

Australian Physical Activity Clinical Practice Guidelines for people with moderate to severe traumatic brain injury

Methodological Review			
	Reviewer Comment	NHMRC Comment	Developer Response
1.	<p>Overarching comments</p> <p>The developers should be commended for the methodological rigour applied in the development of this guideline. The methods are clearly highlighted throughout the Guideline; however, we believe the developers should revise parts of the Guideline to ensure that it has less of a methodological focus, and more focus on the needs of the end-user.</p> <p>For the end-user, a guideline should be self-contained with enough information alongside each recommendation for users to understand what action they should take and what underpins the recommendation, without needing to refer to the Technical report.</p> <p>Currently the Guideline is not written in a way that is easy for the end-user to use for the following reasons:</p> <ul style="list-style-type: none"> • recommendations are presented in broad terms, without explanation of technical terms or context (evidence-base and rationale/justification); • there is more focus on the strength of recommendations than the recommendations themselves (e.g., strength of recommendation wording is presented first, emphasised by colour, and presented in a box, while actual recommendation wording appears unhighlighted below (p.27-36); recommendations in the 'executive summary' are presented in order of strength of recommendation rather than by topic (p.5-6)); • information on the scope of the Guideline is split between different sections (e.g., target audience (p.8), specific health care settings (p.3), clinical questions (Technical Report, p.44-244)); and • some sections of the Guideline are presented without introductory text to explain their purpose. <p>For the Guideline to be more self-contained and user-friendly we suggest that:</p> <ul style="list-style-type: none"> • each recommendation is written in specific, actionable language, with technical terms explained (see D.1, D.2 for further guidance), • each recommendation is accompanied by a summary of its evidence base (see D.3, D.8), and a justification or rationale for making the recommendation, • the 'Scope and purpose' section contains all relevant information (target audience, healthcare settings, clinical questions) (see B.1, B.2), 		<p>Thank you for the comments and thorough review of the guideline. We have made extensive changes to the format of the guideline in response.</p>

	<ul style="list-style-type: none"> the recommendations themselves are highlighted and accompanied by the indication of their strength, each section begins with some brief introductory text. <p>If feasible, it may be useful to consult a medical writer for this task.</p>		
2.	<p>NHMRC desirable requirement A. 2.1 The developer may wish to consider providing information on the amount of funding received to develop the guideline.</p>	Please consider this suggestion.	We have added information about the funder (MRFF) in the Guideline and Administrative reports. We have included the funding amount in the Administrative report.
3.	<p>NHMRC mandatory requirements A.4 and A.6 Details of consumer involvement, recruitment, and support and details of competing interest processes and declarations are currently outlined in the Guideline (Section 2). To meet this requirement, this information would also need to be provided in a separate Administrative report.</p>	Please review the comments and develop an Administrative report separate to the Guideline document which contains the required information.	An Administrative report has been developed and contains details as suggested.
4.	<p>NHMRC mandatory requirement A.7 Ensure that the list of organisations that have formally endorsed the guideline appears in the finalised Guideline document.</p>	Please list organisations that will be invited to endorse the final guidelines when completed.	<p>The list of organisations approached, and who have endorsed the guideline, are listed in the guideline and in the introduction to the Expert Review and Public Consultation section of the Administrative report.</p> <p>The logo of organisations that have already endorsed the guideline appear on the 2nd page of the Guideline document; we will add additional logos if and when endorsed by other organisations.</p>
5.	<p>NHMRC mandatory requirement A.8 Information about the participation by representatives of Aboriginal and Torres Strait Islander peoples and culturally and linguistically diverse communities to be included in Administrative report .</p>	Please include this information in an Administrative report.	An Administrative report has been developed and contains details as requested.
6.	<p>NHMRC mandatory requirement B. 1 To give the reader a clearer picture of the scope of the guideline it is suggested that the clinical questions are presented together in a single list alongside the description of the purpose in the Guideline.</p>	Please consider this suggestion.	The list of clinical questions and scope and purpose of the guideline are presented in the Executive summary section of the Guideline document.
7.	<p>NHMRC mandatory requirement B. 2 Suggest that the health care settings information also be included in the 'Scope and purpose' section of the Guideline (p.8) alongside the target audience to give a more complete picture of the scope of the Guideline.</p>	Please consider this suggestion.	The population, target audience and target settings are presented under the scope and purpose section in the

