studied sports injury prevention intervention,⁹ yet when Step 1 of the intervention development process was applied to FootyFirst, it was identified that the scientific evidence underpinning physical training as an

injury prevention intervention is limited.²⁰ Randomized controlled trials to reduce injury rates may be ineffective because the principles underpinning the trialed prevention strategies were not based on the evidence of injury etiology and mechanisms, or because the implementation context was not adequately considered during the intervention development process.^{4,31,32} These issues are common in sports medicine,^{4,9} and in public health more broadly,³³ and both are addressed by the proposed intervention development process (in Steps 1 and 3 specifically).

Step 2 provides a practitioner-expert perspective on the intervention under development. This is particularly valuable when full scientific evidence about what might work is either absent from, or limited in, the scientific literature and intervention developers need to rely on critical evaluation of the intervention by others in the field. In the example of FootyFirst, the expert consensus opinion generally reflected the available scientific evidence. The exercises that were more strongly supported by published evidence remained largely unchanged. The round in which consensus was reached on each exercise was commensurate with the level of evidence available.^{20,21} A side benefit of this expert consultation was that it assisted in attaining endorsement of FootyFirst from relevant experts working in high-performance AF.

The intervention development process and its application to the development of FootyFirst highlighted that the intervention content experts often lacked expertise in effectively communicating those interventions to the target audience. The FFDG focused initially on ensuring that scientific evidence and exercise training and biomechanical principles underpinned the program content, rather than precisely describing the exercises. Interpretation difficulties experienced while testing the intervention (Step 4 specifically) were not anticipated by the FFDG, nor were they identified during either the expert (Step 2) or end user (Step 3) consultations. Participants in the end user consultations were asked if they understood the instructions and whether they believed that community AF players could complete the exercises. They were not asked if they understood exactly how to do the exercises. The challenges experienced while testing FootyFirst highlight the distinction between generally understanding an intervention and being able to deliver or instruct someone else to participate in it with high fidelity.

Although some program planning frameworks recommend that potential program participants are involved right from the needs assessment/problem identification stage,⁶ in the sports medicine and science context, end users are not typically directly engaged in the intervention development process outlined in this paper until Step 3. However, this should not preclude intervention developers from confirming earlier that the injury issue being addressed is important and ensuring that the proposed method of intervention is acceptable from the end user's perspective. This may be particularly relevant when addressing injury issues or proposing intervention methods that are less well documented than for LLIs in team ball sports. It may also be advantageous to gain feedback from the end users when critically evaluating a proposed intervention against a theory or model (Step 5).

Step 4 in the intervention development process focuses on testing the intervention. In our experiences with FootyFirst, this was challenging owing to the short break between the end of 1 community AF season and the start of preseason training for the next season (often as little as 6 weeks). FootyFirst was not tested with a full community AF team, and coaches were not observed delivering it to their teams before the program was made publically available. Only small-scale tests of the program were possible, which did not reflect its intended real-world use. Furthermore, the program required participants to progress from one level to another over a relatively short period of time and a number of training sessions. Even after the evidence underpinning the content of a program is confirmed, intervention development is a long and time-consuming process, ideally involving long lead times with early testing of the proposed interventions within the target setting.

Following the development of an intervention, it is important to develop an evidence-informed and context-specific implementation plan to facilitate uptake of the intervention by end users.^{24,28} The effectiveness of the intervention and implementation plan should then be evaluated under both ideal and real-world conditions.⁴

5. Conclusion

Sports scientists, sports medicine clinicians, and sports injury prevention researchers need to be competent in developing interventions that are informed by the best available research evidence, suitable for the context in which they are to be implemented, and compatible with the needs, capacity, and values of potential end users. The 6-step intervention development process outlined here provides, for the first time, a practical, feasible, and generalizable process for doing this. It is applicable to intervention development across a range of topics and sports settings and levels.

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Authors' contributions

CFF, DGL, BJG, JC, and AD conceived of and planned the study. BJG coordinated the literature review with support from DGL and JC. DGL, BJG, JC, and WY developed the first draft of FootyFirst and contributed to all stages of the program's revision. AD coordinated and conducted the expert consultation, end user engagement, feedback from early implementers of FootyFirst and production of final FootyFirst program material. AD coordinated and all authors contributed to the evaluation against theory. DGL and WY coordinated the testing of FootyFirst with support from BJG and JC. PW coordinated the early stages of the development of FootyFirst and gathered the background information for the manuscript. AD conceived the "6-step process for developing sports injury prevention interventions" with feedback from all authors. All authors contributed to early drafts of the manuscript and have read and approved the final version of the manuscript, and agree with the order of presentation of the authors.

Competing interests

None of the authors declare competing financial interests.

Appendix: Supplementary material

Supplementary data to this article can be found online at doi:10.1016/j.jshs.2016.01.029

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