## APPENDIX 2: AMENDMENTS TO STUDY PROTOCOL

**Preventing Australian football injuries with a targeted neuromuscular control exercise program: comparative injury rates from a training intervention delivered in a clustered randomised controlled trial**

### INTRODUCTION

The protocol for the Preventing Australian Football Injuries through eXercise (PAFIX) study was published in Injury Prevention in 2009.[1] That paper described the aims, study design and methodology of the study, which was designed according to the CONSORT statement for the conducting and reporting of randomised controlled trials.[2] This appendix provides an update to key features of the protocol since it was published in Injury Prevention.[1] This includes the provision of more information, such as explicit inclusion and exclusion criteria, and procedural changes. These changes were necessary because the real-world community sporting setting for the study posed some challenges that needed to be addressed in the conduct of this effectiveness trial. Where appropriate, the changes are indicated according to the CONSORT 2010 statement.

### ITEM NUMBER 4A: ELIGIBILITY

The original protocol paper [1] did not include specific eligibility criteria. These are outlined in the methods of the main paper and detailed in full here.

Players were eligible to be included in the final cRCT if:

a) they were formally registered to play for one of the teams participating in the trial, irrespective of how many games they subsequently played during the season;

b) they were confirmed as being aged at least 18 years by the last week of February in the calendar year in which they were recruited. The initial protocol stated that players would be over the age of 16 years. However, due to the practical consideration of it being near-to-

impossible to ensure even a satisfactory return of informed consent forms from parents/guardians of players aged 16-17 years, the ethics approval only allowed follow-up and maintenance of records on players over the age of 18 years. Player age was determined from the information provided on the player baseline surveys and the date of 28th February of each recruitment year was taken as the age cut-off to coincide with the period of intervention delivery at the start of the pre-season; and

c) they attended at least one training session during the first 13 weeks of the program, which covered the 8-weeks pre-season and the first 5-weeks into the playing season. This was to ensure that i) each player had some exposure to the intended intervention and so could be include in the intention-to-treat analysis and ii) that the outcomes were assessed against the period of expected intervention fidelity. For example, some players played their first game for the participating team in week 25 of the 28-week season but had not attended any games or training prior to that point and so were not considered as being formally recruited to the trial.

Players were excluded from the final trial data set if:

a) they played for a Colts team (in the Western Australian cohort), which includes players aged 17-19 years, but it was not able to be confirmed that they were over the age of 18 years because they did not complete the baseline player demographic survey (n=137 players); and

b) they attended no training sessions - either during the pre-season or during the season. By definition, none of these players was exposed to the PAFIX program, nor could they contribute to any of the risk factor assessment, because they did not attend training at all (n= 189 players).

Players were not excluded if they were registered for the trial but attended no game/training sessions during the season, but such players contributed nothing to the calculation of in-season injury outcomes during games (the main measure) because there was no outcome

measure able to be reported for them in terms of hours of exposure to risk of injury outcomes. By definition they sustained zero match injuries because they played zero games.

**ITEM 5: INTERVENTION**

Full details of the specific intervention details have been published [3]. However, there were some changes to what was stated in the initial protocol. These included:

a) videotaping and analysing of player movement using Silicon Coach software were not undertaken as this was considered far too cumbersome to implement in practice. This meant that the planned feedback to the players through this means was not undertaken. However, the PDC were trained to assess and provide feedback on whether a certain training drill was not performed as designed; and

b) the aerobic steps, tilt boards, square wobble boards and roller boards were not used. They were replaced with mini hurdles. Other equipment remained unchanged, e.g. round wobble boards, mini trampolines etc.