			Executive summary section of the Guideline document.
8.	<p>NHMRC mandatory requirement B.5 Identify and describe issues relevant to Aboriginal and Torres Strait Islander peoples in the Guideline.</p>	<p>Please clearly identify and describe issues relevant to Aboriginal and Torres Strait Islander peoples (such as particular risks, treatment considerations or sociocultural considerations).</p>	<p>Issues relevant to Aboriginal and Torres Strait Islander peoples have been included in the Guideline document/Executive summary/ Subgroup considerations. There is also additional information and considerations included in the Guideline document in Section three under the different PICO questions and recommendations as well as in the Section four under the Dissemination and Implementation plan. The Administrative report also provides information on engagement with Aboriginal and Torres Strait Islander people within the guideline development under Subgroup involvement.</p>
9.	<p>NHMRC desirable requirement B.5.1 There is no mention of groups with low socioeconomic status in the Sub-group considerations section of the Guideline, Section 2 (p.37-38).</p>	<p>Please consider adding this sub-group to the relevant section of the Guideline.</p>	<p>We have added the following text to the ‘Subgroup considerations’ section within the Executive summary of the Guideline document.</p> <p>“The input of people with low socioeconomic status was not specifically targeted in the development of the guideline, though nor were they excluded. Barriers to seeking support and uptake of physical activity, including access to funding, social supports, and transport should be considered when planning for implementation of the guideline to ensure people with mSTBI from low socioeconomic backgrounds are not further disadvantaged.”</p>

10.	NHMRC mandatory requirement C. 1 Include the clinical questions in the body of the Guideline, not just the Technical report.	Please ensure the clinical questions, presented in a PICO format, are presented in both the main Guideline and the Technical report.	A list of the Clinical questions is presented in the Executive summary section of the Guideline document. In section 3 of the Guideline document, each Clinical question (in PICO format) is presented prior to the recommendations. The Technical report includes the PICO questions at the beginning of each Evidence to Decision Framework.
11.	NHMRC desirable requirement C. 3.4 The documented search strategies did not appear to include search terms to identify evidence related to cost effectiveness and resource implications of practice	Please update this section as applicable.	We did not include search terms specifically looking for cost effectiveness studies. The intervention studies identified were checked for inclusion of economic evaluation, of which there were none. Members of the Guideline Leadership Group with clinical and research expertise in TBI were not aware of any relevant studies. Because of this, we conducted an audit of brain injury health services across Australia to identify current resource uses for delivery and promotion of physical activity. This data has been included in the development of the guideline recommendations.
12.	NHMRC mandatory requirements C. 4 and C.5 Include the search dates and the inclusion and exclusion criteria in the Technical report.	It is noted that the information is included in the Guideline document. However, to meet this requirement the information needs to appear in a Technical report.	The search dates and inclusion/exclusion criteria have been added to the Technical report, located in the section: Systematic Review of the evidence to inform the Guideline/Methods.
13.	NHMRC mandatory requirement C.8 In the Guideline each recommendation needs to be directly accompanied by a summary of the evidence underpinning the recommendation (including the outcomes of each clinical study, the level of evidence and reference details).	Please include a summary of the evidence underpinning each recommendation in the final draft guideline.	A summary of evidence informing each recommendation has been added to section three of the Guideline document for the 10 PICO questions.
14.	NHMRC mandatory requirement D. 1 Revise the wording of the recommendations section to ensure that each recommendation is specific, unambiguous, and clearly describes the action/s to be taken by users. To help in this process we recommend consulting NHMRC guidelines for guidelines, Section 4, Form actionable recommendations (https://www.nhmrc.gov.au/guidelinesforguidelines/plan/implementability)	Please review and revise as appropriate.	With the reformatting of the draft guideline into the three separate reports, we feel we have addressed the issues raised. This includes: <ul style="list-style-type: none"> The evidence-based recommendations no longer appear alone and only appear with the

