

BMJ Open is committed to open peer review. As part of this commitment we make the peer review history of every article we publish publicly available.

When an article is published we post the peer reviewers' comments and the authors' responses online. We also post the versions of the paper that were used during peer review. These are the versions that the peer review comments apply to.

The versions of the paper that follow are the versions that were submitted during the peer review process. They are not the versions of record or the final published versions. They should not be cited or distributed as the published version of this manuscript.

BMJ Open is an open access journal and the full, final, typeset and author-corrected version of record of the manuscript is available on our site with no access controls, subscription charges or pay-per-view fees (<u>http://bmjopen.bmj.com</u>).

If you have any questions on BMJ Open's open peer review process please email <u>info.bmjopen@bmj.com</u>

BMJ Open

Characteristics and outcomes of physical activity interventions for individuals with mild traumatic brain injury: a scoping review protocol

Journal:	BMJ Open
Manuscript ID	bmjopen-2018-027240
Article Type:	Protocol
Date Submitted by the Author:	12-Oct-2018
Complete List of Authors:	Alarie, Christophe; Université de Montréal, École de réadaptation; Centre de recherche interdisciplinaire en réadaptation du Montréal metropolitain Gagnon, Isabelle; McGill University, School of Physical and Occupational Therapy; Montreal Children's Hospital of the McGill University Health Center, Trauma Quilico, Enrico; University of Toronto, Rehabilitation Science Institute Swaine, Bonnie; Université de Montréal, École de réadaptation; Centre de recherche interdisciplinaire en réadaptation du Montréal metropolitain
Keywords:	Physical Activity, Mild Traumatic Brain Injury, Concussion, mTBI, Rehabilitation, Scoping Review



Characteristics and outcomes of physical activity interventions for individuals with mild traumatic brain injury: a scoping review protocol

Corresponding author: Bonnie Swaine, 6363 Chemin Hudson Bureau 061, Montréal, Quebec, Canada, H3S 1M9, Canada, bonnie.swaine@umontreal.ca, (514) 340-2085 # 4776.

Co-authors information:

Christophe Alarie^{1,2}, Isabelle J. Gagnon^{3,4}, Enrico Quilico⁵, Bonnie Swaine^{1,2}.

- 1. École de Réadaptation, Faculté de Médecine, Université de Montréal, Montréal, Québec, Canada.
- 2. Centre for Interdisciplinary Research in Rehabilitation of Greater Montreal (CRIR), Montréal, Québec, Canada.
- 3. School of Physical and Occupational Therapy, Faculty of Medicine, McGill University, Montréal, Québec, Canada.
- 4. Trauma Center and Pediatric Emergency Medicine, Montreal Children's Hospital, McGill University Health Center, Montréal, Québec, Canada.
- 5. Rehabilitation Science Institute, University of Toronto, Toronto, Canada.

Co-authors e-mail addresses:

Christophe Alarie: christophe.alarie@umontreal.ca

Isabelle J. Gagnon: isabelle.gagnon8@mcgill.ca

Enrico Quilico: enrico.quilico@utoronto.ca

Word count: 2562 words.

ABSTRACT

Introduction: Traumatic Brain Injury (TBI) is a major public health problem and it is estimated that 85% of TBIs are diagnosed as mild (mTBI), and commonly referred to as a concussion. In adults, symptoms are expected to resolve within 10 to 14 days after the injury, but up to 15% of individuals continue to have symptoms beyond this period. Recent clinical recommendations suggest the use of physical activity (PA) as a therapy to manage persisting symptoms. However, the recommendations regarding PA lack clarity about important intervention parameters to help clinicians deliver the intervention. The objectives of this scoping review are thus to identify the characteristics, the measurement tools and the health-related outcomes of PA-based interventions for adults with persisting symptoms of a mTBI.

Methods and analysis: This scoping review protocol will follow the Arksey and O'Malley's 6-step iterative process enhanced by Levac et al. and will be conducted by a team of researchers and clinical experts. Five databases (MEDLINE, CINAHL, PsycINFO, SPORTDiscuss and EMBASE), as well as Google will be searched using an extensive search strategy to capture relevant scientific literature and grey literature. Articles will be selected if they report on an intervention designed to have an impact on health-related outcomes or participation among individuals having sustained a mTBI. A data extraction form based on the Consensus on Exercise Report Template (CERT) and the Template for Intervention Description and Replication (TIDieR) checklists will be created. Quantitative and qualitative data will be analyzed accordingly, synthesized and collated in tables.

Ethics and dissemination: This scoping review generates new knowledge from published and publicly available literature, thus an ethical approval is unnecessary to conduct this research. Dissemination of the results will involve all team members in activities aimed to generate knowledge uptake among TBI rehabilitation clinical experts locally, nationally and internationally.

Keywords: physical activity, mild traumatic brain injury, concussion, mTBI, rehabilitation, scoping review.

ARTICLE SUMMARY
Strengths and limitations of this study:
1. This will be the first scoping review to critically appraise the characteristics of PA-based interventions designed to improve health-related outcomes in adults with persistent symptoms post mTBI.
2. Clinical partners will be integrated into the research process in a creative yet feasible way to ensure enhanced interpretation and better applicability of the results.
3. The combination of two expert consensus-based checklists (CERT & TIDieR) to guide the data extraction will allow better identification of key characteristics of PA-based interventions.
4. Although this study aims to describe the characteristics of PA-based interventions, it will not allow inferences about the effectiveness of these parameters which could be further investigated in a systematic review.
3

INTRODUCTION

Traumatic brain injury (TBI) is a major public health problem and it is estimated that each year, more than 10 million individuals worldwide will experience a TBI that may result in either mortality or hospitalization.(1) Up to 85% of TBIs are diagnosed as mild TBI (mTBI),(2) and commonly referred to as a concussion.(3) A wide range of consequences may result from mTBI (e.g., headaches, anxiety, difficulty concentrating, fatigue and sleep disturbances),(4) which in turn, may limit the individual's activities, restrict their participation and decrease their quality of life.(5)

The symptoms typically subside within 10 to 14 days after the injury in adults.(4) A failure to completely recover mTBI-related symptoms within this time-frame is considered as having persisting symptoms,(4) and it is likely that 15% of individuals who sustain a mTBI will have persisting symptoms beyond three months.(6) Interventions aiming to reduce persisting physical and cognitive symptoms are critical in order to return to pre-injury functioning.(7, 8)

Clinical practice guidelines (CPGs) aim to improve the quality and decrease the variability of healthcare services by providing clinical experts key evidenced-based recommendations to implement within their practices.(9) Based on the highest available evidence, CPGs for the management of adults with persisting symptoms of mTBI were developed to support clinical decision-making and improve rehabilitation outcomes. The Ontario Neurotrauma Foundation's CPG for adults with persisting symptoms of mTBI and the CPG for military personnel with mTBI produced by the American Department of Defense and Veterans Affairs both recommend using physical activity (PA) as a therapy to alleviate mTBI-related symptoms (e.g., headache, fatigue or sleep disturbances) and improve mood, health status and exercise tolerance. (6, 10) These CPGs corroborate recommendations from the latest Consensus Statement on Concussion in Sport, which suggests including a symptom-limited, progressive exercise intervention for individuals who experience persisting symptoms (>1 month) after mTBI.(4) Collectively, these

BMJ Open

recommendations promote the use of PA as an intervention that can help decrease and manage prolonged persistent symptoms of mTBI in adults.

These CPGs and consensus statements are fairly recent, but they lack specific information about how PA interventions should be delivered by service providers. Important PA intervention characteristics such as frequency, intensity, time, type of exercise and progression patterns, for example, are missing. This lack of clear parameters leaves clinicians using trial and error methods instead of an evidence-based approach. Indeed, the complexity and lack of applicability of recommendations are CPG-related barriers to the implementation and use of evidence-based recommendations.(11) Insufficient information about PA interventions leaves many clinical questions unanswered: Should the PA intervention be delivered in a group or individually? Should PA adherence be measured and if yes, how? Service providers who apply recommendations from CPGs also require assessment tools to evaluate the health-related outcomes of PA-interventions. For example, with the exception of the post-concussion symptoms scale in the CPGs, it is unclear which clinical tool should be used to measure the effectiveness of a PA intervention. Clear parameters that guide PA interventions may promote optimal dosage and type of planned PA in order to maximize benefits and accommodate individual preferences through different activities.(12)

A critical appraisal of the literature about the characteristics of existing interventions is therefore needed to address the current gaps with regard to clinical decision-making and clear parameters about PA-based intervention designed for adults with persistent symptoms post mTBI. The primary objective of this scoping review is to identify characteristics of PA-based interventions available in the scientific and grey literature designed to improve health-related outcomes in adults with persistent symptoms of a mTBI. The secondary objectives are to document the health-related outcomes and the measurement tools related to PA interventions found in the literature.

METHODS AND ANALYSIS

Protocol

This scoping review will follow the 6-step iterative framework of Arksey and O'Malley, which was later enhanced by Levac, Colquhoun, and O'Brien in 2010 to ensure structure and rigor during a thorough investigation of the scientific and grey literature.(13, 14) This work will be conducted currently by a team of two doctoral students who are supervised by two rehabilitation scientists and assisted by four clinical experts and administrators from a specialized mTBI rehabilitation program (administrator, clinical coordinator, kinesiologist, and physiotherapist). The clinical team was involved in the design of the study, and will participate in multiple key steps of this review as described below. This collaborative approach is a creative yet feasible way to involve clinical partners, as well as ensure an accurate interpretation of the review results and their applicability in the clinical setting. To better report this scoping review protocol, the authors used the PRISMA-P reporting guidelines.(15)

Step 1: Identifying the research question

A preliminary consultation with the clinical partners led to the development of an initial research question that was used as a starting point to guide the development of the search strategy: *What are the characteristics and health-related outcomes of physical activities interventions designed for individuals with mild traumatic brain injury?* In the context of this review, PA is defined as any bodily movement produced by skeletal muscles that requires energy expenditure.(16) This broad definition may refer to different types of activities, ranging from recreation activities to high-intensity aerobic training. The research question is subject to change during the process as new questions and reflections might emerge during each iterative step of the scoping review.

Page 7 of 20

BMJ Open

Step 2: Identifying relevant studies

Literature will be selected if it reports on an intervention, provided in any setting (e.g. inpatient or outpatient rehabilitation) or in the community, designed to impact on health-related (physical, mental, psychosocial) outcomes or participation in individuals of all ages having sustained any severity of TBI. However, at least one participant in the study sample must have sustained a mTBI. Moreover, the intervention may target persons with all types of injury severity, but it must be pertinent for persons with mTBI. For example, interventions such as constraint-induced movement therapy is indicated for an individual with a motor impaired upper extremity and not particularly for someone with a mTBI.(17, 18) Consequently, articles on this intervention would be excluded. Articles with participants of all ages will be included because the age range of subjects in pediatric studies can include teenagers, which might overlap with young adults.

