Development of the Concussion Recovery Questionnaire - A Self-Report Outcome Measure of Functional Status Following Concussion

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To all those who have gone before me, thank you for your guidance. To all those who have joined me in my journey, thank you for your support and encouragement. To all those who follow in my footsteps, I hope I give you inspiration.

Authorization

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Chapter 3: Identifying the concepts contained within health-related quality of life outcome measures in concussion research using the International Classification of Functioning, Disability, and Health as a reference- a systematic review

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Abstract

Tradition measures of recovery, such as patient-reported symptoms, objective measures such as balance, specific dimensions such as depression, fatigue, cognitive status, and exercise tolerance do not fully capture the *impact* of the concussion on performing individual activities and participating in life situations as experienced by the patient. No concussion-specific measure of functional status currently exists.

Objectives

The overarching purpose of this dissertation was to develop a concussion-specific measure of functional status. There were two specific objectives:

1. To examine the concept of functioning post-concussion;
2. To generate questionnaire items based on a conceptual model of functioning.

Methods

This dissertation follows the recommendations of the Association for Medical Education in Europe as a framework with which to meet the objectives. The first objective was addressed by (1) generating a list of concussion-specific concepts through a systematic review (Chapter 3), and (2) qualitative interviews with individuals with persistent post-concussion symptoms and clinicians with concussion expertise (Chapter 4). The relationships between the concepts that emerged from those studies are presented graphically in a conceptual model to meet the second objective. The concepts were then transformed into questionnaire items and pretested through cognitive interviews with individuals with PPCS and clinicians with concussion expertise. Finally, the questionnaire items were critically evaluated for proportion of shared content

against existing measures used in concussion clinical trials by coding all items to the International Classification of Functioning, Disability and Health.

Results

Objective 1

Three main themes emerged from the qualitative findings: (1) functioning at the level of the individual and society; (2) environmental barriers and facilitators; and (3) capacity, defined as the length of time one could perform a task before the onset of symptoms, and the length of time it took to recovery from those symptoms.

Objective 2

The final questionnaire is presented as the CORE-Q, which is comprised of 53 items over three complimentary subscales, namely the Post-Concussion Functional Scale, the Concussion Modifiers Scale, and the Global Functional Recovery Scale. Each subscale corresponds to one of the three main themes. No existing outcome measure contained more than 40% of the content within the CORE-Q, or 55% of any subscale.

Conclusions

The CORE-Q is a unique measure of functional status post-concussion that considers functioning from a biopsychosocial perspective. Further studies are needed to assess the psychometric properties of the CORE-Q before it is adopted into clinical practice and intervention trials.

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List of Abbreviations

CDE	Common Data Elements
CHART-SF	Craig Handicap and Assessment Reporting Technique Short Form
CMS	Concussion Modifiers Scale
CONQOL	Concussion Quality of Life
CORE-Q	Concussion Recovery Questionnaire
EMA	European Medicines Agency
EQ-5D	EuroQOL-5 Dimensions
FDA	Food and Drug Administration
GCS	Glasgow Coma Scale
GFRS	Global Functional Recovery Scale
GOS-E	Glasgow Outcome Scale - Extended
HRQOL	Health-related quality of Life
ICD	International Classification of Disease
ICF	International Classification of Functioning, Disability and Health
LOC	Loss of consciousness
mTBI	Mild traumatic brain injury
NINDS	National Institute of Neurological Disorders and Stroke (NINDS)
ONF	Ontario Neurotrauma Foundation
PCD	Postconcussional disorder
PCFS	Post-Concussion Functional Scale
PCS	Postconcussion syndrome
PPCS	Persistent postconcussion symptoms
PQOL	Perceived Quality of Life Scale
PROM	Patient-reported outcome measure
PTA	Posttraumatic amnesia
QOLIBRI	Quality of Life after Brain Injury
SF-36	Short Form-36 Health Survey
TBI	Traumatic brain injury
TBI-QOL	Traumatic Brain Injury Quality of Life
WHO	World Health Organization
WHOQOL-100	World Health Organization Quality of Life-100

WHOQOL-BREF World Health Organization Quality of Life-BREF

Chapter 1: General introduction and review of the literature

1.1 Concussion

Concussion as a Subset of Traumatic Brain Injury.

Concussion has been recognized as a public health issue, with an annual incidence of up to 653 per 100,000 adults in Ontario, Canada (Ryu, Feinstein, Colantonio, Streiner, & Dawson, 2009). While concussion is a known clinical entity, large variations exist in how it is defined by different consensus groups, professional organizations, taskforces, and position statements (Carroll, Cassidy, Holm, Kraus, & Coronado, 2004; Harmon et al., 2019; Kristman et al., 2014; McCrory, Feddermann-Demont, et al., 2017). Concussion is commonly considered a form mild traumatic brain injury (mTBI), and the terms are often used interchangeably in the literature (Figure 1.1) (Evans et al., 2012; Levin & Diaz-Arrastia, 2015; McCarthy & Kosofsky, 2015; McCrory, Feddermann-Demont, et al., 2017).

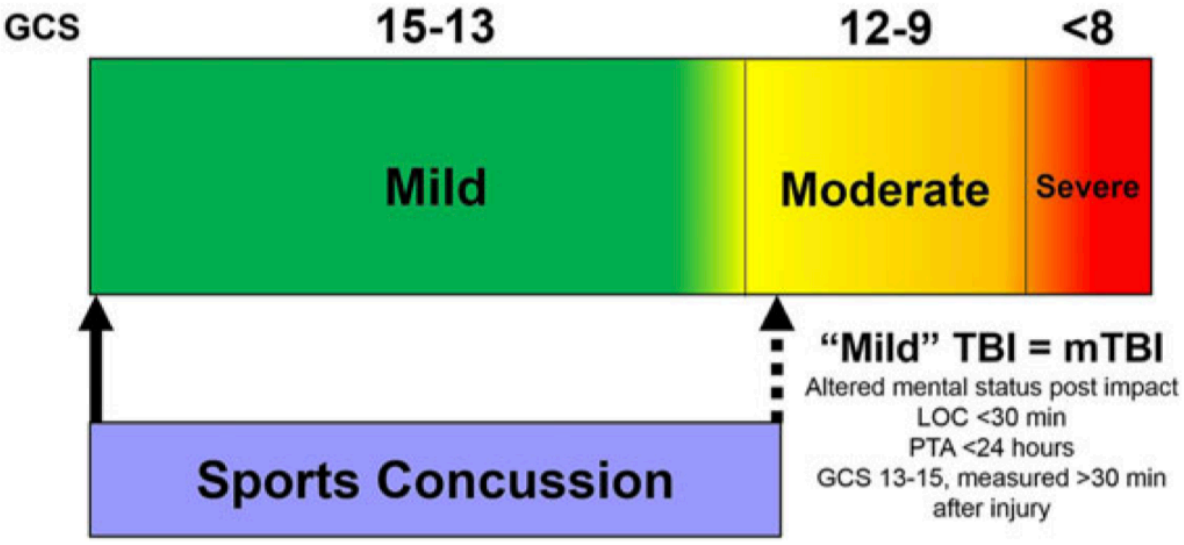

Figure 1.1. Continuum of TBI severity. Reproduced with permission from Wiley and Sons. McCarthy, M. T., & Kosofsky, B. E. (2015). Clinical features and biomarkers of concussion and mild traumatic brain injury in pediatric patients. *Annals of the New York Academy of Sciences*, *1345*(1), 89-98.