<p>Where resources are recommended in the 'good practice points', the year of publication of the resource and a link to the resource would be useful for the end user.</p> <p>More details are provided in the 'good practice points' for some recommendations but not others. As the recommendations are summarised at the start of the document, without accompanying 'good practice points', the detail is lost when the recommendation is viewed on its own.</p> <p>The wording of the recommendations matches the GRADE strength of the body of evidence, however, the recommendations are mostly written in broad terms without enough actionable detail and without accompanying definitions or clarification of terms. For example, one recommendation in the Guideline (p.30) states:</p> <p>'For adults and older adults after moderate to severe traumatic brain injury, we recommend individually tailored muscle strengthening exercise, including ballistic training, across the continuum of care'.</p> <p>Several elements of this recommendation are not clear, including:</p> <ul style="list-style-type: none"> - Who is considered an adult or an older adult? - Who should be tailoring this intervention and in what setting? - What is ballistic training? <p>More details are provided in the 'good practice points' for some recommendations but not others. As the recommendations are summarised at the start of the document, without accompanying 'good practice points', the detail is lost when the recommendation is viewed on its own.</p> <p>The 'good practice points' that refer to other sources of information would benefit if more identifying information was provided. For example, the 'good practice points' for aerobic exercise, Guideline (p.27-28) suggest that:</p> <p>'aerobic exercise is prescribed using the Frequency, Intensity, Time, and Type (FITT) principles according to American College of Sports Medicine guidelines for stroke and brain injury'.</p> <p>However, there is no year of publication to determine which version of the guideline they are referring to (which may be important now or if in the future there is more than one version of the guideline) and there is no link to the resource.</p>		<p>accompanying good practice points and precautionary points.</p> <ul style="list-style-type: none"> • Section three of the guideline document presents the recommendations for each PICO with improved context to support health professionals to implement the recommendations. This includes definitions, summary of evidence, references, more detail for some interventions e.g., more specifics from ACSM guidelines which are referred to in the good practice points. • We have revised the wording of the good practice points and precautionary points to ensure they are clear and actionable. • The wording of the evidence-based recommendations was developed, agreed upon and voted on in the guideline development meeting which included several people living with mSTBI and clinicians. The development of these evidence-based recommendations was also guided by our Methodological Expert, Dr Zac Munn and based on the evidence presented. The children's aerobic exercise guideline wording was modified based on public consultation, followed by discussion with paediatric expert on our Guideline Development group.
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	To meet this requirement the wording of the recommendations needs to be revised to ensure that it is specific, unambiguous, and clearly describes the action/s to be taken by users, within the recommendation itself.		
15.	NHMRC mandatory requirement D. 2 Provide information accompanying the recommendations to explain terms that not all end-users would understand. For example, terms such as aerobic exercise, ballistic training, etc.	Please consider the reviewer's comments and update as appropriate.	We have added statements to accompany the recommendations to clarify key terms used in the recommendation. We have also added definitions of the physical activity interventions within section three of the guideline (detailed recommendations) as well as in the glossary of the Guideline document.
16.	NHMRC mandatory requirement D. 3 Provide the list of references that underpin each evidence-based recommendation in the Guideline.	Please include.	A list of references that underpin each set of recommendations for each PICO questions have been added in section three to the Guideline document.
17.	NHMRC mandatory requirements D.6 and D.15 Include the following in the Administrative report: <ul style="list-style-type: none"> the methods used to arrive at consensus-based recommendations or practice points the independent AGREE-II assessments, when completed. 	Please consider the reviewer's suggestions and develop an Administrative report separate to the Guideline document. Please provide confirmation that AGREE II assessments have been carried out on the final draft guideline before it is submitted to NHMRC (<i>note you do not have to provide the reviews or the names of the reviewers – confirmation that they were done will be sufficient</i>).	We have created an Administrative report, which includes the methods used to arrive at the recommendations. We have had two independent reviewers complete the AGREE-II assessment. A summary of this process and their scores is included in the Administrative report.
18.	NHMRC mandatory requirement D. 8 Provide a summary of the evidence base alongside each recommendation in the Guideline. The summary should include a brief description of the body of evidence, its strengths and limitations, and any areas of uncertainty. The general lack of high-quality direct evidence is acknowledged in the Guideline (p.40-41), however, the specific evidence used to formulate each recommendation is only discussed within the 'Evidence to Decision frameworks' in Section 3, which the developers consider to be the Technical report (see E.11). A guideline should be self-contained from the perspective of the end user, with each recommendation accompanied by a summary of the evidence and a justification or rationale. They should not need to consult the Technical report unless they are looking for more detail about the evidence, processes, or methods.	Please review and revise as appropriate.	We have restructured each recommendation within the Guideline document (section three) to include a summary of the evidence base and rationale for each recommendation as suggested. The evidence is provided split into direct evidence from TBI literature and indirect evidence from other relevant sources.