PA interventions are used in many fields of research (i.e. rehabilitation sciences, education, psychology, exercise sciences) and thus can be presented in many formats. Consequently, the literature search will cover published and unpublished literature (grey literature), including original research, theses and books. A broad yet feasible range of five databases (MEDLINE, CINAHL, PsycINFO, SPORTDiscuss and EMBASE) will be accessed using an extensive search strategy validated by a specialized university librarian. Keywords related to TBI and PA corresponding to subject headings (or MeSH) will be included in the search strategy (e.g. Brain Injuries, Traumatic, Brain Concussion, Exercise Therapy, Exercise). Other relevant keywords will be added to the search strategy to enhance the strategy, and are used to search titles, abstracts and subjects of references contained in the databases (e.g. mild traumatic brain injury, mTBI, physical fitness, motor activity). Through an iterative and concerted process, analysis of the search results and retrieved articles will guide the refinement of the search strategy to achieve a balance between feasibility and breadth. Opinion articles, posters, oral presentations, and abstracts from conferences will be excluded because they may lack explicit information about reported interventions. Systematic reviews will be excluded, but their reference

lists will be examined by the authors to ensure relevant articles are retained. Animal model studies will also be excluded due to their lack of applicability to human study contexts.

The grey literature search will be conducted on Google online in the future using a modified version of the final search strategy to find TBI-related PA interventions described in other formats such as PDF documents, books, and websites in the first 10 pages of results (approximately 100 results). Moreover, a hand search of reference lists of all selected documents will be performed to ensure that all key studies are captured. Each added reference to the initial search will be documented and will be reported in a PRISMA flow chart created for this study.(19) Languages will be restricted to both French and English, as authors are fluent in both languages. Searches will be limited to published literature after 1990 when recommendations about PA were first established.(20) Results will be managed using reference manager software (Endnote) and duplicates will be removed before selection.

Step 3: Study Selection

Study selection will be conducted by two independent reviewers in two subsequent phases: 1) abstract and title review; 2) full-text review. Based on initial eligibility criteria, the reviewers will start to examine/discuss a random sample of 100 retrieved references to determine whether the article should be considered, rejected, or if they are unsure. Inter-rater reliability (IRR) will be computed with a 3-level Kappa (κ) statistic. As needed, the eligibility criteria will be discussed by the researchers and modified for more clarity. This initial selection process will be repeated with a sample of 300-500 references until the agreement between the two reviewers reaches a mean $\kappa > .75$ (κ >.75= excellent agreement).(21) When acceptable agreement is achieved, the reviewers will independently assess the remaining articles. They will also meet at the mid-point and endpoint of remaining articles to discuss any changes, thoughts or needs for clarification. The full-text review phase will follow the same rigorous method in order to determine IRR.

Page 9 of 20

BMJ Open

This time, 10 to 20 articles will be randomly selected and cross-examined by the same two reviewers, and then re-examined independently until they reach excellent agreement or a mean $\kappa > .75$. If a disagreement cannot be resolved through consensus in any of the two phases, a third independent reviewer will be consulted. Reasons for excluded articles during the second phase will be reported in the PRISMA flow chart. As the selection unfolds, criteria can be refined or clarified if needed and if a criterion is modified at a later stage of the article selection, authors will ensure that the previous steps will comply with the change and report the changes in the PRISMA flow chart.

Step 4: Charting the Data

A preliminary data extraction form will be created in an Excel spreadsheet based on the combination of the 12-item Template for Intervention Description and Replication checklist (TIDieR) and the 16-item Consensus on Exercise Reporting Template checklist (CERT).(22, 23) Both checklists were systematically developed to improve the quality of reporting interventions in rehabilitation sciences. However, the CERT includes specific key items to better report an exercise program (e.g. motivation strategies, decision rules for determining exercise progression, decision rules to describe the starting level, etc.). CERT was designed to be used in conjunction with the TIDieR Checklist. The extraction form will also consist of other categories including, but not limited to, primary and secondary outcomes, outcome measures and results. The clinical partners will validate this extraction form during a second consultation and additional categories may be included during the iterative process if deemed appropriate by the team.

Data will be extracted from the selected articles and tabulated by two independent reviewers. A sample of 5 studies will be extracted by each reviewer and then compared during a work session to ensure compatibility between extraction methods and to enhance the extraction form, with new or more precise categories if needed. The extraction team will repeat this process until the extractors/reviewers agree that they consistently assess and extract information from each article in a compatible way. Then, reviewers will meet regularly (e.g., every 10 - 20 articles) to address any challenges and ensure concordance with their reporting methods.

Step 5: Collating, summarizing and reporting the results

Analyses of the quantitative and qualitative data will be performed by the researchers. Quantitative data such as numerical descriptive characteristics of PA interventions (e.g. year of publication, age and number of mTBI individuals in the study, number of interventions using motivation strategies) will be summarized into tables. In addition, selected articles reporting on PA interventions will be carefully assessed with the CERT Checklist assessment form. (23) Each of the checklist's 16 items will be categorized as yes if the information was provided or *no* if the information is missing. Following a similar process for reliability, two independent reviewers will assess a small subset of articles and will compare their results. Discrepancies in assessment will be resolved through discussion and this step will be repeated until reviewers reach excellent IRR of $\kappa > .75$. Then, the first author will assess the remaining article. Qualitative data will be synthesized and collated in tables. Quantitative results may be presented graphically (e.g. number of PA interventions per study per year, % of types of interventions) and qualitative results will also be presented graphically and narratively. The different PA characteristics, key PA principles and outcomes measures will be summarized and reported in multiple matrices.

Step 6: Consultation with stakeholders

The clinical experts mentioned above will be consulted throughout the review process (i.e., prior to the development of the study in order to define the research question, and while designing the research protocol to validate and possibly enhance the data extraction form). Consultation will also occur at the end of the review to assist with the interpretation of the results in order to improve their clinical relevance and determine the best ways to mobilize the knowledge generated by the review.

ETHICAL CONSIDERATIONS AND DISSEMINATION

A scoping review generates new knowledge from published and publicly available literature and does not involve human participants. Therefore, a Research Ethics Board approval is unnecessary to conduct this research. Although our clinical partners will be involved in multiple steps of the study, they are primarily involved as expert consultants and their input may deepen the understanding and enhance the scope of the results. Members of the group will work together during work sessions to co-create a final document that will be used to help disseminate the results of this review to other clinicians working in TBI rehabilitation. Dissemination of the results will involve all team members through regional, national and international scientific and clinical activities and conferences, the publication of a manuscript, and other activities aimed to generate awareness and increase knowledge uptake of TBI rehabilitation clinical experts.

CONCLUSION

The results of this scoping review will provide detailed information about the state of the existing literature regarding the important characteristics, intervention parameters, and tools to measure health-related outcomes of PA-based interventions designed for adults with persistent symptoms of mTBI. These results may assist clinical experts with the use of PA in the management of mTBI adults and ultimately improve patient outcomes. Moreover, the results of this scoping review will inform researchers about the effectiveness of multiple PA parameters, which may be further investigated in a systematic review.

REFERENCES

1. Hyder AA, Wunderlich CA, Puvanachandra P, et al. The impact of traumatic brain injuries: a global perspective. *NeuroRehabilitation* 2007;22(5):341-53.

2. Feigin VL, Theadom A, Barker-Collo S, et al. Incidence of traumatic brain injury in New Zealand: a population-based study. *Lancet Neurol* 2013;12(1):53-64.

3. Marshall S, Bayley M, McCullagh S, et al. Updated clinical practice guidelines for concussion/mild traumatic brain injury and persistent symptoms. *Brain Inj* 2015;29(6):688-700.

4. McCrory P, Meeuwisse W, Dvorak J, et al. Consensus statement on concussion in sport—the 5th international conference on concussion in sport held in Berlin, October 2016. *Br J Sports med* 2017;0 :1-10.

5. Perroux M, Lefebvre H, Levert MJ, et al. Besoins perçus et participation sociale des personnes ayant un traumatisme crânien léger. *Santé Publique* 2013;25(6):719-728.

6. Ontario Neurotrauma Foundation. Guideline For Concussion/mild Traumatic Brain Injury & Persistent Symptoms 3Rrd Edition, For Adults Over 18 Years of Age. 2018. Available from: http://braininjuryguidelines.org/concussion/index.php?id=1 (accessed october 2018).

7. Makdissi M, Schneider KJ, Feddermann-Demont N, et al. Approach to investigation and treatment of persistent symptoms following sport-related concussion: a systematic review. *Br J Sports med* 2017;51(12):958-968.

BMJ Open

8. Schneider KJ, Leddy JJ, Guskiewicz KM, et al. Rest and treatment/rehabilitation following sport-related concussion: a systematic review. *Br J Sports med* 2017;51(12):930-934.

9. Lohr KN, Field MJ. Guidelines for clinical practice: from development to use. Washington, WASH DC, *National Academies Press* 1992.

10. Department of Veterans Affairs, Department of Defense. VA/DoD clinical practice guideline for management of concussion/mild traumatic brain injury. 2016. Available from: https://www.healthquality.va.gov/guidelines/Rehab/mtbi/ (accessed october 2018).

11. Fischer F, Lange K, Klose K, et al. Barriers and Strategies in Guideline Implementation—A Scoping Review. *Healthcare* 2016;4(3):36.

12. Ammann BC, Knols RH, Baschung P, et al. Application of principles of exercise training in sub-acute and chronic stroke survivors: a systematic review. *BMC neurol* 2014;14(1):167-178.

13. Arksey H, O'Malley L. Scoping studies: towards a methodological framework. *Int J Soc Res Methodol* 2005;8(1):19-32.

14. Levac D, Colquhoun H, O'Brien KK. Scoping studies: advancing the methodology. *Implement Sci* 2010;5(1):69-78.

15. Moher D, Shamseer L, Clarke M, et al. Preferred Reporting Items for Systematic Review and Meta-Analysis Protocols (PRISMA-P) 2015 statement. *Syst Rev* 2015;4(1):1.

16. World health organisation. Global Strategy on Diet, Physical Activity and Health. 2018. Available from: https://www.who.int/dietphysicalactivity/pa/en/ (accessed october 2018).

17. Sirtori V, Corbetta D, Moja L, et al. Constraint-induced movement therapy for upper extremities in stroke patients. *Cochrane Database Syst Rev.* 2009;7(4).

18. Hoare BJ, Wasiak J, Imms C, et al. Constraint-induced movement therapy in the treatment of the upper limb in children with hemiplegic cerebral palsy. *Cochrane Database Syst Rev* 2007;18(2).

19. Moher D, Liberati A, Tetzlaff J, et al. Preferred reporting items for systematic reviews and meta-analyses: the PRISMA statement. *Ann Intern Med* 2009;151(4):264-269.

20. Pollock MLP, Froelicher VFMD. Position Stand of the American College of Sports Medicine: The Recommended Quantity and Quality of Exercise for Developing and Maintaining Cardiorespiratory and Muscular Fitness in Healthy Adults. *J Cardiopulm Rehabil* 1990;10(7):235-45.