**ITEM 6A: OUTCOMES**

The following changes were made to the biomechanical, neuromuscular and mobility outcome measures:

a) Laboratory tests followed the general protocol presented previously,[1] with some small changes to outcome measures. The measures examined from the players performing cutting and landing tasks in response to a light stimulus now entailed: i) peak knee flexion during weight acceptance phase (the period from initial foot contact to 30ms post contact); ii) range of knee flexion in weight acceptance phase; iii) position and movement of the trunk and pelvis position relative to foot; iv) knee joint mean flexion, peak valgus, and peak internal rotation moments in weight acceptance; and v) patterns of hamstrings, quadriceps and gastrocnemii muscle activation and co-contraction in weight acceptance; [4-6]

b) Measures from other neuromuscular laboratory tests were i) isometric hip extension, flexion, abduction and adduction strength; ii) isokinetic knee extension and flexion strength; iii) standing balance; and iv) greatest jump height from two maximum effort counter movement jumps;

c) The battery of laboratory tests was performed on three to four players randomly selected from each team in the cRCT arms in Perth only. The tests were performed before commencement or in the first week of training and again half way into the season;

d) In-field neuromuscular and mobility tests were performed in both WA and VIC. These were: i) isometric lower-body strength; ii) single leg standing balance; iii) reactive agility test; iv) change of direction test, and v) sprint test. In 2007, these tests were conducted three times throughout the season, with the exception of the isometric strength test, which was not performed in the middle test session. However, in 2008 these tests were conducted only two times throughout the season since testing often went longer than anticipated in 2007 resulting in there been overlap of testing sessions two and three. Testing session one was performed at the start of the season the final test session was conducted towards the end of the season. The exact timing of these test sessions was impacted upon by factors such as player/team availability, and weather. For example, the testing was conducted outdoors so inclement weather often meant testing had to be rescheduled; and

f) it was determined that the penetrometer was no longer the most appropriate device for measuring ground hardness and so the objective measures of ground hardness were collected using a 2.25 kg Clegg hammer at a purposive sample of grounds on a weekly basis during each season.[7] In addition, a subjective checklist on the condition of the ground was completed by the Primary Data Collectors (PDC) at every game throughout the two seasons.

**ITEMS 8A AND 8B: RANDOMISATION SEQUENCE ALLOCATION**

This detail was not provided in the initial protocol paper.[1] The PAFIX trial was a group

clustered randomised trial with randomisation at the level of a club, so that all teams (and their members) would be allocated to the same intervention arm. At the start of each season, the names of the nominated clubs (with all relevant senior and reserve teams nested within a sampling unit) were provided to a statistician who was independent to the design and conduct of the study. Not every club had the same number of teams, but randomisation was based on clubs, with some consideration given to balancing the overall numbers of teams allocated to each study arm. Using a simple random number generator, the same statistician allocated nominating clubs/teams to each study arm in each of 2007 and 2008, separately.

**ITEM 9: RANDOMISATION ALLOCATION CONCEALMENT MECHANISM**

This detail was not fully provided in the initial protocol paper.[1] The PAFIX RCT was unable to be fully blinded because the nature of the "active" neuromuscular control intervention being trialled was different to that of the control or "sham" intervention group. Only the two project managers working with the teams were aware of which club was allocated to which study arm, so they could allocate each primary data collector (PDC) to the appropriate intervention arm. The three major study chief investigators, data managers and statisticians were blinded to the nature of the study arm allocation until after the analysis was completed, although they could differentiate the two groups. A PDC was appointed to each team to deliver the interventions, record all injury and exposure data, to assist with the physical testing of players. Importantly the PDC's were not informed of the nature of the particular study arm to which they were allocated or any details of the other study arm's program. Each PDC was required to attend a two-day training session and these training sessions were held separately for the PDCs from different study arms, so as not to contaminate information from one group to another. Finally, no player in any of the teams knew which study arm they were allocated to.

**ITEM 10: RANDOMISATION IMPLEMENTATION**

Full details of this were not provided in the initial study protocol.[1] The project managers were responsible for initially recruiting all clubs (and their teams) to the study. All clubs (and

their nominated teams) were told that they would be randomly allocated to one of two study arms and that they would receive an exercise training intervention that would be slightly different depending on which study arm they were randomised too. The independent statistician responsible for the randomisation provided the study arm allocation to the two state-based project managers who then informed the clubs about the intervention that would be delivered to their teams. Within their respective states, the project managers and their appointed research assistants, recruited players from each of the randomised teams during training sessions during the usual football club pre-season period. This recruitment was continued during the 8-week pre-season period and the first four weeks of the playing season. The players were only informed that their club/team had agreed to be part of the study and told about the exercise program to be delivered through their club.