GCS, Glasgow coma scale; LOC, loss of consciousness; mTBI, mild traumatic brain injury; PTA, posttraumatic amnesia; TBI, traumatic brain injury

The ability to study athletes before and after injury, and the need for return-to-sport recommendations has led to a proliferation of studies examining sport-related concussion as a sub-type of concussion (McCrory, Feddermann-Demont, et al., 2017). Differences in health outcomes based on mechanism of injury is currently unknown. Although the majority of definitions depend on the Glasgow Coma Scale (GCS) either solely, or in combination with loss of consciousness (LOC) or posttraumatic amnesia (PTA), agreement does not exist on the GCS score (Kristman et al., 2014). While the American Congress of Rehabilitation Medicine (ACRM) (American Congress of Rehabilitation Medicine, 1993) and WHO Collaborating Centre Task Force on Mild Traumatic Brain Injury (Carroll et al., 2004) recommend a score of 13-15 following 30 minutes or later after injury, others consider the prognosis following a GCS score of 13 to be more compatible with a diagnosis of a moderate TBI (Levin & Diaz-Arrastia, 2015). Other proposed diagnostic criteria for concussion include symptom onset and duration, resolution of impairment, physical signs, neurocognitive testing, and findings on standard neurodiagnostic imaging (McCrory, Feddermann-Demont, et al., 2017). The lack of consistency among definitions around specific recommendations regarding LOC, PTA, disorientation/confusion, and neurologic signs in the definition of concussion was considered a key issue by the International Collaboration on Mild Traumatic Brain Injury that required further study (Kristman et al., 2014). Additional knowledge gaps include reliance on clinically oriented diagnostic criteria, the lack of a gold standard against which to assess diagnostic

criteria, the inability of the definition to describe the underlying pathophysiology of the injury, and the inability to differentiate between grades of injury severity (McCrory, Feddermann-Demont, et al., 2017). Differences in definitions make it difficult to compare study findings, limiting our understanding of expected recovery and prognosis (Carroll et al., 2004). This thesis aligns with the definition of mTBI/concussion proposed by the ACRM as a traumatically induced physiological disruption of brain function resulting in at least one of: (1) LOC; (2) memory loss before or after the event; (3) any alteration in mental state; and (4) focal neurological deficit(s) whereby the severity of the injury does not exceed LOC of 30 minutes or less, a GCS of 13-15 after 30 minutes, and PTA not greater than 24 hours (American Congress of Rehabilitation Medicine, 1993).

The clinical presentation of concussion contrasts significantly with that seen following a moderate-severe TBI. The heterogeneous nature of TBI results in persons experiencing recovery on a spectrum from complete functional recovery after transient neurological deficits typically seen with concussion, to severe permanent disability or increased likelihood of death following moderate-severe TBI. Identification of structural abnormalities such as intracranial bleeding and cranial fractures is consistent with moderate-severe TBI. In contrast, an expert consensus panel considered concussion to be a functional disturbance in the absence of structural injury as seen on standard neurodiagnostic imaging (McCrory et al., 2013).

To date, most concussion research has focused on the etiology, resultant pathophysiology, and prognostic factors. Differences in predictors,

macrostructural damage seen on neurodiagnostic imaging, management strategies, and functional outcome between concussion and moderate-severe TBI suggest that recovery from these two injuries should be evaluated differently. This thesis will focus solely on concussion injuries. The majority of persons do not experience LOC, PTA, or focal neurological deficits following a concussion. Nevertheless, concussion is a complex injury that presents not only as a heterogeneous constellation of symptoms, but also as various functional limitations and restrictions in social, athletic, educational and vocational participation, which may negatively impact a person's health-related quality of life (HRQOL).

Pathophysiology of Concussion.

A concussion occurs when a direct or indirect blow to the brain results in axonal stretching associated with temporary and reversible changes in neurophysiology (McCrea et al., 2009; McCrory, Meeuwisse, et al., 2017). Giza and Hovda (2014) described a neurometabolic cascade triggered by a stretching of the axons that results in an initial ionic flux, glutamate release, and widespread depolarization leading to an energy crisis, impaired glucose metabolism, and diminished cerebral blood flow (Giza & Hovda, 2014; McCrea et al., 2009). Subsequent cytoskeletal damage results in axonal dysfunction, altered neurotransmission, and neuroinflammatory changes (Giza & Hovda, 2014). Giza and Hovda (2014) postulate how these physiological changes may correlate with clinical characteristics of concussion such as migraine symptoms, increased vulnerability to subsequent injury, and cognitive dysfunction. Advanced neurodiagnostic

imaging techniques are providing emerging evidence of prolonged microstructural injury and impaired cerebral blood blow, suggesting that the time period for physiological recovery extends beyond measurable clinical recovery (McCrea et al., 2017; McCrory, Meeuwisse, et al., 2017). While these technologies have fundamentally improved our understanding of the pathophysiology associated with concussion, their clinical diagnostic and prognostic utility requires further validation studies (McCrea et al., 2017). Current recommendations for early management strategies include up to 24 to 48 hours of rest as needed, followed by symptom-limited activity to allow for neurological recovery by minimising brain energy demands associated with high loads of physical and cognitive activity (McCrory, Meeuwisse, et al., 2017; Schneider et al., 2017).

Normal Expected Recovery.

Recovery from concussion has been reported using multiple measures and is generally understood to include resolution of symptoms at rest, no exacerbation of symptoms with cognitive and physical activity, normal cognition, normal balance, and return to previous level of participation, such as school, work, and social life (Willer et al., 2018). Persons typically experience an initial symptom burden immediately following injury that gradually and progressively resolves over time (McCrea et al., 2003). Adults are expected to recover within the first ten to fourteen days (Ontario Neurotrauma Foundation, 2018). Neuropsychological recovery typically progresses in tandem with symptom resolution over the first couple of weeks, with little evidence of significant

impairment by three months following concussion (McCrea et al., 2009). A systematic review by the International Collaboration on Mild Traumatic Brain Injury Prognosis group reported that most workers return to work within three to six months following a concussion, and that concussion was not a significant predictor for long term work disability (Cancelliere et al., 2014).

Persistent Post-Concussion Symptoms.

Although adults with concussion are expected to make a full recovery and return to work and other pre-injury activities within days to months, up to 26% will go on to develop persistent postconcussion symptoms (PPCS), which may persist for months or years (Losoi et al., 2016; Ontario Neurotrauma Foundation, 2018). Two-thirds of those who recover will do so within the first year (Hiploylee et al., 2016). Evidence suggests that no further recovery is seen in persons who remain symptomatic beyond three years (Hiploylee et al., 2016). Persistent post-concussion symptoms commonly include one or more of headache, dizziness, fatigue, mood disorders, sleep disturbances, and cognitive impairments (Cassidy et al., 2014). Controversy as to the origin of these symptoms exists as they are non-specific to concussion. In adults, prolonged recovery is associated with pre-existing medical conditions (e.g. anxiety, history of previous TBI, psychiatric problems), injury-related factors (e.g. initial severity of symptoms, early onset of headache), psychosocial factors (e.g. high levels of stress, lower resilience, lack of social supports), and litigation or financial compensation (Cassidy et al., 2014; Ontario Neurotrauma Foundation, 2018). There is also debate in the literature as to the importance of PPCS for the diagnostic criteria for postconcussion

syndrome (PCS) or postconcussional disorder (PCD). The *International Statistical Classification of Diseases and Related Health Problems, Tenth Revision (ICD-10)* defines PCS as the presence of symptoms in at least three symptom categories for more than four weeks following concussion (World Health Organization, 2007). The diagnosis of PCS is more specific to concussion than the DSM-IV criteria as it relies heavily on symptoms associated with a psychological underpinning (McCauley et al., 2005). The DSM-IV (current at the start of this research) defines PCD as the onset of three or more symptoms and cognitive impairment of attention or memory that persist or worsen for at least three months following concussion that interfere with social and/or occupational functioning (McCauley et al., 2005). While the inclusion of a longer symptom duration in the DSM-IV diagnostic criteria are thought to better reflect the long-term effect of concussion, the DSM-IV has been criticized for the dependence on cognitive impairments that present less frequently beyond three months following concussion (McCauley et al., 2005). A comparison of the two diagnostic criteria sets demonstrated that despite the ICD-10 identifying a higher incidence rate of concussion than the DSM-IV, three-month outcomes in symptoms, community integration, HRQOL, and global outcome were similar, suggesting that both may be useful in clinical practice (McCauley et al., 2005). Given the outcome equivalence between diagnostic criteria sets, the ICD-10 requirements for PCS were chosen for this research in order to capture a larger number of respondents and ensure greater representation of the desired population. Cnossen et al (2018) developed a prediction model to improve early

identification of adults who are at risk of prolonged recovery (Cnossen et al., 2018). Risk factors in the prediction model include factors identifiable in the emergency department (i.e. female sex, nausea or vomiting, headache, or neck pain) and at the two-week mark (i.e. PPCS and posttraumatic stress) (Cnossen et al., 2018).