21. Orwin RG, Cooper IH, Hedges LV. In: Orwin RG, Cooper IH, Hedges LV. The handbook of research synthesis." New York, NY, *Russell Sage Foundation* 1994:139-162.

22. Hoffmann TC, Glasziou PP, Boutron I, et al. Better reporting of interventions: template for intervention description and replication (TIDieR) checklist and guide. *BMJ* 2014;348:g1687.

23. Slade SC, Dionne CE, Underwood M, et al.Consensus on Exercise Reporting Template (CERT): explanation and elaboration statement. *Br J Sports Med* 2016;0:1-10.

AUTHORS CONTRIBUTIONS

Acknowledgement: We thank the clinical partners, Pierre Vincent, Geneviève Léveillé and Pierre Goulet for their involvement in the identification of the research question and future involvement in the consultation steps.

Author statement: CA, IG, EQ and BS designed the protocol. CA drafted the manuscript. CA, IG, EQ and BS reviewed the manuscript and approved the final version. All authors will participate in the 6 steps.

FUNDING

This work is supported by the Edith Strauss Rehabilitation Research Projects Foundation. This grant will provide salary support to CA and EQ.

COMPETING INTEREST

None declared. ETHICS Ethical approval: None required.

DATA SHARING

There are no additional data to be shared with this study protocol.

Reporting checklist for protocol of a systematic review.

Based on the PRISMA-P guidelines.

Instructions to authors

Complete this checklist by entering the page numbers from your manuscript where readers will find each of the items listed below.

Your article may not currently address all the items on the checklist. Please modify your text to include the missing information. If you are certain that an item does not apply, please write "n/a" and provide a short explanation.

Upload your completed checklist as an extra file when you submit to a journal.

In your methods section, say that you used the PRISMA-P reporting guidelines, and cite them as:

Moher D, Shamseer L, Clarke M, Ghersi D, Liberati A, Petticrew M, Shekelle P, Stewart LA. Preferred Reporting Items for Systematic Review and Meta-Analysis Protocols (PRISMA-P) 2015 statement.

Syst Rev. 2015;4(1):1.

43 44 45			Reporting Item	Page Number
46 47 48 49 50 51	Identification	<u>#1a</u>	Identify the report as a protocol of a systematic review	1, 6
52 53 54 55 56	Update	<u>#1b</u>	If the protocol is for an update of a previous systematic review, identify as such	n/a
57 58 59 60		<mark>#2</mark> For ₁	If registered, provide the name of the registry (such peer review only - http://bmjopen.bmj.com/site/about/guidelines.xhtml	n/a, not registered

1 2			as PROSPERO) and registration number	
3 4 5 6 7	Contact	<u>#3a</u>	Provide name, institutional affiliation, e-mail address	
			of all protocol authors; provide physical mailing	1
7 8 9			address of corresponding author	
10 11 12	Contribution	<u>#3b</u>	Describe contributions of protocol authors and	
13 14			identify the guarantor of the review	1, 15
15 16		#4	If the protocol represents an amendment of a	
17 18		<u></u>		
19 20			previously completed or published protocol, identify	n/a, It is an original
21 22			as such and list changes; otherwise, state plan for	protocol.
23 24			documenting important protocol amendments	
25 26	0			
27 28	Sources	<u>#5a</u>	Indicate sources of financial or other support for the	15
29 30			review	
31 32 33 34 35 36 37 38	Sponsor	<u>#5b</u>	Provide name for the review funder and / or sponsor	15
	Role of sponsor	<u>#5c</u>	Describe roles of funder(s), sponsor(s), and / or	15
	or funder		institution(s), if any, in developing the protocol	15
39 40 41	Rationale	<u>#6</u>	Describe the rationale for the review in the context of	
42 43			what is already known	4,5
44 45				
46 47	Objectives	<u>#7</u>	Provide an explicit statement of the question(s) the	
48 49			review will address with reference to participants,	5,6
50 51			interventions, comparators, and outcomes (PICO)	
52 53 54	Eligibility criteria	<u>#8</u>	Specify the study characteristics (such as PICO,	
55 56			study design, setting, time frame) and report	7,8
57 58			characteristics (such as years considered, language,	
59 60		For	peer review only - http://bmjopen.bmj.com/site/about/guidelines.xhtml	

1 2			publication status) to be used as criteria for eligibility	
3 4			for the review	
5 6 7	Information	<u>#9</u>	Describe all intended information sources (such as	
8 9	sources		electronic databases, contact with study authors,	7, 8
10 11			trial registers or other grey literature sources) with	7,0
12 13 14			planned dates of coverage	
15 16	Search strategy	<u>#10</u>	Present draft of search strategy to be used for at	
17 18 19			least one electronic database, including planned	7,8
20 21 22			limits, such that it could be repeated	
23 24	Study records -	<u>#11a</u>	Describe the mechanism(s) that will be used to	
25 26 27	data		manage records and data throughout the review	8
27 28 29 30	management			
31 32	Study records -	<u>#11b</u>	State the process that will be used for selecting	
33 34	selection		studies (such as two independent reviewers) through	8,9
35 36 37	process		each phase of the review (that is, screening,	0,0
38 39 40			eligibility and inclusion in meta-analysis)	
41 42	Study records -	<u>#11c</u>	Describe planned method of extracting data from	9
43 44	data collection		reports (such as piloting forms, done independently,	
45 46	process		in duplicate), any processes for obtaining and	
47 48 49 50 51 52			confirming data from investigators	
53 54	Data items	<u>#12</u>	List and define all variables for which data will be	
55 56 57			sought (such as PICO items, funding sources), any	9
57 58 59			pre-planned data assumptions and simplifications	
60		For p	eer review only - http://bmjopen.bmj.com/site/about/guidelines.xhtml	

1 2	Outcomes and	<u>#13</u>	List and define all outcomes for which data will be	
3 4	prioritization		sought, including prioritization of main and additional	10
5 6 7			outcomes, with rationale	
7 8	D			(
9 10	Risk of bias in	<u>#14</u>	Describe anticipated methods for assessing risk of	n/a The main
11 12	individual		bias of individual studies, including whether this will	objective of this
13 14	studies		be done at the outcome or study level, or both; state	study is to appraise
15 16			how this information will be used in data synthesis	interventions'
17 18 19				characteristics, thus
20 21				does not need to
22 23				assess risk of bias
24 25				at this stage.
26 27				
28 29	Data synthesis	<u>#15a</u>	Describe criteria under which study data will be	10
30 31			quantitatively synthesised	
32 33 34		<u>#15b</u>	If data are appropriate for quantitative synthesis,	
35 36			describe planned summary measures, methods of	
37 38			handling data and methods of combining data from	10
39 40			studies, including any planned exploration of	
41 42 43			consistency (such as I2, Kendall's т)	
44 45				
46 47		<u>#15c</u>	Describe any proposed additional analyses (such as	n/a
48 49			sensitivity or subgroup analyses, meta-regression)	
50 51		<u>#15d</u>	If quantitative synthesis is not appropriate, describe	10. For qualitative
52 53			the type of summary planned	data.
54 55 56 57	Meta-bias(es)	<u>#16</u>	Specify any planned assessment of meta-bias(es)	n/a
58 59 60		For p	eer review only - http://bmjopen.bmj.com/site/about/guidelines.xhtml	

1			(such as publication bias across studies, selective	
2 3 4			reporting within studies)	
5 6 7	Confidence in	<u>#17</u>	Describe how the strength of the body of evidence	n/a The main
, 8 9	cumulative		will be assessed (such as GRADE)	objective of this
10 11	evidence			study is to appraise
12 13				interventions'
14 15 16				characteristics, thus
17 18				does not need to
19 20				address the strength
21 22				of the evidence at
23 24 25				this stage.
26 27	The PRISMA_P o	bocklist	is distributed under the terms of the Creative Commo	ns Attribution License
28 29				
30 31			st can be completed online using <u>https://www.goodrepo</u>	<u>oris.org/</u> , a toor made
32 33	by the <u>EQUATOR</u>		ork in collaboration with <u>Penelope.ai</u>	
34 35 36				
30 37 38				
39 40				
41 42				
43 44				
45 46				
47 48				
49 50				
51 52				
53 54				
55 56				
57 58				
59 60		For p	peer review only - http://bmjopen.bmj.com/site/about/guidelines.xht	ml

BMJ Open

Characteristics and outcomes of physical activity interventions for individuals with mild traumatic brain injury: a scoping review protocol

Journal:	BMJ Open
Manuscript ID	bmjopen-2018-027240.R1
Article Type:	Protocol
Date Submitted by the Author:	08-Jan-2019
Complete List of Authors:	Alarie, Christophe; Université de Montréal, École de réadaptation; Centre de recherche interdisciplinaire en réadaptation du Montréal metropolitain Gagnon, Isabelle; McGill University, School of Physical and Occupational Therapy; Montreal Children's Hospital of the McGill University Health Center, Trauma Quilico, Enrico; University of Toronto, Rehabilitation Science Institute Swaine, Bonnie; Université de Montréal, École de réadaptation; Centre de recherche interdisciplinaire en réadaptation du Montréal metropolitain
Primary Subject Heading :	Sports and exercise medicine
Secondary Subject Heading:	Rehabilitation medicine, Health services research
Keywords:	Physical Activity, Mild Traumatic Brain Injury, Concussion, mTBI, Rehabilitation, Scoping Review

SCHOLARONE[™] Manuscripts

BMJ Open

Characteristics and outcomes of physical activity interventions for individuals with mild traumatic brain injury: a scoping review protocol

Corresponding author: Bonnie Swaine, École de réadaptation, Faculté de médecine, Université de Montréal, C. P. 6128, succursale Centre-ville, Montréal (Québec) H3C 3J7 Canada, bonnie.swaine@umontreal.ca, (514) 343-7361.

Co-authors information:

Christophe Alarie^{1,2}, Isabelle J. Gagnon^{3,4}, Enrico Quilico⁵, Bonnie Swaine^{1,2}.

- 1. École de Réadaptation, Faculté de Médecine, Université de Montréal, Montréal, Québec, Canada.
- 2. Centre for Interdisciplinary Research in Rehabilitation of Greater Montreal (CRIR), Montréal, Québec, Canada.
- 3. School of Physical and Occupational Therapy, Faculty of Medicine, McGill University, Montréal, Québec, Canada.
- 4. Trauma Center and Pediatric Emergency Medicine, Montreal Children's Hospital, McGill University Health Center, Montréal, Québec, Canada.
- 5. Rehabilitation Science Institute, University of Toronto, Toronto, Canada.

Co-authors e-mail addresses:

Christophe Alarie: christophe.alarie@umontreal.ca

Isabelle J. Gagnon: isabelle.gagnon8@mcgill.ca

Enrico Quilico: enrico.quilico@utoronto.ca

Word count: 2840 words.