**ITEM 13A: PARTICIPANT FLOW**

All players who were approached gave their informed consent to participate in the study. One player later withdrew their consent to be included in the study for reasons unrelated to the intervention itself, but in response to an action on the part of their coach.

Some players played for more than one team within a club across the season. The seniors/reserves players were considered as a single block for intervention delivery and randomisation because they trained together. For analysis purposes, players were allocated to the team where they played most of their games when this information was provided.

**ITEM 14A: RECRUITMENT**

The dates defining the periods of recruitment and follow-up are shown in Figure A1. This figure also outlines the periodisation plan for the intervention delivery. There were some minor differences in the timing of the trial start in the two states. For example, in 2007, extreme drought conditions affected the overall length of the playing season in Victoria and the pre-season starting dates. Players were actively recruited into the study during the Pre 1, Pre 2 and In1 periods.

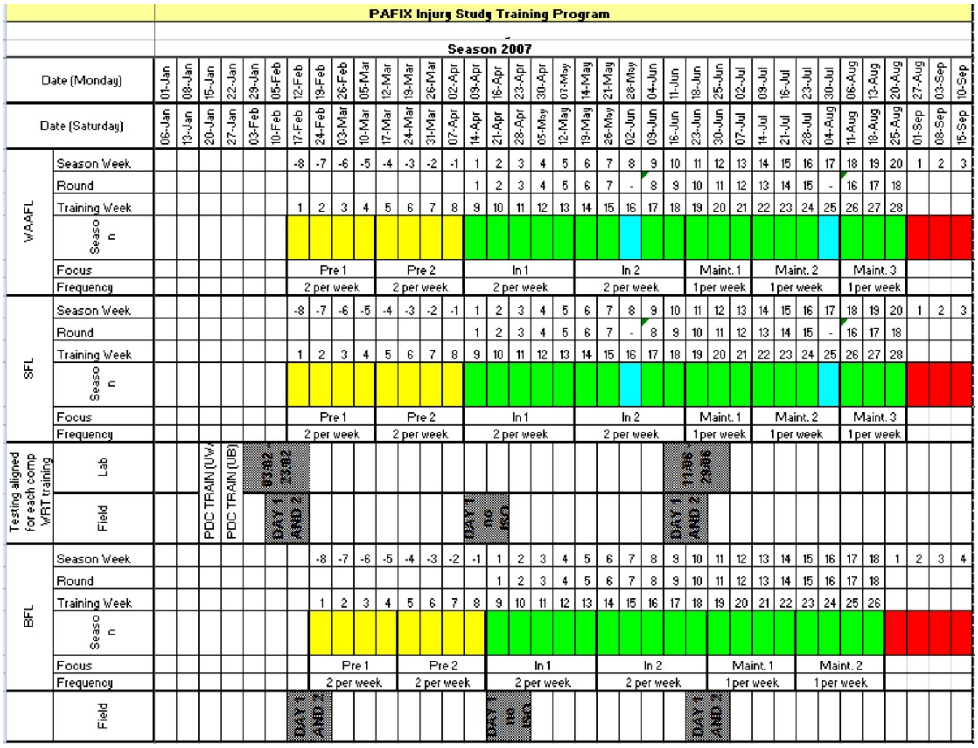
## ITEM 25: FUNDING

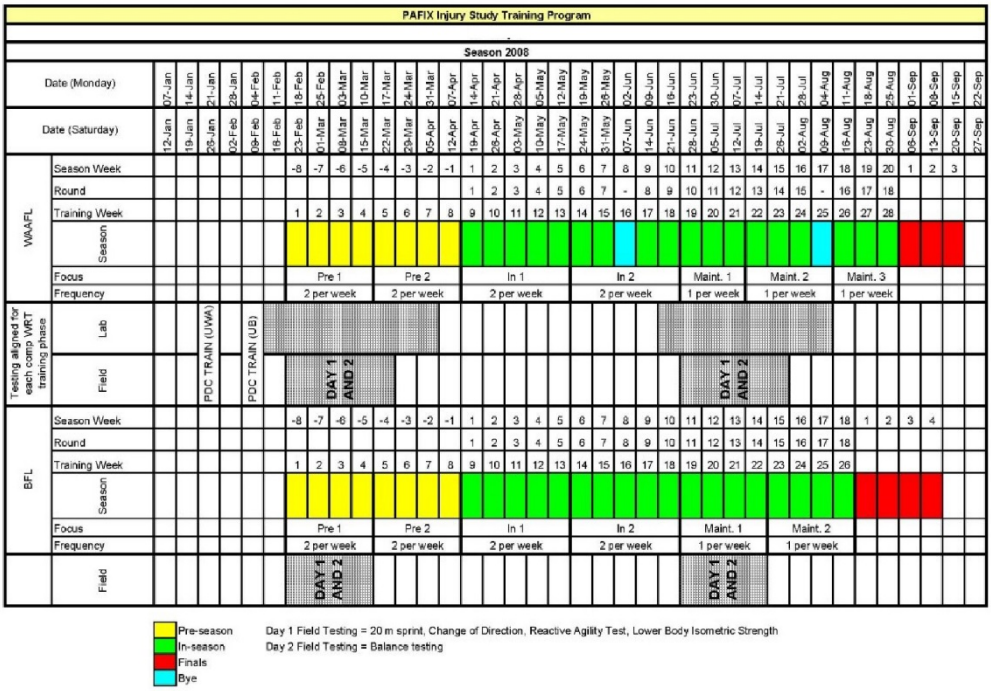
In addition to the National Health and Medical Research Council (NHMRC) Project Grant Funding mentioned in the study protocol,[1] this study received additional funding support from the Western Australian Medical Health and Research Infrastructure Fund, the University of Western Australia Research Grants Scheme, and from NHMRC equipment grant funding at both the University of Ballarat and the University of Western Australia.