The multidimensionality of cognitive, physical, emotional, behavioural, and social problems reported following a concussion underscore the complexity of the underlying pathology. Recovery from concussion has traditionally been evaluated by multimodal measures, such as person-reported symptoms (King, Crawford, Wenden, Moss, & Wade, 1995), objective measures such as loss of consciousness (American Congress of Rehabilitation Medicine, 1993), specific dimensions such as depression (Silver, McAllister, & Arciniegas, 2009) or fatigue (Norrie et al., 2010), cognitive status (McInnes, Friesen, MacKenzie, Westwood, & Boe, 2017), and exercise tolerance (Leddy et al., 2019). However, these measures do not fully capture the *impact* of the impairments on level of individual activities and societal participation as experienced by the person. The diverse pattern of impairment and recovery experienced by these persons dictates a lengthy, detailed, and comprehensive multidisciplinary approach to assessment to determine the appropriate care plan. Furthermore, clinicians may fail to recognize those issues that are most important to the person, by emphasizing symptoms, such as dizziness, at the expense of person-centred priorities, such as the ability to maintain gainful employment, or the impact of their injury on family dynamics. In the traditional acute care model of health approach, medical

management is based on criteria such as clinical tests, imaging reports, and laboratory results for a singular dimension of health. Similar pathways for management do not exist for persons with PPCS, since the complexity of problems associated with the injury crosses multiple dimensions. It is often unclear what issues warrant further investigation, and what the most appropriate management strategy is. These challenges highlight the importance of the person-centred perspective in informing healthcare decisions (Frank, Basch, & Selby, 2014; Selby, Beal, & Frank, 2012).

1.2 Patient-reported outcome measures

Patient-reported outcome measures (PROMs) are a subjective measure of health or treatment outcome as evaluated directly by the person. A trend is emerging in healthcare whereby persons seeking care are asked directly whether functional recovery and management strategies translate into improvements along a continuum of health. Increasingly, PROMs are being emphasized as an important end point in care plans, clinical trials, and health policy decisions (Carlozzi, Tulsky, & Kisala, 2011). In a systematic review of the experience of professionals using PROMs in healthcare, Boyce et al. (2014) concluded that healthcare professionals are more likely to use PROMs when they help with clinical decision-making (Boyce, Browne, & Greenhalgh, 2014). Methodological barriers, however, have been identified as a common theme in the lack of routine use of PROMs (Boyce et al., 2014; Duncan & Murray, 2012; Patrick & Deyo, 1989). Consequently, clinicians may forgo the use of subjective outcome measures due their inherent preference for “hard” objective data such

as laboratory results, imaging, and physiological function, due to their lack of formal training in questionnaire methodology (Patrick & Deyo, 1989). This can be problematic when applied to a condition such as PPCS where physiological biomarkers have not been identified, standard neurodiagnostic imaging appears normal, and mortality rates remain unchanged. Hence, evidence of rigorous methodology in PROM development is essential for their adoption in clinical practice.

Using PROMs to monitor a person's recovery has multiple benefits for both the person accessing care and the clinician. Chen et al. (2013) reported a very strong to moderate positive effect on improved satisfaction of persons accessing care with the routine collection of PROMs in 16 of 27 studies systematically reviewed (Chen, Ou, & Hollis, 2013). Kotronoulas et al. (2014) found overall satisfaction with the use of PROMs in at least 80% of persons accessing care (Kotronoulas et al., 2014). Reasons for satisfaction included ease of use, a means of describing their issues, and improved communication with health-care providers. Persons in the study appreciated being asked about their emotional well-being and expressed a willingness to continue the use of PROMs in routine care. PROMs have been recommended as an effective screening tool for undiagnosed problems, as a means to improve person-clinician communication, and to improve satisfaction in persons accessing care (Boyce et al., 2014). Patient-reported outcome measures can be classified as either generic (e.g. Short-Form-36 Health Survey [SF-36]) (McLean et al., 2009), Functional Status Examination (Dikmen, Machamer, Miller, Doctor, & Temkin,

2001), Craig Handicap and Assessment Reporting Technique Short Form (Wilde et al., 2010) or condition-specific (e.g. Neck Disability Index (Cleland, Childs, & Whitman, 2008), Migraine Disability Assessment Scale (Mac Donald et al., 2017)). Selection of generic versus condition-specific PROM depends on the objective for measuring the outcome.

Generic patient-reported outcome measures.

Generic PROMs incorporate items across multiple domains to capture a broad spectrum of issues that apply across various diseases, populations, and interventions. Each domain may be further subdivided into different subdomains, which are each assessed with only a few items. While generic PROMS may be used to assess health-related outcomes, they also allow comparison between different groups for the purpose of cost-effectiveness research to allocate resources and provide an understanding of differences in health burden across different conditions (Patrick & Deyo, 1989). Generic PROMs are generally thought to demonstrate lower content validity in a condition-specific population since the broad concepts assessed may have little relevance for those persons and the unique nature of their condition (Patrick & Deyo, 1989). For example, the most common generic measure of health status, the SF-36, contains the question: “I seem to get sick a little easier than other people”, which may be of little concern to persons with concussion whose primary complaint is post-traumatic headaches (Ware & Sherbourne, 2012). Likewise, the lack of input from persons with lived experience with a specific condition, or clinicians with

expertise in that area when developing a generic questionnaire means items relevant to that population may not be addressed.

Condition-specific patient-reported outcome measures.

Condition-specific PROMs on the other hand, have the advantage of exploring specific domains of health in depth by incorporating items most relevant to specific diagnostic groups, and are therefore more sensitive to clinically important changes that occur within those persons (Guyatt, 2002). Furthermore, condition-specific PROMs tend to use wording in items or instructions that is more detailed or relevant for the intended user (Patrick & Deyo, 1989). For example, the Quality of Life after Brain Injury scale asks: “How bothered are you by effects of any other injuries you sustained at the same time as your brain injury?” (von Steinbuchel et al., 2010). Condition-specific PROMs are often the measure of choice for researchers seeking to assess smaller within-subject changes necessary for determining statistical power or sample size when designing a clinical trial (Patrick & Deyo, 1989). Similarly, clinicians seeking to monitor an person’s recovery or response to treatment may also prefer the higher responsiveness of a condition-specific PROM.

Functional status.

Contrary to the body of literature relating to physiological recovery from concussion, functional status, as a PROM of functioning, is less well defined. The World Health Organization defines functioning as “an umbrella term encompassing all body functions, activities and participation” (World Health Organization, 2016). Functioning at the level of the individual includes

performing daily activities such as learning, mobility, household tasks, and self-care and progresses across a spectrum of engagement to include the broader context of social participation in major life areas and the community, such as interpersonal relationships, employment, recreation, and leisure (World Health Organization, 2016). The International Classification of Functioning, Disability and Health (ICF) describes activity limitations as difficulty in performing tasks at the level of the individual, whereas participation restrictions refer to how a person experiences problems within life situations (World Health Organization, 2016). Consensus is lacking on whether to disentangle the concepts of activities and participation and measure them separately or consider them together as a collective. Concussion affects many areas of activities and participation, suggesting a comprehensive approach to assessment is needed that includes both for a more inclusive definition of functioning. The Interagency Core Data Elements (CDE) Traumatic Brain Injury (TBI) Outcomes Workgroup identified participation, as defined by the ICF, as a core construct to be assessed, covering domains relevant to concussion; applied as either part of a comprehensive battery, or in addition to other outcome measures (Wilde et al., 2010). As part of their recommendations, the Workgroup selected only one generic PROM, the Craig Handicap and Assessment Reporting Technique Short Form, as an acceptable core outcome measure to assess participation restrictions (Wilde et al., 2010). The Craig Handicap and Assessment Reporting Technique Short Form is a 19-item questionnaire that measures participation within the 6 domains of physical independence, cognitive independence, mobility, occupation, social

integration, and economic self-sufficiency (Wilde et al., 2010). A similar initiative by the National Institute of Neurological Disorders and Stroke Common Data Elements team recommended the Mayo-Portland Adaptability Inventory-4 as the only core measure of global outcome ("National Institute of Neurological Disorders and Stroke Sport-Related Concussion Common Data Elements," n.d.). The Mayo-Portland Adaptability Inventory-4 measures thirty items across three broad domains of basic physical abilities, adjustment, and social community participation activities (Kean, Malec, Cooper, & Bowles, 2013). No concussion-specific measure of functional status currently exists.