ABSTRACT

Introduction: Traumatic Brain Injury (TBI) is a major public health problem and it is estimated that 85% of TBIs are diagnosed as mild (mTBI), and commonly referred to as a concussion. In adults, symptoms are expected to resolve within 10 to 14 days after the injury, but up to 15% of individuals continue to have symptoms beyond this period. Recent clinical recommendations suggest the use of physical activity (PA) as a therapy to manage persisting symptoms. However, the recommendations regarding PA lack clarity about important intervention parameters to help clinicians deliver the intervention. The objectives of this scoping review are thus to identify the characteristics, the measurement tools, the health-related outcomes and report effectiveness of PA-based interventions for adults with persisting symptoms of a mTBI.

Methods and analysis: This scoping review protocol will follow the Arksey and O'Malley's 6-step iterative process enhanced by Levac et al. and will be conducted by a team of researchers and clinical experts. Five databases (MEDLINE, CINAHL, PsycINFO, SPORTDiscuss and EMBASE), as well as Google will be searched using an extensive search strategy to capture relevant scientific and grey literature. Articles will be selected if they report on an intervention designed to have an impact on health-related outcomes or participation among individuals having sustained a mTBI. A data extraction form based on the Consensus on Exercise Report Template (CERT) and the Template for Intervention Description and Replication (TIDieR) checklists will be created. Quantitative and qualitative data will be analyzed accordingly, synthesized and collated in tables.

Ethics and dissemination: This scoping review generates new knowledge from published and publicly available literature, thus an ethical approval is unnecessary to conduct this research. Dissemination of the results will involve all team members in activities aimed to facilitate knowledge uptake among TBI rehabilitation clinical experts locally, nationally and internationally.

Keywords: physical activity, mild traumatic brain injury, concussion, mTBI, rehabilitation, scoping review.

ARTICLE SUMMARY
Strengths and limitations of this study:
1. This will be the first scoping review to critically appraise the characteristics of PA-based interventions designed to improve health-related outcomes in adults with persistent symptoms post mTBI.
2. Clinical partners will be integrated into the research process in a creative yet feasible way to ensure enhanced interpretation and better applicability of the results.
3. The combination of two expert consensus-based checklists (CERT & TIDieR) to guide the data extraction will allow better identification of key characteristics of PA-based interventions.
4. Although this study aims to describe the characteristics of PA-based interventions, it will not allow inferences about the effectiveness of these parameters which could be further investigated in a systematic review.
3

INTRODUCTION

 Traumatic brain injury (TBI) is a major public health problem and it is estimated that each year, more than 10 million individuals worldwide will experience a TBI that may result in either mortality or hospitalization.(1) Up to 85% of TBIs are diagnosed as mild TBI (mTBI),(2) and commonly referred to as a concussion.(3) A wide range of consequences may result from mTBI (e.g., headaches, anxiety, difficulty concentrating, fatigue and sleep disturbances),(4) which in turn, may limit the individual's activities, restrict their participation and decrease their quality of life.(5)

The symptoms of mTBI typically subside within 10 to 14 days after the injury in adults.(4) An individual who fails to recover completely within this time-frame is considered to have persisting symptoms,(4) and it is likely that 15% to 26% of individuals who sustain a mTBI will have persisting symptoms beyond three months.(6,7) Interventions aiming to reduce persisting physical and cognitive symptoms are critical in order to return to pre-injury functioning.(8,9)

Clinical practice guidelines (CPGs) aim to improve the quality and decrease the variability of healthcare services by providing clinical experts key evidenced-based recommendations to implement within their practices. (10) Based on the highest available evidence, CPGs for the management of adults with persisting symptoms of mTBI were developed to support clinical decision-making and improve rehabilitation outcomes. The Ontario Neurotrauma Foundation's CPG for adults with persisting symptoms of mTBI and the CPG for military personnel with mTBI produced by the American Department of Defense and Veterans Affairs both recommend using physical activity (PA) as a therapy to alleviate mTBI-related symptoms (e.g., headache, fatigue or sleep disturbances) and improve mood, health status and exercise tolerance. (6, 11) These CPGs corroborate recommendations from the latest Consensus Statement on Concussion in Sport, which suggests including a symptom-limited, progressive exercise intervention for individuals who experience persisting symptoms (>1 month) after mTBI.(4) Collectively, these

BMJ Open

recommendations promote the use of PA as an intervention that can help decrease and manage prolonged persistent symptoms of mTBI in adults.

These CPGs and consensus statements are fairly recent, but they lack specific information about how PA interventions should be delivered by service providers. Important PA intervention characteristics such as frequency, intensity, time, type of exercise and progression patterns, for example, are missing. This lack of clear parameters leaves clinicians using trial and error methods instead of an evidence-based approach. Indeed, the complexity and lack of applicability of recommendations are CPG-related barriers to the implementation and use of evidence-based recommendations.(12) Insufficient information about PA interventions leaves many clinical questions unanswered: Should the PA intervention be delivered in a group or individually? Should PA adherence be measured and if yes, how? Service providers who apply recommendations from CPGs also require assessment tools to evaluate the health-related outcomes of PA-interventions. For example, with the exception of the post-concussion symptoms scale in the CPGs, it is unclear which clinical tool should be used to measure the effectiveness of a PA intervention. Clear parameters that guide PA interventions may promote optimal dosage and type of planned PA in order to maximize benefits and accommodate individual preferences through different activities.(13)

The primary objective of this scoping review is to identify characteristics of PA-based interventions available in the scientific and grey literature designed to improve health-related outcomes in adults with persistent symptoms of a mTBI and report on the intervention's effectiveness, if available. The secondary objectives are to document the health-related outcomes and the measurement tools related to PA interventions found in the literature. This information could help researchers, health care-providers and clinicians select appropriate outcomes and outcome measurement tools for future research or PA program design and implementation.

METHODS AND ANALYSIS

Protocol

This scoping review will follow the 6-step iterative framework of Arksey and O'Malley, which was later enhanced by Levac, Colquhoun, and O'Brien in 2010 to ensure structure and rigor during a thorough investigation of the scientific and grey literature.(14, 15) This work will be conducted by a team of two doctoral students who are supervised by two rehabilitation scientists and assisted by four clinical experts and administrators from a specialized mTBI rehabilitation program (administrator, clinical coordinator, kinesiologist, and physiotherapist). The multidisciplinary clinical team was involved in the design of the study, and will participate in multiple key steps of this review as described below. This collaborative approach is a creative yet feasible way to involve clinical partners, as well as ensure an accurate interpretation of the review results and their applicability in the clinical setting. To better report this scoping review protocol, the authors used the PRISMA-P reporting guidelines and the PRISMA-ScR for scoping review extension.(16, 17)

Step 1: Identifying the research question

A preliminary consultation with the clinical partners led to the development of an initial research question that was used as a starting point to guide the development of the search strategy: *What are the characteristics and health-related outcomes of physical activities interventions designed for individuals with mild traumatic brain injury?* In the context of this review, we define PA based on a combination of two definitions. The World Health Organization (2018) defines PA "as any bodily movement produced by skeletal muscles that requires energy expenditure" and the 2007 Oxford dictionary's definition adds: "Any form of body movement that has a significant metabolic demand. Thus, physical activities include training for and participation in athletic competitions, the performance of strenuous occupations, doing household chores, and non-sporting leisure activities involve physical effort."(18,19). This definition would thus refer to different types of activities involving a physical effort, ranging from recreation activities such as walking slowly to high-intensity aerobic training. Knitting in a chair, would not be

BMJ Open

considered a PA in the scoping review. The research question is subject to change during the process as new questions and reflections might emerge during each iterative step of the scoping review.

Step 2: Identifying relevant studies

Literature will be selected if it reports on an intervention, provided in any setting (e.g. inpatient or outpatient rehabilitation) or in the community, designed to impact on health-related (physical, mental, psychosocial) outcomes or participation in individuals of all ages having sustained any severity of TBI. However, at least one participant in the study sample must have sustained a mTBI. Moreover, the intervention may target persons with all types of injury severity, but it must be pertinent for persons with mTBI. For example, interventions such as constraint-induced movement therapy is indicated for an individual with a motor impaired upper extremity and not particularly for someone with a mTBI.(20, 21) Consequently, articles on this intervention would be excluded. Articles with participants of all ages will be included because the age range of subjects in pediatric studies can include teenagers, which might overlap with young adults.

PA interventions are used in many fields of research (i.e. rehabilitation sciences, education, psychology, exercise sciences) and thus can be presented in many formats. Consequently, the literature search will cover published and unpublished literature (grey literature), including original research, theses and books. A broad yet feasible range of five databases (MEDLINE, CINAHL, PsycINFO, SPORTDiscuss and EMBASE) will be accessed using an extensive search strategy validated by a specialized university librarian. Keywords related to TBI and PA corresponding to subject headings (or MeSH) will be included in the search strategy (e.g. *Brain Injuries, Traumatic, Brain Concussion, Exercise Therapy, Exercise*). Other relevant keywords will be added to the search strategy to enhance the strategy, and are used to search titles, abstracts and subjects of references contained in the databases (e.g. *mild traumatic brain injury, mTBI, physical fitness, motor activity*). The search strategy is provided in the supplementary file (Supplementary file I).

Through an iterative and concerted process, analysis of the search results and retrieved articles will guide the refinement of the search strategy to achieve a balance between feasibility and breadth. Opinion articles, posters, oral presentations, and abstracts from conferences will be excluded because they may lack explicit information about reported interventions. Systematic reviews will be excluded, but their reference lists will be examined by the authors to ensure relevant articles are retained. Animal model studies will also be excluded due to their lack of applicability to human study contexts.

The grey literature search will be conducted on Google online in the future using a modified version of the final search strategy to find TBI-related PA interventions described in other formats such as PDF documents, books, and websites in the first 10 pages of results (approximately 100 results). Moreover, a hand search of reference lists of all selected documents will be performed to ensure that all key studies are captured. Each added reference to the initial search will be documented and will be reported in a PRISMA flow chart created for this study.(22) Languages will be restricted to both French and English, as authors are fluent in both languages. Searches will be limited to published literature after 1990 when recommendations about PA were first established.(23) Results will be managed using reference manager software (Endnote) and duplicates will be removed before selection.

Page 9 of 20

Step 3: Study Selection

Study selection will be conducted by two independent reviewers in two subsequent phases: 1) abstract and title review; 2) full-text review. Based on initial eligibility criteria, the reviewers will start to examine/discuss a random sample of 100 retrieved references to determine whether the article should be considered, rejected, or if they are unsure. Inter-rater reliability (IRR) will be computed with a 3-level Kappa (κ) statistic. As needed, the eligibility criteria will be discussed by the researchers and modified for more clarity. This initial selection process will be repeated with a sample of 300-500 references until the agreement between the two reviewers reaches a mean $\kappa > .75$ (κ >.75= excellent agreement).(24) When acceptable agreement is achieved, the reviewers will independently assess the remaining articles. They will also meet at the mid-point and endpoint of remaining articles to discuss any changes, thoughts or needs for clarification. The full-text review phase will follow the same rigorous method in order to determine IRR. This time, 10 to 20 articles will be randomly selected and cross-examined by the same two reviewers, and then re-examined independently until they reach excellent agreement or a mean $\kappa > .75$. If a disagreement cannot be resolved through consensus in any of the two phases, a third independent reviewer will be consulted. Reasons for excluded articles during the second phase will be reported in the PRISMA flow chart. As the selection unfolds, criteria can be refined or clarified if needed and if a criterion is modified at a later stage of the article selection, authors will ensure that the previous steps will comply with the change and report the changes in the PRISMA flow chart.