	<p>In its current configuration this Guideline is not self-contained as the recommendations are presented without any context, information regarding the evidence is currently only in the Technical report.</p> <p>To meet this requirement, we suggest that alongside each recommendation in the Guideline there is a summary of the evidence base that includes a brief description of the body of evidence, its strengths and limitations, and any areas of uncertainty. For an example of this, see the recently published Australian PCOS Guideline: https://www.monash.edu/medicine/mchri/pcos/guideline</p>		
19.	<p>NHMRC desirable requirement D. 9.2 The developer may wish to consider including cost effectiveness or resource implications, where relevant, in the Guideline text.</p>	Please consider this suggestion.	There is a distinct lack of published evidence to inform a discussion on the cost effectiveness and resource implications of physical activity interventions in this clinical population. Within the Guideline document in section three, under each PICO, we have discussed the results of our clinical audit of rehabilitation services in Australia with respect to the resource implications in clinical practice. We have also included information on resource implications discussed in our stakeholder focus groups. In section four of the guideline document, we have also indicated research on cost effectiveness and resource implications is a research priority.
20.	<p>NHMRC desirable requirement D. 11.1 The developer has indicated that Guideline, Section 2 (p.37-41) and Section 3 (p.44-246) contain this information, however, they have not highlighted any specific instances where evidence of sociocultural factors affecting outcomes has been identified and considered in the formulation of recommendations.</p>	Please include additional information as requested.	Information regarding sociocultural factors influencing outcomes is included in the subgroup section of the Executive summary of the Guideline document. This is also discussed within section four of the Guideline document regarding plans for future implementation of the guideline and the need to understand these aspects in greater detail.
21.	<p>NHMRC mandatory requirement D. 12 Provide a text alongside each recommendation in the Guideline that discusses harms and benefits of each intervention and the rationale for the recommendation. This information is currently outlined in the 'Evidence to Decision frameworks' section.</p>	Please consider the reviewer's comments and revise. To meet this requirement the developer should include text in the Guideline (accompanying each recommendation) that	We have restructured the detailed recommendation section for each PICO (section three of the Guideline document) to include a statement on the benefits

		discusses harms and benefits of each intervention and the rationale for the recommendation.	and harms of each intervention within the justification for the recommendations.
22.	NHMRC mandatory requirement D.14 Describe the potential impact of each recommendation on clinical practice or outcomes in the Guideline text.	Please ensure this detail is included in the final draft guideline submitted to NHMRC.	We have restructured the detailed recommendation section for each PICO (section three of the Guideline document) to include a section on impact on clinical practice.
23.	NHMRC mandatory requirement E. 1 Ensure the publisher, copyright information, reprint address and ISBN are added to the Guideline upon publication.	Please include all information in the final draft guideline.	The information is currently drafted in the final draft Guideline document submitted. We have liaised with our institution research support team and drafted the forms to request ISBN.
24.	NHMRC mandatory requirement E. 2 Clearly label the Technical report or present it as a separate document with links and cross referencing to the Guideline. The developer may wish to consider numbering the recommendations.	Please consider the suggestions and update as appropriate.	We have developed separate Technical, Administrative and Guideline reports and cross referenced the reports. Live links between reports will be created for the final reports once they are housed in the University of Sydney research repository.
25.	NHMRC mandatory requirement E. 3 Consider revising the plain English summary to include information more relevant to the end-user, such as a broad overview of the condition and of the recommendations	Please consider the reviewer's suggestion and amend the plain English summary. A recent example is the Australian PCOS Guideline (p.7) (https://www.monash.edu/medicine/mchri/pcos/guideline)	We have reviewed and revised the plain language summary to make it more use friendly to the end-user (i.e., Health Professionals working with people with moderate to severe TBI). It is presented at the front of the Guideline document after the abstract.
26.	NHMRC mandatory requirement E. 4. Summary of recommendations to be developed following finalisation of recommendations after public consultation	Please ensure that a summary of recommendations is provided at final submission.	A summary of the recommendations is provided in a table in section two of the Guideline document.
27.	NHMRC mandatory requirement E.5 Provide a glossary of technical terms, acronyms, and abbreviations in the Guideline.	Please include these sections in the final draft guideline submitted to NHMRC.	A glossary and list of abbreviations and acronyms is provided in the Appendix of the Guideline document.
28.	NHMRC mandatory requirement E. 7 The developers have not stated whether the Guideline is suitable for people with visual impairment. It is not possible to determine whether the PDF meets accessibility requirements.	Please consider this comment.	We have provided a summary of all recommendations in a table format (section two of Guideline document) which enables the recommendations to be "...identified easily within the text". We have included this information in the "How to use this guideline" section in the Guideline document as well as a