Environmental factors.

There is a growing interest in measuring how environmental and personal factors influence functioning as experienced by the person on a continuum from barrier to facilitator. Functioning is thought to be the result of a complex interaction between a health condition, the physical, social, and attitudinal environment in which a person lives, and personal factors intrinsic to the person, such as gender, age, coping styles, life events, and psychological characteristics (World Health Organization, 2016). Environmental factors affect a person at an individual, community or social, and societal or systems level (Whiteneck et al., 2004). Mallinson and Hammel (2010) emphasized the need to measure activities and participation within the context of the environmental and personal barriers, and a person's needs and goals to promote person-centred rehabilitation (Mallinson & Hammel, 2010). Disability rights advocates assert that restrictions in social participation are the result of environmental barriers (Whiteneck et al.,

2004). Heinemann et al. (2015) assert that PROMs are best suited to assess the impact of environmental factors on participation as experienced by the person (Heinemann et al., 2015). The importance of these factors, however, may vary between persons with different conditions. Issue-specific measures of environmental barriers have been developed to assess individual aspects such as physical accessibility, attitudes towards people with disabilities, family support, and social issues (Whiteneck et al., 2004). Generic measures of environmental factors would enable comparisons between persons with different health conditions. In an attempt to quantify the effect of environmental barriers on participation across multiples conditions, Whiteneck et al. (2004) developed the Craig Hospital Inventory of Environmental Factors. The Craig Hospital Inventory of Environmental Factors is a generic PROM that measures frequency and magnitude of environmental barriers across the domains of attitudes and supports, services and assistance, physical and structural, policy, and work and school in persons across multiple disabilities (Whiteneck et al., 2004). More recently the development of a PROM that assesses environmental barriers to participation in neurological disorders has been described (Heinemann et al., 2015). No evidence of its content, psychometric properties, or use in persons with concussion was identified in the literature. Currently, no standardized concussion-specific measure of environmental barriers exists. Focusing on modifiable environmental barriers to participation specific to concussion would enable clinicians and health care users to target goals for rehabilitation interventions that mitigate the effects of PPCS.

1.3 Developing an outcome measure

A multitude of both generic and condition-specific PROMs already exist. Generally, it is advisable to use an existing PROM to facilitate the collection and analysis of common data elements across studies. The development of a new outcome measure may be warranted if there are no existing condition-specific PROMs for that condition (Streiner, Norman, & Cairney, 2014; Velentgas, Dreyer, Nourjah, Smith, & Torchia, 2013). The Association for Medical Education in Europe, an international organization that promotes educational excellence in medical education, has published industry standard recommendations for the development of new medical research questionnaires (Artino, La Rochelle, Dezee, & Gehlbach, 2014). The International Society for Pharmacoeconomics and Outcomes Research PROM Content Validity Good Research Practices Task Force has also established methodologic recommendations for the development and evaluation of new PROMs to ensure good content validity (Patrick, Burke, Gwaltney, Leidy, Martin, Molsen, et al., 2011; Patrick, Burke, Gwaltney, Leidy, Martin, Molson, et al., 2011). The Task Force recommends developing a conceptual model, developing a qualitative research protocol and conducting interviews and/or focus groups, analyzing the qualitative data, developing questionnaire items, designing and conducting cognitive interviews, revising the PROM, and documenting the above process. These recommendations align with those of Association for Medical Education in Europe, thus supporting a standardized approach to the process. The methodology of this thesis is consistent with the Association for Medical Education in Europe and Task Force

recommendations outlined below, and culminates in the development of a new functional status PROM for persons with PPCS (Figure 1.2). This multi-step design process describes a systematic approach to establishing evidence of reliability and validity in the final PROM.

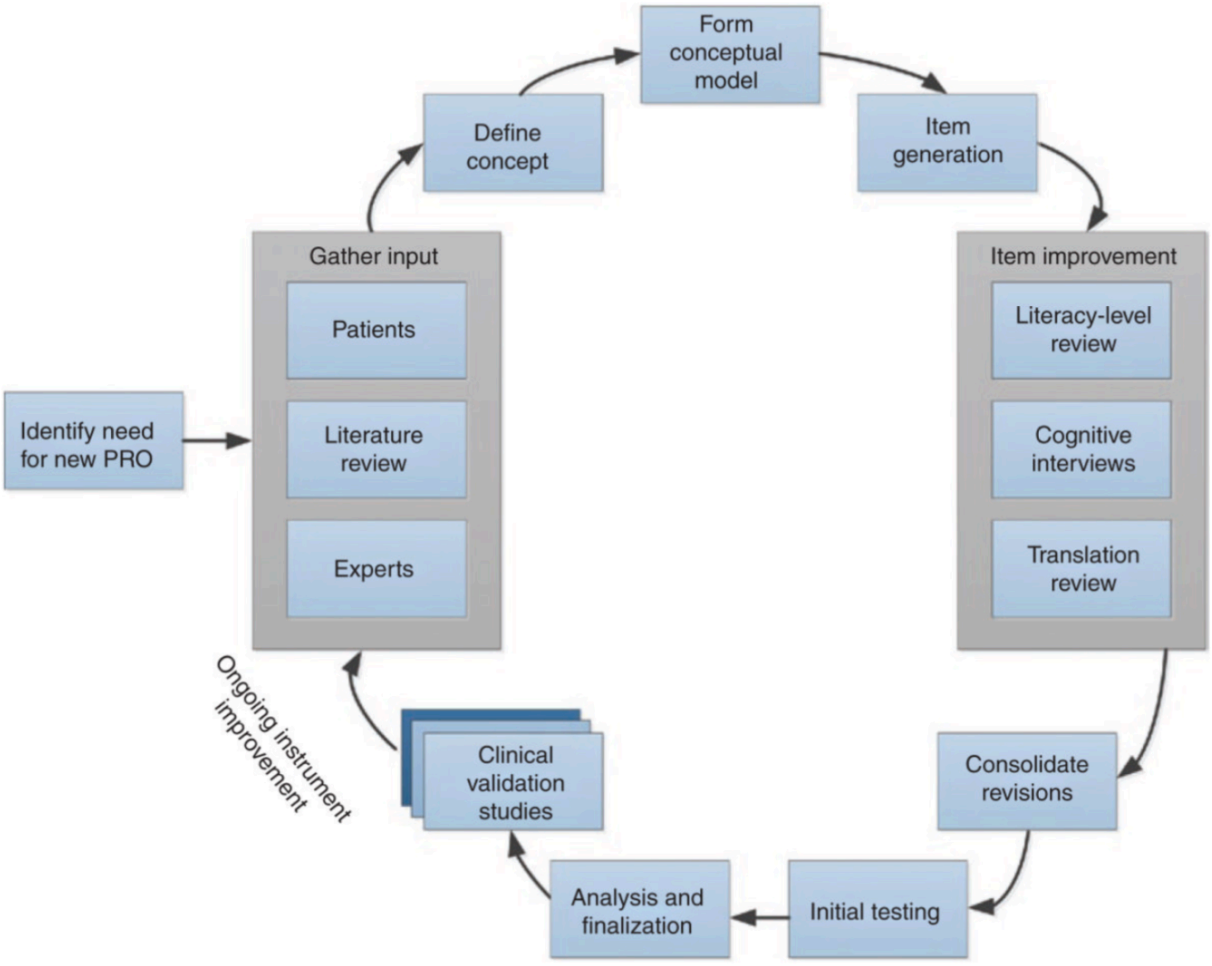

Figure 1.2. Patient-reported outcome measure development process. Reproduced with permission from Wiley and Sons. Rothrock, N. E., Kaiser, K. A., & Cella, D. (2011). Developing a valid patient-reported outcome measure. *Clinical Pharmacology & Therapeutics*, *90*(5), 737-742.