Step 4: Charting the Data

A preliminary data extraction form will be created in an Excel spreadsheet based on the combination of the 12-item Template for Intervention Description and Replication checklist (TIDieR) and the 16-item Consensus on Exercise Reporting Template checklist (CERT).(25, 26) Both checklists were systematically developed to improve the quality of reporting interventions in rehabilitation sciences. However, the CERT includes specific key items to better report an exercise program (e.g. motivation strategies, decision rules for

determining exercise progression, decision rules to describe the starting level, etc.). Descriptive quantitative data about the number, the age and the gender of participants with an mTBI included in each article will be extracted. More qualitative information related to each item of the extraction form will be extracted from each selected article. For example, all information related to the type of exercise equipment (CERT Item 1), a home-program (CERT Item 8), description of the exercise intervention (CERT Item 13), the setting in which the exercises are performed (CERT Item 12) or about the extracted. If no information was provided about a specific item in an article, it will also be noted and compiled. CERT was designed to be used in conjunction with the TIDIER Checklist. Due to the overlap of items from both checklist information, only 2 items from the TIDIER will be included in the data extraction form (Item 1: Name of the intervention; Item 2: Rationale, theory or goals of the intervention).

The extraction form will also consist of other categories including, but not limited to, primary and secondary outcomes, measurement tools and effectiveness. The clinical partners will validate this extraction form during a second consultation and additional categories may be included during the iterative process if deemed appropriate by the team.

Data will be extracted from the selected articles and tabulated by two independent reviewers. A sample of 5 studies will be extracted by each reviewer and then compared during a work session to ensure compatibility between extraction methods and to enhance the extraction form, with new or more precise categories if needed. The extraction team will repeat this process until the extractors/reviewers agree that they consistently assess and extract information from each article in a compatible way. Then, reviewers will meet regularly (e.g., every 10 - 20 articles) to address any challenges and ensure concordance with their reporting methods.

Step 5: Collating, summarizing and reporting the results

Analyses of the quantitative and qualitative data will be performed by the researchers. Quantitative data such as numerical descriptive characteristics of PA interventions (e.g. year of publication, age and number of mTBI individuals in the study, number of interventions using motivation strategies) will be summarized into tables. In addition, selected articles reporting on PA interventions will be carefully assessed with the CERT Checklist assessment form. (26) Each of the checklist's 16 items will be categorized as yes if the information was provided or *no* if the information is missing. Following a similar process for reliability, two independent reviewers will assess a small subset of articles and will compare their results. Discrepancies in assessment will be resolved through discussion and this step will be repeated until reviewers reach excellent IRR of $\kappa > .75$. Then, the first author will assess the remaining article. Qualitative data will be synthesized and collated in tables. Quantitative results may be presented graphically (e.g. number of PA interventions per study per year, % of types of interventions) and qualitative results may be presented narratively and/or in tables. The different PA characteristics and key PA principles will be summarized and reported in multiple matrices. Outcome constructs and measurement tools will be reported and summarized in tables. Measurements tools used in the different studies/articles will also aggregated into categories and summarized in tables.

Step 6: Consultation with stakeholders

The clinical experts mentioned above will be consulted throughout the review process (i.e., prior to the development of the study to define the research question, and while designing the research protocol to validate and possibly enhance the data extraction form). Consultation will also occur at the end of the review to assist with the interpretation of the results in order to improve their clinical relevance and determine the best ways to mobilize the knowledge generated by the review.

Patient and public involvement:

Patients and the public will not be involved in this scoping review.

ETHICAL CONSIDERATIONS AND DISSEMINATION

A scoping review generates new knowledge from published and publicly available literature and does not involve human participants. Therefore, a Research Ethics Board approval is unnecessary to conduct this research. Although our clinical partners will be involved in multiple steps of the study, they are primarily involved as expert consultants and their input may deepen the understanding and enhance the scope of the results. Members of the group will work together during work sessions to co-create a final document that will be used to help disseminate the results of this review to other clinicians working in TBI rehabilitation. Dissemination of the results will involve all team members through regional, national and international scientific and clinical activities and conferences, the publication of a manuscript, and other activities aimed to generate awareness and increase knowledge uptake of TBI rehabilitation clinical experts.

CONCLUSION

The results of this scoping review will provide detailed information about the state of the existing literature regarding the important characteristics, intervention parameters, and tools to measure health-related outcomes of PA-based interventions designed for adults with persistent symptoms of mTBI. These results may assist clinical experts with the use of PA in the management of mTBI adults and ultimately improve patient outcomes. Moreover, the results of this scoping review will inform researchers about the effectiveness of multiple PA parameters, which may be further investigated in a systematic review.

REFERENCES

1. Hyder AA, Wunderlich CA, Puvanachandra P, et al. The impact of traumatic brain injuries: a global perspective. *NeuroRehabilitation* 2007;22(5):341-53.

2. Feigin VL, Theadom A, Barker-Collo S, et al. Incidence of traumatic brain injury in New Zealand: a population-based study. *Lancet Neurol* 2013;12(1):53-64.

3. Marshall S, Bayley M, McCullagh S, et al. Updated clinical practice guidelines for concussion/mild traumatic brain injury and persistent symptoms. *Brain Inj* 2015;29(6):688-700.

4. McCrory P, Meeuwisse W, Dvorak J, et al. Consensus statement on concussion in sport—the 5th international conference on concussion in sport held in Berlin, October 2016. *Br J Sports med* 2017;0 :1-10.

5. Perroux M, Lefebvre H, Levert MJ, et al. Besoins perçus et participation sociale des personnes ayant un traumatisme crânien léger. *Santé Publique* 2013;25(6):719-728.

6. Ontario Neurotrauma Foundation. Guideline For Concussion/mild Traumatic Brain Injury & Persistent Symptoms 3Rrd Edition, For Adults Over 18 Years of Age. 2018. Available from: http://braininjuryguidelines.org/concussion/index.php?id=1 (accessed october 2018).

7. Cassidy JD, Cancelliere C, Caroll LJ, et al. Systematic Review of Self-Reported Prognosis in Adults After Mild Traumatic Brain Injury: Results of the International Collaboration on Mild Traumatic Brain Injury Prognosis. *Arch Phys Med Rehabil* 2014;95(3):S132-S151.

8. Makdissi M, Schneider KJ, Feddermann-Demont N, et al. Approach to investigation and treatment of persistent symptoms following sport-related concussion: a systematic review. *Br J Sports med* 2017;51(12):958-968. 9. Schneider KJ, Leddy JJ, Guskiewicz KM, et al. Rest and treatment/rehabilitation following sport-related concussion: a systematic review. *Br J Sports med* 2017;51(12):930-934.

10. Lohr KN, Field MJ. Guidelines for clinical practice: from development to use. Washington, WASH DC, *National Academies Press* 1992.

11. Department of Veterans Affairs, Department of Defense. VA/DoD clinical practice guideline for management of concussion/mild traumatic brain injury. 2016. Available from: https://www.healthquality.va.gov/guidelines/Rehab/mtbi/ (accessed october 2018).

12. Fischer F, Lange K, Klose K, et al. Barriers and Strategies in Guideline Implementation—A Scoping Review. *Healthcare* 2016;4(3):36.

13. Ammann BC, Knols RH, Baschung P, et al. Application of principles of exercise training in sub-acute and chronic stroke survivors: a systematic review. *BMC neurol* 2014;14(1):167-178.

14. Arksey H, O'Malley L. Scoping studies: towards a methodological framework. *Int J Soc Res Methodol* 2005;8(1):19-32.

15. Levac D, Colquhoun H, O'Brien KK. Scoping studies: advancing the methodology. *Implement Sci* 2010;5(1):69-78.

16. Moher D, Shamseer L, Clarke M, et al. Preferred Reporting Items for Systematic Review and Meta-Analysis Protocols (PRISMA-P) 2015 statement. *Syst Rev* 2015;4(1):1.

17. Tricco AC, Lillie E, Zarin W et al. PRISMA Extension for Scoping Reviews (PRISMA-ScR): Checklist and Explanatation. *Ann Intern Med* 2018;169(7):467-473.

World health organisation. Global Strategy on Diet, Physical Activity and Health.
Available from: https://www.who.int/dietphysicalactivity/pa/en/ (accessed october 2018).

19. Kent, M. Oxford dictionary of sports science and medicine. *J Sports Sci Med* 2007;6(1):152-152.

20. Sirtori V, Corbetta D, Moja L, et al. Constraint-induced movement therapy for upper extremities in stroke patients. *Cochrane Database Syst Rev* 2009;7(4).

21. Hoare BJ, Wasiak J, Imms C, et al. Constraint-induced movement therapy in the treatment of the upper limb in children with hemiplegic cerebral palsy. *Cochrane Database Syst Rev* 2007;18(2).

22. Moher D, Liberati A, Tetzlaff J, et al. Preferred reporting items for systematic reviews and meta-analyses: the PRISMA statement. *Ann Intern Med* 2009;151(4):264-269.

23. Pollock MLP, Froelicher VFMD. Position Stand of the American College of Sports Medicine: The Recommended Quantity and Quality of Exercise for Developing and Maintaining Cardiorespiratory and Muscular Fitness in Healthy Adults. *J Cardiopulm Rehabil* 1990;10(7):235-45.

24. Orwin RG, Cooper IH, Hedges LV. In: Orwin RG, Cooper IH, Hedges LV. The handbook of research synthesis." New York, NY, *Russell Sage Foundation* 1994:139-162.

25. Hoffmann TC, Glasziou PP, Boutron I, et al. Better reporting of interventions: template for intervention description and replication (TIDieR) checklist and guide. *BMJ* 2014;348:g1687.

26. Slade SC, Dionne CE, Underwood M, et al.Consensus on Exercise Reporting Template (CERT): explanation and elaboration statement. *Br J Sports Med* 2016;0:1-10.

to beet terien only

AUTHORS CONTRIBUTIONS

Acknowledgement: We thank the clinical partners, Pierre Vincent, Geneviève Léveillé and Pierre Goulet for their involvement in the identification of the research question and future involvement in the consultation steps.

Author statement: CA, IG, EQ and BS designed the protocol. CA drafted the manuscript. CA, IG, EQ and BS reviewed the manuscript and approved the final version. All authors will participate in the 6 steps.

FUNDING

This work is supported by the Edith Strauss Rehabilitation Research Projects Foundation. This grant will provide salary support to CA and EQ.

