

Appendix 1. CONSORT 2010 checklist of information to include when reporting a cluster randomised trial applied to the “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”

CONSORT 2010 Section/Topic	Item number	CONSORT 2010 Checklist item	Item addressed: Yes (✓) or no (✗) Where to find information*
Title and abstract			
	1a	Identification as a cluster randomised trial in the title	✓ title
	1b	Structured summary of trial design, methods, results, and conclusions for cRCTs	✓ abstract
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale for using a cluster design	✓ refer to protocol paper
	2b	Whether objectives pertain to the cluster level, the individual participant level or both	✓ refer to protocol paper and results section
Methods			
Trial design	3a	Description of trial design including allocation ratio and definition of cluster and description of how the design features apply to the clusters	✓ refer to protocol paper
	3b	Important changes to methods after trial commencement, with reasons	✓ refer to protocol paper and appendix 2
Participants	4a	Eligibility criteria for clusters	✓ refer to appendix 2
	4b	Settings and locations where the data were collected	✓ refer to protocol paper
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered. Whether interventions pertain to the cluster level, the individual participant level or both	✓ refer to appendix 2
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed. Whether outcome measures pertain to the cluster level, the individual participant level or both.	✓ refer to appendix 2
	6b	Any changes to trial outcomes after the trial commenced, with reasons	✓no change
Sample size	7a	How sample size was determined. Method of calculation, number of clusters(s) (and whether equal or unequal cluster sizes are assumed), cluster size, a coefficient of intracluster correlation (ICC or k), and an indication of its uncertainty	✓ refer to protocol paper and results paper
	7b	When applicable, explanation of any interim analyses and stopping guidelines	n/a
Randomisation:			
Sequence generation	8a	Method used to generate the random allocation sequence	✓ refer to appendix 2

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	8b	Type of randomisation; details of any restriction. Details of stratification or matching if used.	✓ refer to appendix 2
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence, describing any steps taken to conceal the sequence until interventions were assigned. Specification that allocation was based on clusters rather than individuals and whether allocation concealment (if any) was at the cluster level, the individual participant level or both.	✓ refer to appendix 2
Implementation	10a	Who generated the random allocation sequence, who enrolled clusters, and who assigned clusters to interventions	✓ refer to protocol paper and appendix 2
	10b	Mechanism by which individual participants were included in clusters for the purposes of the trial (such as complete enumeration, random sampling)	✓ refer to protocol paper and appendix 2
	10c	From whom consent was sought (representatives of the cluster, or individual cluster members, or both), and whether consent was sought before or after randomisation	✓ refer to protocol paper and appendix 2
Blinding	11a	If done, who was blinded after assignment to interventions and how	✓ refer to protocol paper
	11b	If relevant, description of the similarity of interventions	n/a
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes. How clustering was taken into account.	✓ refer to protocol paper and methods section
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	✓ refer to protocol paper and methods section
Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of clusters that were randomly assigned, received intended treatment, and were analysed for the primary outcome	✓ refer to appendix 2, results section and figure 1
	13b	For each group, losses and exclusions for both clusters and individual cluster members	✓ refer to appendix 2, results section and figure 1
Recruitment	14a	Dates defining the periods of recruitment and follow-up	✓ refer to methods section
	14b	Why the trial ended or was stopped	n/a
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group. Baseline characteristics for the individual and cluster levels as applicable for each group	✓ refer to results section and tables 1 and 2
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups. For each group, number of clusters included in each analysis	✓ refer to results section
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision. Results at the individual or cluster level as applicable and a coefficient of intracluster correlation	✓ refer to methods and results tables 3 and 4

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		(ICC or k) for each primary outcome	
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	✓ refer to methods and results
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	n/a
Harms	19	All important harms or unintended effects in each group	✓ there were no unintended harms
Discussion			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	✓ refer to discussion section
Generalisability	21	Generalisability of the trial findings. Generalisability to clusters and/or individual participants (as relevant)	✓ refer to discussion section
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	✓ refer to discussion section
Other information			
Registration	23	Registration number and name of trial registry	n/a
Protocol	24	Where the full trial protocol can be accessed, if available	✓ protocol paper clearly referenced in relevant text
Funding	25	Sources of funding and other support, role of funders	✓ funding sources provided

*Protocol paper available at: 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.