Step 1: Literature review.

Patient-reported outcome measures are scales comprised of multiple items that measure the intended construct (Boateng, Neilands, Frongillo, Melgar-Quiñonez, & Young, 2018). Thus, the first step in the development of a PROM is to conduct a literature review to conceptualize or define the construct (Artino et al., 2014). The construct is the underlying theory that is believed to exist, but cannot be objectively measured (Rickards, Magee, & Artino, 2012). For the purpose of this thesis, the construct is functional status following concussion. Placing the construct within the existing literature provides initial evidence for interpreting construct validation. Establishing the relationship of the construct with other constructs is necessary for convergent validation. Examining how the construct differs from similar constructs supports divergent validation. Items from existing PROMs should then be examined to determine if they apply to the population of interest and, thus, could be used or adapted for the current purpose (Artino et al., 2014).

Step 2: Interviews and Focus Groups.

The second step is to understand the construct from the perspective of all relevant stakeholder groups and to see how they align with the proposed definition (Artino et al., 2014). The US Food and Drug Administration (FDA) stresses the importance of input from the target population to ensure high content validity in the development of a new PROM (US Food and Drug Administration, 2006). Content validity is the measure of the extent to which an instrument's content measures the construct and the population it was intended

for (Patrick, Burke, Gwaltney, Leidy, Martin, Molson, et al., 2011; US Food and Drug Administration, 2006).

Interviews or focus groups with experts and end-users enable persons to define the construct in their own words using open-ended questions. The researcher than follows up with prompting to clarify their interpretation of the respondents' answers and identify any gaps in the literature. Data collection continues until no new themes emerge from the interviews, at which point saturation has been reached (Guest, Bunce, & Johnson, 2006). Qualitative evidence of how the target population conceptualizes the construct is then synthesized with the literature in the next step.

Step 3: Synthesize literature review and interviews/focus groups.

In step 3, the researcher synthesizes findings from the literature and the interviews and focus groups to come to a final definition of the construct and the concepts within it (Artino et al., 2014). The list of concepts should preferentially be comprehensive and in the language of the end-user. Subsequent steps confirm which concepts should be retained through interviews with experts who have content knowledge, clinical experience, or lived experience with the construct, in this case, persistent postconcussion symptoms (PPCS) (Artino et al., 2014). Those concepts that are most relevant to the target population can be presented as a conceptual model to provide a platform upon which to build a new PROM. A conceptual model is a graphical representation of the relationship between the concepts and defined construct.

Step 4: Develop questionnaire items.

Next, these concepts are transformed into questionnaire items using the words of the respondents wherever possible (Artino et al., 2014). Design considerations include the number and complexity of items, wording, and response options. The challenge in determining the number of items in is to balance how deeply the construct will be assessed with respondent burden (Streiner et al., 2014). Artino et al. (2014) recommends including a more comprehensive sampling initially to avoid losing important content, as a number of items will likely be revised or deleted in steps 5 and 6 of the design process (Artino et al., 2014). Best practice recommendations for writing clear and concise questionnaire items include keeping the language simple, avoiding double-barreled questions, wording items positively, and using questions rather than statements (Artino et al., 2014; Rickards et al., 2012; Rothrock, Kaiser, & Cella, 2011).

Another consideration in the design process is deciding on the most appropriate response option to assess the construct (Artino et al., 2014). Common response options among functional status measures include frequency (e.g. never, rarely, sometimes, often, always), duration (e.g. a few minutes, several hours to an hour, several hours, 1-2 days, >2 days), intensity (e.g. none, mild, moderate, severe, very severe), and interference with functioning (e.g. without any difficulty, with a little difficulty, with some difficulty, with much difficulty, unable to do) (DeWalt, Rothrock, Yount, & Stone, 2007).

General agreement response options (e.g. strongly disagree, disagree, neutral, agree, strongly agree) are often criticized for being prone to considerable

measurement error due to acquiescence and decreased need to think through the question(Rickards et al., 2012). Norman and Streiner (2015) and DeWalt et al. (2007) recommend between four and six response levels as being suitable to adequately assess an item (DeWalt et al., 2007; Streiner et al., 2014). Fewer response options may lack the precision necessary to sufficiently describe the item, while respondents may have difficulty discriminating between a greater number of response levels (DeWalt et al., 2007).

Step 5: Expert validation.

The fundamental next step in the development of a new PROM is building evidence of content validity of the questionnaire (Artino et al., 2014). Experts in the field are asked to evaluate each item on the scale for clarity and relevance with the construct and ensure adequate coverage (Polit & Beck, 2006; Rickards et al., 2012). Five to seven experts are recommended to provide an assessment (Boateng et al., 2018). Experts may be identified by their knowledge of the content as evidenced by participation in professional groups or important publications in the field (Artino et al., 2014). The goal is to identify items that need to be revised, deleted, or substituted if they are unclear or misleading, difficult to answer, or minimally relevant to the construct (Polit & Beck, 2006; Rickards et al., 2012). Assessments may be qualitative, quantitative, or both. Qualitative assessments allow experts to provide detailed feedback that can be incorporated into the questionnaire content or design. Multiple quantitative methods allow for standardized rating of item relevance, including the item- and scale-level content validity index measuring proportion of agreement between

experts (Polit & Beck, 2006); Cohen's coefficient kappa (k) for between-expert reliability (Boateng et al., 2018); or content validity ratio, for quantifying retention or rejection of each item (Zamanzadeh, Rassouli, Abbaszadeh, Majd, & Nikanfar, Alireza., & Ghahramanian, 2015). Alternatively, the Delphi method can be used to assess relevance of each item to the construct by seeking consensus between a group of experts over multiple rounds (Boateng et al., 2018).

Step 6: Cognitive interviews.

Once the experts have helped revise the questionnaire items, it is important to assess whether respondents interpret the questionnaire items and response options as intended, and whether different respondents interpret the items similarly (Rickards et al., 2012). This involves face-to-face cognitive interviews (pre-testing) with representatives of the target population. A sample of 5 to 15 respondents is generally considered sufficient to elicit feedback to reduce response error in the questionnaire (Jacobson et al., 2015; Peterson, Peterson, & Powell, 2017). Cognitive interviewing assumes that respondents work through 4 steps in order to respond to a question. These include *comprehension* of the item and response choices, *retrieval* from memory of relevant information, *judgement* on how to best answer the question, and *selection* of a response (Tourangeau, Rips, & Rasinkski, 2000). Cognitive interviewing methods involve either the "think-aloud" technique, or verbal probing (Willis, 1999). With the "think-aloud" technique, respondents are asked to talk through their though process as they attempt to answer each question. This technique minimizes interview bias and may elicit unexpected responses, but requires subject training

and it may be difficult for some persons to stay on track (Willis, 1999). With the verbal probing technique, the interviewer probes for further information after the respondent has answered the question. This has the advantage of being easy for the respondent to answer, and allows the interviewer to focus on particular sources of error; however it leaves open the potential for bias by asking leading questions (Willis, 1999).

Step 7: Pilot testing.

The goal of this step is assess for reliability and construct validity (Rickards et al., 2012; Streiner et al., 2014). Reliability analysis includes exploring the number of domains within the scale (test for dimensionality), internal consistency, and reproducibility (Boateng et al., 2018). A small sample of representatives from the target population is administered the questionnaire using the planned delivery mode (e.g. web-based or paper-based) (Rickards et al., 2012). Best practice recommended sample size is 10 respondents per questionnaire item, or approximately 200 to 300 participants for factor analysis (Boateng et al., 2018).