COMPETING INTEREST

None declared. ETHICS Ethical approval: None required.

Patient consent: None required.

DATA SHARING

There are no additional data to be shared with this study protocol.

Cumplementers file I
Supplementary file I Full search strategy for Medline database
1. exp brain injuries, traumatic/ or exp brain concussion/
2. (mild traumatic brain injur* or concussi* or postconcuss* or post-concuss*or traumatic brain injur* or TBI or mTBI or Closed head injur*).ab,kf,kw,ti.
3. exp Exercise Therapy/
4. exp Physical Fitness/
5. exp Exercise/
6. exp Motor Activity/
7. (Physical activit* or Motor activit* or Exercise* or Physical fitness or Exercise therap*).ab,kf,kw,ti.
8. 1 or 2
9. 3 or 4 or 5 or 6 or 7
10. 8 and 9
11. limit 10 to (humans and yr="1990 -Current" and (english or french))

PRISMA Extension for Scoping Reviews (PRISMA-ScR): Checklist

1	
2	
3	
4	
5	
6	
7	
, 8	
9	
9 10	
11	
12	
13	
14	
15	
16	
17	
18	
19	
20	
20	
21 22	
22 23	
24	
25	
26	
27	
28	
29	
30	
31	
32	
33	
34	
34 35	
36	
37	
38	
39	
40	
41	
42	
43	
44	
45	
46	
40 47	
48	
49	
50	
51	
52	
53	
54	
55	
56	
57	
58	
20	

59

Section	Item	Prisma-ScR Checklist Item	Page number and comments.
Title	1	Identify the report as a scoping review.	1, 6
Abstract (Structured summary)	2	Provide a structured summary.	2
Introduction			
Rationale	3	Describe the rationale for the review in the context of what is already known.	4,5
Objectives	4	Provide an explicit statement of the question(s) the review will address with reference to participants, interventions, comparators, and outcomes (PICO).	5,6
Methods			
Protocol and registration	5	Indicate whether a review protocol exist.	n/a This is the submission for the review protocol.
Elligibility criteria	6	Specify characteristics of the sources of the evidence used as eligibility criteria.	7,8
Information sources	7	Describe all intended information sources.	7,8
Search strategy	8	Present the full electronic search strategy for at least one database.	7.8 for examples and an appendix wi be provided.
Selection of sources of evidence	9	State the process for selecting sources of evidence.	7,8,9
Data charting process	10	Describe the methods of charting data from the included sources of evidence.	9,10
Data items	11	List and define all variables for which data were sought and any assumptions and simplifications made.	9,10
Critical appraisal of individual source of evidence	12	If done, provide a rationale for conducting a critical appraisal of included source of evidence.	9,10
Summary measures	13	Not applicable for scoping reviews.	
Synthesis of results	14	Describe the methods of handling and summarizing the data were charted.	n/a, this is a protocol.
Risk of bias across studies	15	Not applicable for scoping reviews.	
Additional analyses	16	Not applicable for scoping reviews.	
RESULTS			
Selection of	17	Give number of source of evidence screened,	Will be provided in a flow diagram.

sources of evidence		assessed for eligibility, and included in the review, with reason for exclusion at each stage, ideally using a flow diagram.	Page 8
Characteristic of source of evidence	18	For each sources of evidence, present characteristics for which data were charted and provide the citations.	Will be provided
Critical appraisal within source of evidence	19	If done, present data on critical appraisal of included sources of evidence.	Will be provided
Results of individual sources of evidence	20	For each included source of evidence, present the relevant data that were charted that relate to the review questions and objectives.	Will be provided
Synthesis of results	21	Summarize and/or present the charting results as they relate to the review questions and objectives.	10,11
Risk of bias across studies	22	Not applicable for scoping reviews.	
Additional analyses	23	Not applicable for scoping reviews.	
Discussion			
Summary of evidence	24	Summarize the main results	Will be provided
Limitations	25	Discuss the limitations of the scoping review process.	Will be provided but some are mentioned at page 3
Conclusions	26	Provide a general interpretation of the results with respect to the review questions and objectives, as well as potential implications and/or next steps.	Will be provided.
Funding	27	Describe sources of funding for the included sources of evidence as well as sources for the scoping review.	Will be provided. Page 17
			2

BMJ Open

Characteristics and outcomes of physical activity interventions for individuals with mild traumatic brain injury: a scoping review protocol

Journal:	BMJ Open
Manuscript ID	bmjopen-2018-027240.R2
Article Type:	Protocol
Date Submitted by the Author:	19-Feb-2019
Complete List of Authors:	Alarie, Christophe; Université de Montréal, École de réadaptation; Centre de recherche interdisciplinaire en réadaptation du Montréal metropolitain Gagnon, Isabelle; McGill University, School of Physical and Occupational Therapy; Montreal Children's Hospital of the McGill University Health Center, Trauma Quilico, Enrico; University of Toronto, Rehabilitation Science Institute Swaine, Bonnie; Université de Montréal, École de réadaptation; Centre de recherche interdisciplinaire en réadaptation du Montréal metropolitain
Primary Subject Heading :	Sports and exercise medicine
Secondary Subject Heading:	Rehabilitation medicine, Health services research
Keywords:	Physical Activity, Mild Traumatic Brain Injury, Concussion, mTBI, Rehabilitation, Scoping Review

SCHOLARONE[™] Manuscripts

BMJ Open

Characteristics and outcomes of physical activity interventions for individuals with mild traumatic brain injury: a scoping review protocol

Corresponding author: Bonnie Swaine, École de réadaptation, Faculté de médecine, Université de Montréal, C. P. 6128, succursale Centre-ville, Montréal (Québec) H3C 3J7 Canada, bonnie.swaine@umontreal.ca, (514) 343-7361.

Co-authors information:

Christophe Alarie^{1,2}, Isabelle J. Gagnon^{3,4}, Enrico Quilico⁵, Bonnie Swaine^{1,2}.

- 1. École de Réadaptation, Faculté de Médecine, Université de Montréal, Montréal, Québec, Canada.
- 2. Centre for Interdisciplinary Research in Rehabilitation of Greater Montreal (CRIR), Montréal, Québec, Canada.
- 3. School of Physical and Occupational Therapy, Faculty of Medicine, McGill University, Montréal, Québec, Canada.
- 4. Trauma Center and Pediatric Emergency Medicine, Montreal Children's Hospital, McGill University Health Center, Montréal, Québec, Canada.
- 5. Rehabilitation Science Institute, University of Toronto, Toronto, Canada.

Co-authors e-mail addresses:

Christophe Alarie: christophe.alarie@umontreal.ca

Isabelle J. Gagnon: isabelle.gagnon8@mcgill.ca

Enrico Quilico: enrico.quilico@utoronto.ca

Word count: 2856 words.

ABSTRACT

Introduction: Traumatic Brain Injury (TBI) is a major public health problem and it is estimated that 85% of TBIs are diagnosed as mild (mTBI), and commonly referred to as a concussion. In adults, symptoms are expected to resolve within 10 to 14 days after the injury, but up to 15% of individuals continue to have symptoms beyond this period. Recent clinical recommendations suggest the use of physical activity (PA) as a therapy to manage persisting symptoms. However, the recommendations regarding PA lack clarity about important intervention parameters to help clinicians deliver the intervention. The objectives of this scoping review are thus to identify the characteristics, the measurement tools, the health-related outcomes and report effectiveness of PA-based interventions for adults with persisting symptoms of a mTBI.

Methods and analysis: This scoping review protocol will follow the Arksey and O'Malley's 6-step iterative process enhanced by Levac et al. and will be conducted by a team of researchers and clinical experts. Five databases (MEDLINE, CINAHL, PsycINFO, SPORTDiscuss and EMBASE), as well as Google will be searched using an extensive search strategy to capture relevant scientific and grey literature. Articles will be selected if they report on an intervention designed to have an impact on health-related outcomes or participation among individuals having sustained a mTBI. A data extraction form based on the Consensus on Exercise Report Template (CERT) and the Template for Intervention Description and Replication (TIDieR) checklists will be created. Quantitative and qualitative data will be analyzed accordingly, synthesized and collated in tables.

Ethics and dissemination: This scoping review generates new knowledge from published and publicly available literature, thus an ethical approval is unnecessary to conduct this research. Dissemination of the results will involve all team members in activities aimed to facilitate knowledge uptake among TBI rehabilitation clinical experts locally, nationally and internationally.

Keywords: physical activity, mild traumatic brain injury, concussion, mTBI, rehabilitation, scoping review.

ARTICLE SUMMARY
Strengths and limitations of this study:
1. This will be the first scoping review to critically appraise the characteristics of PA-based interventions designed to improve health-related outcomes in adults with persistent symptoms post mTBI.
2. Clinical partners will be integrated into the research process in a creative yet feasible way to ensure enhanced interpretation and better applicability of the results.
3. The combination of two expert consensus-based checklists (CERT & TIDieR) to guide the data extraction will allow better identification of key characteristics of PA-based interventions.
4. Although this study aims to describe the characteristics of PA-based interventions, it will not allow inferences about the effectiveness of these parameters which could be further investigated in a systematic review.
3

INTRODUCTION

 Traumatic brain injury (TBI) is a major public health problem and it is estimated that each year, more than 10 million individuals worldwide will experience a TBI that may result in either mortality or hospitalization.(1) Up to 85% of TBIs are diagnosed as mild TBI (mTBI),(2) and commonly referred to as a concussion.(3) A wide range of consequences may result from mTBI (e.g., headaches, anxiety, difficulty concentrating, fatigue and sleep disturbances),(4) which in turn, may limit the individual's activities, restrict their participation and decrease their quality of life.(5)

The symptoms of mTBI typically subside within 10 to 14 days after the injury in adults.(4) An individual who fails to recover completely within this time-frame is considered to have persisting symptoms,(4) and it is likely that 15% to 26% of individuals who sustain a mTBI will have persisting symptoms beyond three months.(6,7) Interventions aiming to reduce persisting physical and cognitive symptoms are critical in order to return to pre-injury functioning.(8,9)

Clinical practice guidelines (CPGs) aim to improve the quality and decrease the variability of healthcare services by providing clinical experts key evidenced-based recommendations to implement within their practices. (10) Based on the highest available evidence, CPGs for the management of adults with persisting symptoms of mTBI were developed to support clinical decision-making and improve rehabilitation outcomes. The Ontario Neurotrauma Foundation's CPG for adults with persisting symptoms of mTBI and the CPG for military personnel with mTBI produced by the American Department of Defense and Veterans Affairs both recommend using physical activity (PA) as a therapy to alleviate mTBI-related symptoms (e.g., headache, fatigue or sleep disturbances) and improve mood, health status and exercise tolerance. (6, 11) These CPGs corroborate recommendations from the latest Consensus Statement on Concussion in Sport, which suggests including a symptom-limited, progressive exercise intervention for individuals who experience persisting symptoms (>1 month) after mTBI.(4) Collectively, these

BMJ Open

recommendations promote the use of PA as an intervention that can help decrease and manage prolonged persistent symptoms of mTBI in adults.