			<p>statement that the Guideline document is not suitable for people with visual impairments.</p> <p>This document is primarily for health professionals working with people living with msTBI. Our team plans to co-design resources for people with msTBI to support guideline implementation; these will meet accessibility requirements.</p>
29.	<p>NHMRC mandatory requirement E. 11</p> <p>The Technical report is included in the Guideline (as Section 3) however it is not labelled as such. The guideline would benefit from having the Technical report clearly labelled, or moved into a separate document that is readily accessible with its location indicated in the Guideline.</p>	Please consider the reviewer's comments and either clearly label or separate the Technical report from the Guideline.	We have developed a separate Technical report and cross referenced it in the other two reports (Administrative and Guideline). Live links between reports will be created for the final reports once they are housed in the University of Sydney research repository.
30.	<p>NHMRC mandatory requirement E.12</p> <p>Develop an Administrative report that is either included in the Guideline, or in a readily accessible location, which is indicated in the Guideline.</p> <p>For information on what to include in an Administrative report see https://www.nhmrc.gov.au/guidelinesforguidelines/plan/transparency.</p>	Please consider the reviewer's comments and develop an administrative report.	We have developed a separate Administrative report and cross referenced it in the other two reports (Technical and Guideline). Live links between reports will be created for the final reports once they are housed in the University of Sydney research repository.
31.	<p>NHMRC mandatory requirement F.1</p> <p>Include details of the public consultation process (that is in compliance with Section 14A of the Commonwealth <i>National Health and Medical Research Council Act 1992</i> and accompanying regulations) in the Administrative report.</p>	Please ensure details of the public consultation processes are included in the Administrative report.	We have described the public consultation process in the Administrative report.
32.	<p>NHMRC mandatory requirement F. 2</p> <p>Upon completion of public consultation, provide a public consultation submissions summary that provides details of submissions received and the response of the guideline development group to the submissions (including whether, why and how the guideline was altered).</p>	Please include a public consultation summary report when the final draft guideline is submitted to NHMRC.	A de-identified public consultation summary report has been developed and included in Appendix section of the Administrative report.
33.	<p>NHMRC desirable requirement F. 2.1</p> <p>No Administrative report was provided by the developer. When the developers put together an Administrative report, they may wish to include a de-identified version of the public consultation submissions summary.</p>	Please consider including a de-identified version of the public consultation submissions summary in the Administrative report.	A de-identified public consultation summary report has been developed and included in the Appendix section of the Administrative report.
34.	<p>NHMRC mandatory requirement F.3</p> <p>As part of the public consultation process, undertake consultation with the Director-General, Chief Executive or Secretary of each state, territory, and Commonwealth health department. Document this in the Administrative report and the Public consultation submissions summary.</p>	Please include details of consultation with Commonwealth, state and territory health departments in the administration and/or	The draft guideline has been sent to the relevant head of state and territory health departments of Australia and feedback has been invited. Any feedback received

		technical report when the final draft guideline is submitted to NHMRC.	will be added to the public consultation process section included in the Administrative report.
35.	NHMRC mandatory requirement F. 4 Include key professional and consumer organisations in the public consultation process to have their say about the finished guideline (in addition to involvement in its development).	Please include details of the professional and consumer organisations who participated in the public consultation process in the public consultation summary report when the final draft guideline is submitted to NHMRC.	The list of organisations approached for feedback, in addition to those approached for endorsement of the guideline, are listed under the Consumer involvement and Public consultation sections of the Administrative report. A summary of this is also included within the Stakeholder/public consultation of the Executive summary in the Guideline document.
36.	NHMRC mandatory requirement G.1 and G.2 Develop a separate <i>Dissemination plan</i> that highlights the recommendations that are most likely to lead to improvements in health outcomes.	Please provide a separate plan for the dissemination of the guideline when the final draft guideline is submitted to NHMRC.	A Dissemination and Implementation plan has been developed and is included in section four of the Guideline document.
37.	Requirement G.3, G.4, G.5, G.6, G.7, G.9 It is noted that planning for implementation is the focus of another component of the BRIDGES project.	Please consider the development of separate resources to support implementation, including consumer information, suggestions for local adaption and an evaluation strategy.	