Initially, factor analysis is used to assess for a set of underlying factors that explains the interrelationships between the items on the PROM. The eigenvalue is used to express how much variance in scores is explained by a factor (Watson, 2017). A factor with an eigenvalue of ≥1 captures more of the variance in score than any single item. Factors with the largest eigenvalues are retained within the scale. Factor loading is used to express how strongly each item is associated with the underlying factor. The number of items on a scale may be reduced by removing those that load weakly on a factor (e.g. less

than $|0.4|$), or load on more than one factor (Streiner et al., 2014). However, a scale developer may decide to retain an item that loads weakly on any one factor if it assesses a clinically important variable.

Internal consistency, expressed as Cronbach's α, is a measure of how each item correlates with other items on the scale (Streiner et al., 2014). An α of 0.7 or great is considered acceptable (Streiner et al., 2014). Items that assess the same underlying factor (domain) should correlate with each other. For example, the SF-36 is a generic PROM that measures health status across eight domains of health (Ware & Sherbourne, 2012). Internal consistency for the SF-36 has been shown to range from 0.83 to 0.91 in a mild TBI group, demonstrating that the items within each domain produce similar scores (Findler, Cantor, Haddad, Gordon, & Ashman, 2001).

After the number of factors (domains) has been determined and the items shown to be interrelated, a composite score is created using the mean of the items within each domain (Artino et al., 2014). Using the mean score helps deal with missing values, and allows for an easier interpretation of scores across multiple domains using the same response levels (Artino et al., 2014).

Once the PROM can be scored, it should then be assessed for test-retest reliability (e.g. consistency of respondent scores at multiple time points) (Boateng et al., 2018). Evidence of consistency of scores is necessary to have confidence in the stability of a PROM. Test-retest reliability is expressed as a correlation coefficient (*r*) on a scale from 0 to 1. A correlation coefficient of at least 0.7 is considered the minimum acceptable level of reliability (Streiner et al., 2014).

Although reliability is a necessary precondition for validity, PROMs must also demonstrate they are a valid measure of the intended construct within the target population (Artino et al., 2014; Streiner et al., 2014).

The next step in the development of a PROM is to assess for evidence of construct validity in the target population. In the case where a new PROM has been developed because no other suitable measure exists, construct validity may be assessed by comparing the differences in scores between two or more known groups that are assumed to differ in the construct being tested (Streiner et al., 2014). If the two groups differ significantly (e.g. $p \leq 0.5$), then evidence of construct validity for both the PROM and the theory is supported (Streiner et al., 2014). For example, we may hypothesize that functional status will be lower in persons with concussion than in healthy peers. To test this hypothesis, we could design a study to assess whether persons with diagnosed PPCS using multimodal clinical criteria have lower scores on a new concussion-specific measure of functioning than healthy controls.

1.4 Aim of dissertation

Currently, no published condition-specific measures of functional status exist to evaluate the impact of PPCS from the person perspective. Thus, there is a need for the development of a psychometrically robust, standardized instrument that is sensitive enough to evaluate the specific health concerns which impact a person suffering from PPCS. The overarching aim of this dissertation was to develop a concussion-specific PROM developed around a new conceptual model of functioning for persons with PPCS. The limited evidence detailing which issues

are most relevant from a person perspective made it clear that several research questions needed to be answered in order to develop a new outcome measure with good content validity in this population. The manuscripts that make up this dissertation attempt to address each of these issues in order to further our understanding the functional impact of concussion on adults. These manuscripts are outlined below and comprise the sequential steps taken to meet recommended guidelines for the development of a PROM (Artino et al., 2014; Boateng et al., 2018; Patrick, Burke, Gwaltney, Leidy, Martin, Molson, et al., 2011; US Food and Drug Administration, 2006). Briefly, the purpose and objective of each of these manuscripts is presented in Figure 1.3 and described below.

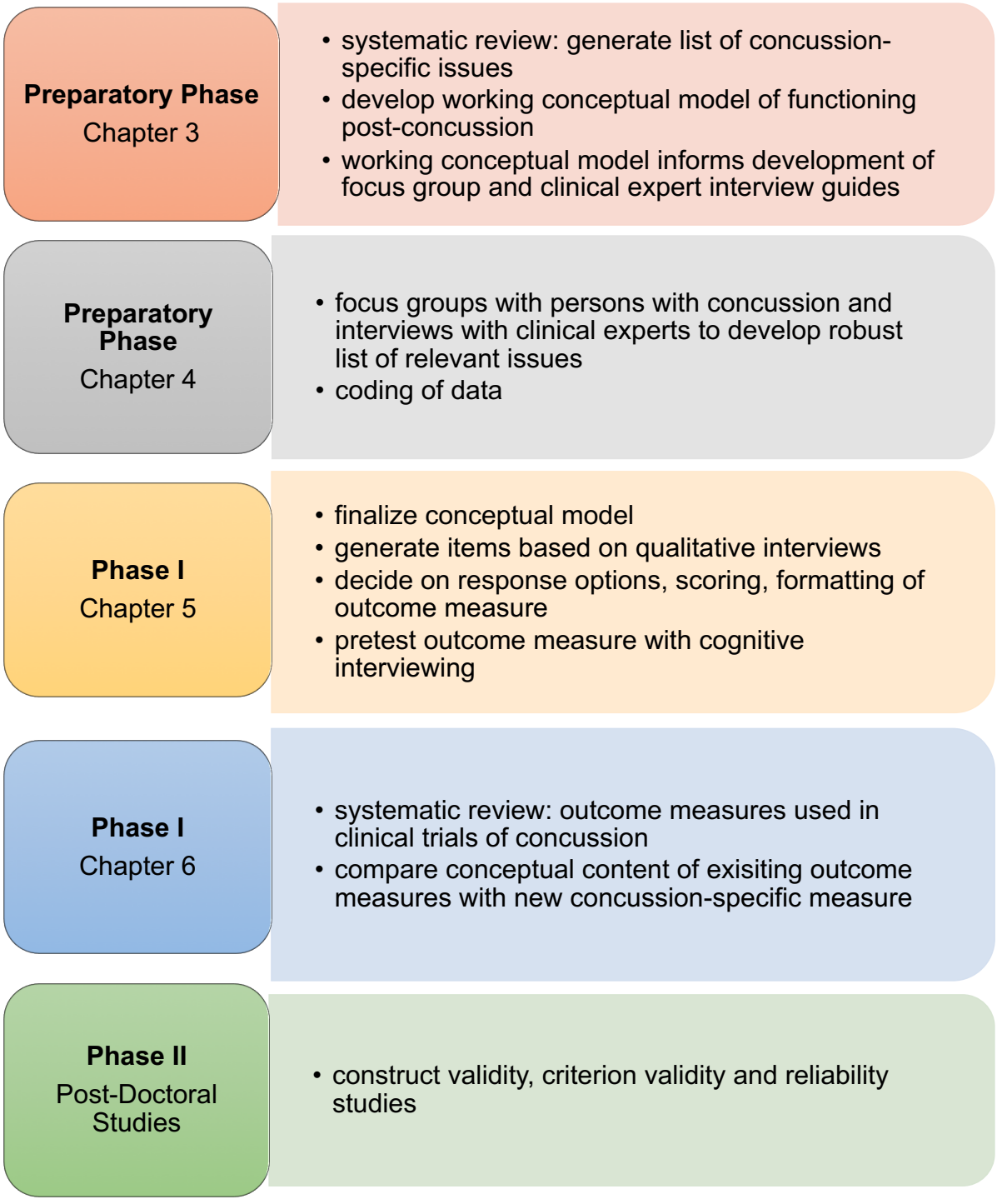

Figure 1.3. Planned phases in the development and evaluation of a concussion-specific functional status outcome measure.