These CPGs and consensus statements are fairly recent, but they lack specific information about how PA interventions should be delivered by service providers. Important PA intervention characteristics such as frequency, intensity, time, type of exercise and progression patterns, for example, are missing. This lack of clear parameters leaves clinicians using trial and error methods instead of an evidence-based approach. Indeed, the complexity and lack of applicability of recommendations are CPG-related barriers to the implementation and use of evidence-based recommendations.(12) Insufficient information about PA interventions leaves many clinical questions unanswered: Should the PA intervention be delivered in a group or individually? Should PA adherence be measured and if yes, how? Service providers who apply recommendations from CPGs also require assessment tools to evaluate the health-related outcomes of PA-interventions. For example, with the exception of the post-concussion symptoms scale in the CPGs, it is unclear which clinical tool should be used to measure the effectiveness of a PA intervention. Clear parameters that guide PA interventions may promote optimal dosage and type of planned PA in order to maximize benefits and accommodate individual preferences through different activities.(13)

The primary objective of this scoping review is to identify characteristics of PA-based interventions available in the scientific and grey literature designed to improve health-related outcomes in adults with persistent symptoms of a mTBI and report on the intervention's effectiveness, if available. The secondary objectives are to document the health-related outcomes and the measurement tools related to PA interventions found in the literature. This information could help researchers, health care-providers and clinicians select appropriate outcomes and outcome measurement tools for future research or PA program design and implementation.

METHODS AND ANALYSIS

Protocol

This scoping review will follow the 6-step iterative framework of Arksey and O'Malley, which was later enhanced by Levac, Colquhoun, and O'Brien in 2010 to ensure structure and rigor during a thorough investigation of the scientific and grey literature.(14, 15) This work will be conducted by a team of two doctoral students who are supervised by two rehabilitation scientists and assisted by four clinical experts and administrators from a specialized mTBI rehabilitation program (administrator, clinical coordinator, kinesiologist, and physiotherapist). The multidisciplinary clinical team was involved in the design of the study, and will participate in multiple key steps of this review as described below. This collaborative approach is a creative yet feasible way to involve clinical partners, as well as ensure an accurate interpretation of the review results and their applicability in the clinical setting. To better report this scoping review protocol, the authors used the PRISMA-P reporting guidelines and the PRISMA-ScR for scoping review extension.(16, 17)

Step 1: Identifying the research question

A preliminary consultation with the clinical partners led to the development of an initial research question that was used as a starting point to guide the development of the search strategy: *What are the characteristics and health-related outcomes of physical activities interventions designed for individuals with mild traumatic brain injury?* In the context of this review, we define PA based on a combination of two definitions. The World Health Organization (2018) defines PA "as any bodily movement produced by skeletal muscles that requires energy expenditure" and the 2007 Oxford dictionary's definition adds: "Any form of body movement that has a significant metabolic demand. Thus, physical activities include training for and participation in athletic competitions, the performance of strenuous occupations, doing household chores, and non-sporting leisure activities involve physical effort."(18,19). This definition would thus refer to different types of activities involving a physical effort, ranging from recreation activities such as walking slowly to high-intensity aerobic training. Knitting in a chair, would not be

BMJ Open

considered a PA in the scoping review. The research question is subject to change during the process as new questions and reflections might emerge during each iterative step of the scoping review.

Step 2: Identifying relevant studies

Literature will be selected if it reports on a PA-based intervention, provided in any setting (e.g. inpatient or outpatient rehabilitation) or in the community, designed to impact on health-related (physical, mental, psychosocial) outcomes or participation in individuals of all ages having sustained any severity of TBI. However, at least one participant in the study sample must have sustained a mTBI. Moreover, the intervention may target persons with all types of injury severity, but it must be pertinent for persons with mTBI. For example, interventions such as constraint-induced movement therapy is indicated for an individual with a motor impaired upper extremity and not particularly for someone with a mTBI.(20, 21) Consequently, articles on this intervention would be excluded. Articles with participants of all ages will be included because the age range of subjects in pediatric studies can include teenagers, which might overlap with young adults.

PA interventions are used in many fields of research (i.e. rehabilitation sciences, education, psychology, exercise sciences) and thus can be presented in many formats. Consequently, the literature search will cover published and unpublished literature (grey literature), including original research, theses and books. A broad yet feasible range of five databases (MEDLINE, CINAHL, PsycINFO, SPORTDiscuss and EMBASE) will be accessed using an extensive search strategy validated by a specialized university librarian. Keywords related to TBI and PA corresponding to subject headings (or MeSH) will be included in the search strategy (e.g. *Brain Injuries, Traumatic, Brain Concussion, Exercise Therapy, Exercise*). Other relevant keywords will be added to the search strategy to enhance the strategy, and are used to search titles, abstracts and subjects of references contained in the databases (e.g. *mild traumatic brain injury, mTBI, physical fitness, motor activity*). The search strategy is provided in the supplementary file (Supplementary file I).

Through an iterative and concerted process, analysis of the search results and retrieved articles will guide the refinement of the search strategy to achieve a balance between feasibility and breadth. Opinion articles, posters, oral presentations, and abstracts from conferences will be excluded because they may lack explicit information about reported interventions. Systematic reviews will be excluded, but their reference lists will be examined by the authors to ensure relevant articles are retained. Animal model studies will also be excluded due to their lack of applicability to human study contexts.

The grey literature search will be conducted on Google online in the future using a modified version of the final search strategy to find TBI-related PA interventions described in other formats such as PDF documents, books, and websites in the first 10 pages of results (approximately 100 results). Moreover, a hand search of reference lists of all selected documents will be performed to ensure that all key studies are captured. Each added reference to the initial search will be documented and will be reported in a PRISMA flow chart created for this study.(22) Languages will be restricted to both French and English, as authors are fluent in both languages. Searches will be limited to published literature after 1990 when recommendations about PA were first established.(23) Results will be managed using reference manager software (Endnote) and duplicates will be removed before selection.

Page 9 of 20

Step 3: Study Selection

Study selection will be conducted by two independent reviewers in two subsequent phases: 1) abstract and title review; 2) full-text review. Based on initial eligibility criteria, the reviewers will start to examine/discuss a random sample of 100 retrieved references to determine whether the article should be considered, rejected, or if they are unsure. Inter-rater reliability (IRR) will be computed with a 3-level Kappa (κ) statistic. As needed, the eligibility criteria will be discussed by the researchers and modified for more clarity. This initial selection process will be repeated with a sample of 300-500 references until the agreement between the two reviewers reaches a mean $\kappa > .75$ (κ >.75= excellent agreement).(24) When acceptable agreement is achieved, the reviewers will independently assess the remaining articles. They will also meet at the mid-point and endpoint of remaining articles to discuss any changes, thoughts or needs for clarification. The full-text review phase will follow the same rigorous method in order to determine IRR. This time, 10 to 20 articles will be randomly selected and cross-examined by the same two reviewers, and then re-examined independently until they reach excellent agreement or a mean $\kappa > .75$. If a disagreement cannot be resolved through consensus in any of the two phases, a third independent reviewer will be consulted. Reasons for excluded articles during the second phase will be reported in the PRISMA flow chart. As the selection unfolds, criteria can be refined or clarified if needed and if a criterion is modified at a later stage of the article selection, authors will ensure that the previous steps will comply with the change and report the changes in the PRISMA flow chart.

Step 4: Charting the Data

A preliminary data extraction form will be created in an Excel spreadsheet based on the combination of the 12-item Template for Intervention Description and Replication checklist (TIDieR) and the 16-item Consensus on Exercise Reporting Template checklist (CERT).(25, 26) Both checklists were systematically developed to improve the quality of reporting interventions in rehabilitation sciences. However, the CERT includes specific key items to better report an exercise program (e.g. motivation strategies, decision rules for

determining exercise progression, decision rules to describe the starting level, etc.). Descriptive quantitative data about the number, the age and the gender of participants with an mTBI included in each article will be extracted. More qualitative information related to each item of the extraction form will be extracted from each selected article. For example, all information related to the type of exercise equipment (CERT Item 1), a home-program (CERT Item 8), description of the exercise intervention (CERT Item 13), the setting in which the exercises are performed (CERT Item 12) or about the extracted. If no information was provided about a specific item in an article, it will also be noted and compiled. CERT was designed to be used in conjunction with the TIDIER Checklist. Due to the overlap of items from both checklist information, only 2 items from the TIDIER will be included in the data extraction form (Item 1: Name of the intervention; Item 2: Rationale, theory or goals of the intervention).

The extraction form will also consist of other categories including, but not limited to, primary and secondary outcomes, measurement tools and effectiveness. The clinical partners will validate this extraction form during a second consultation and additional categories may be included during the iterative process if deemed appropriate by the team.

Data will be extracted from the selected articles and tabulated by two independent reviewers. A sample of 5 studies will be extracted by each reviewer and then compared during a work session to ensure compatibility between extraction methods and to enhance the extraction form, with new or more precise categories if needed. The extraction team will repeat this process until the extractors/reviewers agree that they consistently assess and extract information from each article in a compatible way. Then, reviewers will meet regularly (e.g., every 10 - 20 articles) to address any challenges and ensure concordance with their reporting methods.

Step 5: Collating, summarizing and reporting the results

Analyses of the quantitative and qualitative data will be performed by the researchers. Quantitative data such as numerical descriptive characteristics of PA interventions (e.g. year of publication, age and number of mTBI individuals in the study, number of interventions using motivation strategies) will be summarized into tables. In addition, selected articles reporting on PA interventions will be carefully assessed with the CERT Checklist assessment form. (26) Each of the checklist's 16 items will be categorized as yes if the information was provided or *no* if the information is missing. Following a similar process for reliability, two independent reviewers will assess a small subset of articles and will compare their results. Discrepancies in assessment will be resolved through discussion and this step will be repeated until reviewers reach excellent IRR of $\kappa > .75$. Then, the first author will assess the remaining article. Qualitative data will be synthesized and collated in tables. Quantitative results may be presented graphically (e.g. number of PA interventions per study per year, % of types of interventions) and qualitative results may be presented narratively and/or in tables. The different PA characteristics and key PA principles will be summarized and reported in multiple matrices. Outcome constructs and measurement tools will be reported and summarized in tables. Measurements tools used in the different studies/articles will also aggregated into categories and summarized in tables.

Step 6: Consultation with stakeholders

The clinical experts mentioned above will be consulted throughout the review process (i.e., prior to the development of the study to define the research question, and while designing the research protocol to validate and possibly enhance the data extraction form). Consultation will also occur at the end of the review to assist with the interpretation of the results in order to improve their clinical relevance and determine the best ways to mobilize the knowledge generated by the review.

Patient and public involvement:

Patients and the public will not be involved in this scoping review.