## OTHER

The published protocol [1] contains an error in terms of its ethics statement. The correct ethics statement should read that the PAFIX study received ethical approval from the University of Ballarat Human Research Ethics Committee and the University of Western Australia Research Ethics Committee.

**Figure A1:** Intervention delivery plan and timing of outcome assessments in 2007 and 2008



**References**


1. Finch CF, Lloyd DG, Elliott BC. The Preventing Australian Football Injuries with Exercise (PAFIX) Study: a group randomised controlled trial. Inj Prev 2009;15:e1.
2. Altman DG, Schulz KF, Moher D, et al. The revised CONSORT statement for reporting randomized trials:explanation and elaboration. Ann Intern Med 2001;134:663-94.
3. Finch CF, Doyle TLA, Dempsey AR, et al. What do community football players think about different exercise-training programmes? Implications for the delivery of lower limb injury prevention programmes. Br J Sports Med 2014;48:702-07.
4. Stoffel KK, Nicholls RL, Winata AR, et al. The effect of ankle taping on ankle and knee joint biomechanics in sporting tasks. Med Sci Sports Exerc 2010;42:2089-97.
5. Cochrane JL, Lloyd DG, Besier TF, et al. Training affects knee kinematics and kinetics in cutting maneuvers in sport. Med Sci Sports Ex 2010;42:1535-44.
6. Dempsey AR, Lloyd DG, Elliott BC, et al. Changing sidestep cutting technique reduces knee valgus loading. Am J Sports Med 2009;37:2194-200.
7. Twomey D, Ullah S, Petrass L. One, two, three or four: Does the number of Clegg Hammer drops alter ground hardness readings on natural grass? J Sports Eng Technol 2014;228:33-39.