Chapter 2: **Protocol for the mixed-methods development of a concussion-specific health-related quality of life outcome measure based on the International Classification of Functioning, Disability and Health**

The purpose of this study was to outline the proposed steps in the development of a concussion-specific outcome measure from conceptual development to psychometric validation. The rationale for using the ICF as a reference is described. The development of the outcome measure and the expected timeline is presented in 3 phases: (1) preparatory phase – development of a conceptual model; (2) phase I – development of a health-related quality of life questionnaire; and (3) phase II – psychometric testing. The stages within the preparatory phase included performing a systematic review to identify concepts contained in existing outcome measures used in concussion research, and conducting semi-structured interviews with clinicians and focus group interviews with persons with concussion to develop a conceptual model. Stages within phase I included a proposed second systematic review to assess the content validity of outcome measures used in concussion research, the development of the pilot questionnaire through item generation, and cognitive interviewing to refine the pilot questionnaire. Phase II lays the framework for performing test-retest reliability, construct and criterion validation studies. The overall aim of this dissertation was to address the preparatory phase and phase I. Phase II presents an opportunity for postdoctoral work and is presented for the purpose of comprehensiveness to enable the reader to critically evaluate the undertaking in its entirety and its contribution to the literature. In addition, the clinical

significance of the project is proposed as means of facilitating person-centre care for persons with PPCS.

Chapter 3: **Identifying the concepts contained within health-related quality of life outcome measures in concussion research using the International Classification of Functioning, Disability and Health as a reference: a systematic review**

This second study addressed the initial stage within the preparatory phase of the overall project. The purpose of the systematic review was to explore how HRQOL has been measured in concussion-specific research with existing outcome measures. The specific objectives were to: (1) identify the concepts contained in the outcome measures using the ICF as a reference; (2) describe the breadth and depth of concepts between outcome measures; and (3) develop a working conceptual model of HRQOL in persons with PPCS based on the concepts identified. This study identified a wide range of concepts covered by existing outcome measures represented by the ICF components of *body functions*, *activities* and *participation*, and *environment*. These concepts were presented in a working conceptual model of HRQOL post-concussion. The results from this study were used to develop the interview guide for the qualitative interviews in chapter 4.

Chapter 4: **Experiences of adults with concussion and clinicians with the consequences of persistent post-concussion symptoms: a qualitative study**

This study built upon the previous chapter to deepen our understanding of which concepts identified in the systematic review are relevant to persons with concussion, and whether there are gaps in existing outcome measures. The purpose of this third study was to explore the impact of PPCS in adults in order to inform the item generation of a new concussion-specific outcome measure. This study addressed our 3 specific research questions: (1) What was the experience of persons with PPCS and clinicians regarding the consequences of concussion? (2) What influenced recovery following a concussion? (3) How persons with PPCS and clinicians think the consequences of concussion should best be measured on a concussion-specific person-reported questionnaire? When the overarching aim of this dissertation was conceptualized, we proposed that these questions would best be answered by exploring HRQOL to fill the gap in the literature and address a perceived clinical need based on the lack of a concussion-specific HRQOL outcome measure. Early on in the first focus group interview, persons with concussion explicitly asserted that the impact of PPCS would best be captured by a measure of functional status rather than HRQOL. This preference was later expressed in all subsequent interviews, thus confirming the need to change the focus of the project. Based on this feedback, the concepts elicited from the systematic review were reframed within the interview guide to enquire about the impact of concussion on functioning, rather than

HRQOL. The protocol as previously described was otherwise unchanged, and continued to provide the template for the remainder of this PhD research. The three overarching themes that encapsulated the impact of PPCS on a person's life were presented qualitatively using participant quotes to substantiate our interpretation of the data. The findings from chapter 4 contribute to our understanding of the functional consequences of concussion and laid the groundwork for item generation of the new outcome measure by informing user-relevant content and structure.

Chapter 5: **The Concussion Recovery Questionnaire (CORE-Q): conceptual model development and item generation of a concussion-specific measure of functional status**

The purpose of this study was to finalize the development of a concussion-specific outcome measure that is brief enough to be included in a battery of assessment tools, yet comprehensive enough to evaluate relevant concepts identified in the previous chapters. The specific objectives were to: (1) develop a conceptual model of functioning post-concussion; (2) generate questionnaire items based on concepts elicited in study 3 and the conceptual model; and (3) refine questionnaire items based on cognitive interviews with persons with concussion and clinicians with expertise in concussion. This chapter is a summative work that describes the rationale and process involved in operationalizing the findings drawn from chapters 3, 4, and 5. The Concussion Recovery Questionnaire (CORE-Q) is presented as a new concussion-specific measure of functional status for use in clinical practice and intervention trials.

The high-quality content validity of the CORE-Q will broaden the inferences that can be made regarding the recovery of persons experiencing PPCS.

Chapter 6: **Content comparison of a new concussion-specific measure of functional status, the CORE-Q, with existing outcome measures used in concussion research**

The purpose of this study was to examine the concepts contained in existing PROMs used in concussion research and compare them with the concepts contained in the CORE-Q as a whole, and in each of its three subscales, the Post-Concussion Functional Scale (PCFS), Concussion Modifiers Scale (CMS), and Global Functional Recovery Scale (GFRS) to identify any conceptual gaps. The objective was to map the concepts in each PROM onto each subscale of the CORE-Q. The extent of overlap was compared to establish whether existing PROMs adequately represented the content of the CORE-Q (content validity). Evidence that the CORE-Q contained concepts not evaluated by any other measure was considered necessary to justify the introduction of a new functional status PROM into the plethora of existing measures.

Chapters 2 and 3 have been published in peer-reviewed journals, and are formatted according to the journal's specifications. Chapters 4, 5, and 6 have been submitted for publication in peer-reviewed journals, and are formatted according to each journal's specifications.

Chapter 2: Protocol for the mixed-methods development of a concussion-specific health-related quality of life outcome measure based on the international classification of functioning, disability and health

The work in this chapter has been published in *British Medical Journal Open* and is available as open source. The published article is presented in Appendix B. Ethics approval was not required for this study.

Citation: van Ierssel, J., Sveistrup, H., & Marshall, S. (2018). Protocol for the mixed-methods development of a concussion-specific health-related quality of life outcome measure based on the international classification of functioning, disability and health. *BMJ open*, *8*(7), e022240.

2.1 Abstract

Introduction

Recovery from concussion has traditionally been evaluated by patient-reported symptoms, objective measures such as loss of consciousness, specific dimensions such as depression or fatigue, cognitive status, employment status, level of physical activity, and the more complex construct of disability. Increasingly, patient-reported outcome measures of health-related quality of life (HRQOL) are being emphasized as an important end point in patient care, clinical trials, and health policy decisions. Currently, no standardized concussion-specific HRQOL outcome measure exists.

The process for developing a concussion-specific HRQOL outcome measure based on the international classification of functioning, disability, and health (ICF) is outlined.

Methods and analysis

A multi-stage, patient-centred approach to developing the outcome measure will integrate evidence from systematic reviews, qualitative research, and cognitive interviewing into a self-report questionnaire to guide clinical decision-making. The psychometric properties of the questionnaire will be evaluated to assess the inter-rater reliability and construct validity of the measure in individuals with persistent post-concussion symptoms. To date, the systematic review and the clinical expert interviews within the preparatory phase have been completed, and work is progressing on the subsequent phases. It is anticipated

that the outcome measure will be ready for psychometric testing in September 2018.

Ethics and dissemination

Ethical approval was granted by the Ottawa Health Science Network Research Ethics Board (Protocol #20170720-01H) on October 31, 2017 to conduct the patient and clinical expert interviews. Ethical approval for psychometric testing of the outcome measure will be sought by the Ottawa Health Science Network Research Ethics Board in Phase II, after the development of the final HRQOL questionnaire. Results will be disseminated through peer-reviewed journals and professional conferences.

PROSPERO registration

Phase I systematic review registration number CRD42017075588 (June 15, 2017).

Phase II systematic review registration number CRD42017075588 (September 27, 2017).

Article Summary

Strengths and limitations of this study

- This study follows the recommendations of the Food and Drug Administration for the development of patient-reported outcome measures.