ETHICAL CONSIDERATIONS AND DISSEMINATION

A scoping review generates new knowledge from published and publicly available literature and does not involve human participants. Therefore, a Research Ethics Board approval is unnecessary to conduct this research. Although our clinical partners will be involved in multiple steps of the study, they are primarily involved as expert consultants and their input may deepen the understanding and enhance the scope of the results. Members of the group will work together during work sessions to co-create a final document that will be used to help disseminate the results of this review to other clinicians working in TBI rehabilitation. Dissemination of the results will involve all team members through regional, national and international scientific and clinical activities and conferences, the publication of a manuscript, and other activities aimed to generate awareness and increase knowledge uptake of TBI rehabilitation clinical experts.

DISCUSSION

The results of this scoping review will provide detailed information about the state of the existing literature regarding the important characteristics, intervention parameters, and tools to measure health-related outcomes of PA-based interventions designed for adults with persistent symptoms of mTBI. These results may assist clinical experts with the use of PA in the management of mTBI adults and ultimately improve patient outcomes. Moreover, the results of this scoping review will inform researchers about the effectiveness of multiple PA parameters, which may be further investigated in a systematic review.

REFERENCES

1. Hyder AA, Wunderlich CA, Puvanachandra P, et al. The impact of traumatic brain injuries: a global perspective. *NeuroRehabilitation* 2007;22(5):341-53.

2. Feigin VL, Theadom A, Barker-Collo S, et al. Incidence of traumatic brain injury in New Zealand: a population-based study. *Lancet Neurol* 2013;12(1):53-64.

3. Marshall S, Bayley M, McCullagh S, et al. Updated clinical practice guidelines for concussion/mild traumatic brain injury and persistent symptoms. *Brain Inj* 2015;29(6):688-700.

4. McCrory P, Meeuwisse W, Dvorak J, et al. Consensus statement on concussion in sport—the 5th international conference on concussion in sport held in Berlin, October 2016. *Br J Sports med* 2017;0 :1-10.

5. Perroux M, Lefebvre H, Levert MJ, et al. Besoins perçus et participation sociale des personnes ayant un traumatisme crânien léger. *Santé Publique* 2013;25(6):719-728.

6. Ontario Neurotrauma Foundation. Guideline For Concussion/mild Traumatic Brain Injury & Persistent Symptoms 3Rrd Edition, For Adults Over 18 Years of Age. 2018. Available from: http://braininjuryguidelines.org/concussion/index.php?id=1 (accessed october 2018).

7. Cassidy JD, Cancelliere C, Caroll LJ, et al. Systematic Review of Self-Reported Prognosis in Adults After Mild Traumatic Brain Injury: Results of the International Collaboration on Mild Traumatic Brain Injury Prognosis. *Arch Phys Med Rehabil* 2014;95(3):S132-S151.

8. Makdissi M, Schneider KJ, Feddermann-Demont N, et al. Approach to investigation and treatment of persistent symptoms following sport-related concussion: a systematic review. *Br J Sports med* 2017;51(12):958-968. 9. Schneider KJ, Leddy JJ, Guskiewicz KM, et al. Rest and treatment/rehabilitation following sport-related concussion: a systematic review. *Br J Sports med* 2017;51(12):930-934.

10. Lohr KN, Field MJ. Guidelines for clinical practice: from development to use. Washington, WASH DC, *National Academies Press* 1992.

11. Department of Veterans Affairs, Department of Defense. VA/DoD clinical practice guideline for management of concussion/mild traumatic brain injury. 2016. Available from: https://www.healthquality.va.gov/guidelines/Rehab/mtbi/ (accessed october 2018).

12. Fischer F, Lange K, Klose K, et al. Barriers and Strategies in Guideline Implementation—A Scoping Review. *Healthcare* 2016;4(3):36.

13. Ammann BC, Knols RH, Baschung P, et al. Application of principles of exercise training in sub-acute and chronic stroke survivors: a systematic review. *BMC neurol* 2014;14(1):167-178.

14. Arksey H, O'Malley L. Scoping studies: towards a methodological framework. *Int J Soc Res Methodol* 2005;8(1):19-32.

15. Levac D, Colquhoun H, O'Brien KK. Scoping studies: advancing the methodology. *Implement Sci* 2010;5(1):69-78.

16. Moher D, Shamseer L, Clarke M, et al. Preferred Reporting Items for Systematic Review and Meta-Analysis Protocols (PRISMA-P) 2015 statement. *Syst Rev* 2015;4(1):1.

17. Tricco AC, Lillie E, Zarin W et al. PRISMA Extension for Scoping Reviews (PRISMA-ScR): Checklist and Explanatation. *Ann Intern Med* 2018;169(7):467-473.

World health organisation. Global Strategy on Diet, Physical Activity and Health.
Available from: https://www.who.int/dietphysicalactivity/pa/en/ (accessed october 2018).

19. Kent, M. Oxford dictionary of sports science and medicine. *J Sports Sci Med* 2007;6(1):152-152.

20. Sirtori V, Corbetta D, Moja L, et al. Constraint-induced movement therapy for upper extremities in stroke patients. *Cochrane Database Syst Rev* 2009;7(4).

21. Hoare BJ, Wasiak J, Imms C, et al. Constraint-induced movement therapy in the treatment of the upper limb in children with hemiplegic cerebral palsy. *Cochrane Database Syst Rev* 2007;18(2).

22. Moher D, Liberati A, Tetzlaff J, et al. Preferred reporting items for systematic reviews and meta-analyses: the PRISMA statement. *Ann Intern Med* 2009;151(4):264-269.

23. Pollock MLP, Froelicher VFMD. Position Stand of the American College of Sports Medicine: The Recommended Quantity and Quality of Exercise for Developing and Maintaining Cardiorespiratory and Muscular Fitness in Healthy Adults. *J Cardiopulm Rehabil* 1990;10(7):235-45.

24. Orwin RG, Cooper IH, Hedges LV. In: Orwin RG, Cooper IH, Hedges LV. The handbook of research synthesis." New York, NY, *Russell Sage Foundation* 1994:139-162.

25. Hoffmann TC, Glasziou PP, Boutron I, et al. Better reporting of interventions: template for intervention description and replication (TIDieR) checklist and guide. *BMJ* 2014;348:g1687.

26. Slade SC, Dionne CE, Underwood M, et al.Consensus on Exercise Reporting Template (CERT): explanation and elaboration statement. *Br J Sports Med* 2016;0:1-10.

to beet terien only

AUTHORS CONTRIBUTIONS

Acknowledgement: We thank the clinical partners, Pierre Vincent, Geneviève Léveillé and Pierre Goulet for their involvement in the identification of the research question and future involvement in the consultation steps.

Author statement: CA, IG, EQ and BS designed the protocol. CA drafted the manuscript. CA, IG, EQ and BS reviewed the manuscript and approved the final version. All authors will participate in the 6 steps.

FUNDING

This work is supported by the Edith Strauss Rehabilitation Research Projects Foundation. This grant will provide salary support to CA and EQ.

COMPETING INTEREST

COMPETING INTERES. None declared. ETHICS Ethical approval: None required.

DATA SHARING

Data from the full scoping review will be made available upon reasonable request.

Supplementary file I
Full search strategy for Medline database
1. exp brain injuries, traumatic/ or exp brain concussion/
2. (mild traumatic brain injur* or concussi* or postconcuss* or post-concuss*or traumatic brain injur* or TBI or mTBI or Closed head injur*).ab,kf,kw,ti.
3. exp Exercise Therapy/
4. exp Physical Fitness/
5. exp Exercise/
6. exp Motor Activity/
7. (Physical activit* or Motor activit* or Exercise* or Physical fitness or Exercise therap*).ab,kf,kw,ti.
8. 1 or 2
9. 3 or 4 or 5 or 6 or 7
10. 8 and 9
11. limit 10 to (humans and yr="1990 -Current" and (english or french))

PRISMA Extension for Scoping Reviews (PRISMA-ScR): Checklist

1	
2	
3	
4	
5	
6	
7	
, 8	
9	
9 10	
11	
12	
13	
14	
15	
16	
17	
18	
19	
20	
20	
21 22	
22 23	
24	
25	
26	
27	
28	
29	
30	
31	
32	
33	
34	
34 35	
36	
37	
38	
39	
40	
41	
42	
43	
44	
45	
46	
40 47	
48	
49	
50	
51	
52	
53	
54	
55	
56	
57	
58	
20	

59

Section	Item	Prisma-ScR Checklist Item	Page number and comments.
Title	1	Identify the report as a scoping review.	1, 6
Abstract (Structured summary)	2	Provide a structured summary.	2
Introduction			
Rationale	3	Describe the rationale for the review in the context of what is already known.	4,5
Objectives	4	Provide an explicit statement of the question(s) the review will address with reference to participants, interventions, comparators, and outcomes (PICO).	5,6
Methods		6	
Protocol and registration	5	Indicate whether a review protocol exist.	n/a This is the submission for the review protocol.
Elligibility criteria	6	Specify characteristics of the sources of the evidence used as eligibility criteria.	7,8
Information sources	7	Describe all intended information sources.	7,8
Search strategy	8	Present the full electronic search strategy for at least one database.	7.8 for examples and an appendix wi be provided.
Selection of sources of evidence	9	State the process for selecting sources of evidence.	7,8,9
Data charting process	10	Describe the methods of charting data from the included sources of evidence.	9,10
Data items	11	List and define all variables for which data were sought and any assumptions and simplifications made.	9,10
Critical appraisal of individual source of evidence	12	If done, provide a rationale for conducting a critical appraisal of included source of evidence.	9,10
Summary measures	13	Not applicable for scoping reviews.	
Synthesis of results	14	Describe the methods of handling and summarizing the data were charted.	n/a, this is a protocol.
Risk of bias across studies	15	Not applicable for scoping reviews.	
Additional analyses	16	Not applicable for scoping reviews.	
RESULTS			
Selection of	17	Give number of source of evidence screened,	Will be provided in a flow diagram.

sources of evidence		assessed for eligibility, and included in the review, with reason for exclusion at each stage, ideally using a flow diagram.	Page 8
Characteristic of source of evidence	18	For each sources of evidence, present characteristics for which data were charted and provide the citations.	Will be provided
Critical appraisal within source of evidence	19	If done, present data on critical appraisal of included sources of evidence.	Will be provided
Results of individual sources of evidence	20	For each included source of evidence, present the relevant data that were charted that relate to the review questions and objectives.	Will be provided
Synthesis of results	21	Summarize and/or present the charting results as they relate to the review questions and objectives.	10,11
Risk of bias across studies	22	Not applicable for scoping reviews.	
Additional analyses	23	Not applicable for scoping reviews.	
Discussion			
Summary of evidence	24	Summarize the main results	Will be provided
Limitations	25	Discuss the limitations of the scoping review process.	Will be provided but some are mentioned at page 3
Conclusions	26	Provide a general interpretation of the results with respect to the review questions and objectives, as well as potential implications and/or next steps.	Will be provided.
Funding	27	Describe sources of funding for the included sources of evidence as well as sources for the scoping review.	Will be provided. Page 17
			2