- The questionnaire will be developed based on a conceptual model to identify the components of health-related quality of life post-concussion, and the causal relationships between them.
- Patient contribution to item generation will maximize the content validity of the outcome measure by ensuring that the items on the questionnaire are relevant to patients with persistent post-concussion symptoms.
- Linking items on the questionnaire to the International Classification of Functioning, Disability and Health will enable content comparison of outcome measures, and facilitate clinical decision-making by allowing multidisciplinary healthcare professionals to set meaningful patient-directed goals.
- Currently, no concussion-specific HRQOL outcome measure exists; therefore there is no gold-standard measure against which to evaluate criterion validity of a newly developed questionnaire.

2.2 Introduction

Concussion represents a distinct subset of traumatic brain injury (TBI) at the milder end of severity, which falls outside the expected clinical presentation seen with moderate-severe TBI. The term concussion may be used interchangeably with mild TBI (mTBI), and is defined by the American Congress of Rehabilitation Medicine as a traumatically induced physiologic disruption of brain function, as manifested by at least of the following: i) any period of loss of consciousness; ii) any loss of memory for events immediately before or after the accident; iii) any alteration in mental state at the time of injury such as feeling

dazed, disoriented, or confused; and iv) focal neurological deficit(s) which may or may not be transient (American Congress of Rehabilitation Medicine, 1993). The severity of the injury may not exceed the following: i) loss of consciousness of approximately 30 minutes or less; ii) after 30 minutes, an initial Glasgow Coma Scale (GCS) of 13-15; and iii) posttraumatic amnesia (PTA) not greater than 24 hours. Both the International Collaboration of Mild Traumatic Brain Injury Prognosis, and the US Department of Defense differentiate mTBI from moderate-severe TBI by the absence of structural abnormalities on either CT or MRI (Kristman et al., 2014). An expert consensus panel of concussion in sport supports this assertion, stating that the acute clinical symptoms perceived following an mTBI reflect a functional disturbance rather than a structural injury (McCrory et al., 2013). Structural abnormalities seen in patients with a GCS of 13-15 (complicated mTBI) have been associated with increased disability compared to those without intracranial pathology (Levin & Diaz-Arrastia, 2015), supporting the notion that recovery from complicated mTBI is more consistent with that from moderate-severe TBI than uncomplicated mTBI (no evidence of CT abnormalities) (Carroll et al., 2014).

Mild TBI may be further differentiated from moderate-severe TBI based on functional outcome. The Extended Glasgow Outcome Scale (GOS-E) is considered the “gold standard” for functional outcome following TBI. Using a cut-off of 7 on the GOS-E to indicate good recovery, a longitudinal study found that less than one-quarter of mTBI patients continued to experience restrictions in work and social participation, and limitations in activities of daily living at 1 year

after injury. In contrast, GOS-E scores for 62% of patients with severe TBI, and 48% of patients with moderate TBI indicated residual disability at 24 months, with a 'plateauing' of recovery after 12 months (Sandhaug, Andelic, Langhammer, & Mygland, 2015). Moderate to severe TBI is, thus, frequently associated with functional dependence both in and outside the home, and reduced work and social participation due to cognitive and physical disabilities.

Differences in structural damage, mortality rates, functional outcomes, and increased rates of disability suggest that recovery from concussion should be evaluated separately from moderate-severe TBI. This paper will use the term concussion to denote mTBI without the presence of structural abnormalities on standard neurodiagnostic imaging, and will focus on those patients with persistent postconcussion symptoms (PPCS), with persistent defined as 3 months or longer post-injury.

Most concussion patients are expected to make a full recovery and return to work and other pre-injury activities within days to months. Although best evidence suggests that objective cognitive deficits are not measurable beyond the 3 month period of expected normal recovery post-concussion (Carroll et al., 2014), 10-15% will go on to develop PPCS, which may persist for months or years (Ontario Neurotrauma Foundation, 2013). Common symptoms such as headache, fatigue, and difficulty concentrating are non-specific to concussion, and do not differ significantly from general trauma patients (Levin & Diaz-Arrastia, 2015). Since overall mortality and functional dependence following a

concussion is rare, it is unclear whether poor outcomes can be attributed to concussion-related brain changes, pre-existing conditions, or other factors.

Recovery from concussion has traditionally been evaluated by multimodal measures, such as patient-reported symptoms, objective measures such as loss of consciousness, specific dimensions such as depression or fatigue, cognitive status, employment status, level of physical activity, and the more complex construct of disability. However, these measures do not fully capture the *significance* of the impairments or level of participation post-injury as experienced by the individual.

The Interagency Common Data Elements TBI Outcomes Workgroup identified health-related quality of life (HRQOL) as a core construct to be assessed, covering domains relevant to concussion; applied as either part of a comprehensive battery, or in addition to other outcome measures (Wilde et al., 2010). The International Society for Quality of Life Research defines HRQOL as "the functional effect of a medical condition and/or its consequent therapy upon a patient" ("Health-Related Quality of Life Research," n.d.). Health-related quality of life is often erroneously inferred from other measures of health, such as symptoms, functioning, or health status. Symptoms represent a patient's perception of an abnormal physical, emotional, or cognitive state (Anderson & Burckhardt, 1999). Functioning is defined by the International Classification of Functioning, Disability and Health (ICF) as "an umbrella term encompassing all body functions, activities and participation" (World Health Organization, 2001). Whereas the World Health Organization (WHO) describes health as "a state of

complete physical, mental, and social well-being not merely the absence of disease" (World Health Organization, n.d.). When seen from a negative perspective, impairments in body function, activity limitations of the individual, and participation restrictions at a societal level are described as disability (World Health Organization, 2001). While the above measures of health may influence a patient's HRQOL, they do not represent it. What distinguishes HRQOL is the patient's perception of the relative importance of these measures, their own values, and their preferences (Gill, 1994). Although HRQOL is intuitively understood, it must be explicitly distinguished from other related terms, as they represent distinct constructs. Generic HRQOL outcome measures incorporate items across multiple domains to capture a broad spectrum of issues, allowing comparison between populations and various disease states. However, generic measures, such as the WHO Quality of Life-BREF may be insensitive to small, but clinically relevant changes to concepts important to a concussion population, such as persistent problems with cognitive functioning, or social isolation.

Condition-specific HRQOL outcome measures on the other hand, have the advantage of exploring specific health concerns in depth by incorporating items most relevant to a specific patient group, and are therefore more sensitive to clinical changes that occur within those individuals (von Steinbuechel et al., 2016). Currently, no standardized concussion-specific HRQOL outcome measure exists.

It has been suggested that the ICF provides an ideal base for the development of new outcome measures in individuals with TBI (Bernabeu et al.,

2009). Adopted by the WHO in 2001, the ICF serves as a universally accepted reference system to classify functioning and disability (Laxe et al., 2012). Using a biopsychosocial model, the ICF provides a standard language and a conceptual basis to describe health (World Health Organization, 2013) Both comprehensive and brief ICF Core Sets for TBI have been developed as a means of describing concepts most relevant to the health of an individual after TBI (Bernabeu et al., 2009). Questionnaires are constructed of items that measure an intended concept, such as headache. For example, headache is a common post-concussion concept measured by the item “Headache” on the symptom evaluation scale of the Sport Concussion Assessment Tool – 5 (Echemendia et al., 2017), and by the broader item “How often do you suffer (physical) pain?” on the WHO Quality of Life-100 (World Health Organization, 1998). This relationship enables the mapping of concepts to ICF categories (Bernabeu et al., 2009). Linking newly developed questionnaire items to ICF categories would enable the comparison of the content of various outcome measures, and facilitate communication between multidisciplinary healthcare providers by providing a common language with which to describe function, disability and health.

Persistent post-concussion symptoms significantly impact a broad set of concepts that span across all domains of the ICF. These concepts then influence HRQOL. Measuring HRQOL as a construct determined by these concepts makes conceptual sense in a TBI population, since there is often no relationship between these causal indicators (World Health Organization, 1998).

The purpose of this paper is, thus, to present the steps in the development of a concussion-specific HRQOL outcome measure based on the ICF (Figure 2.1). The construct of health-related quality of life will be measured as a reflection of multidimensional concepts. In keeping with patient-centred outcomes research, the process is patient driven, and consists of multiple phases.

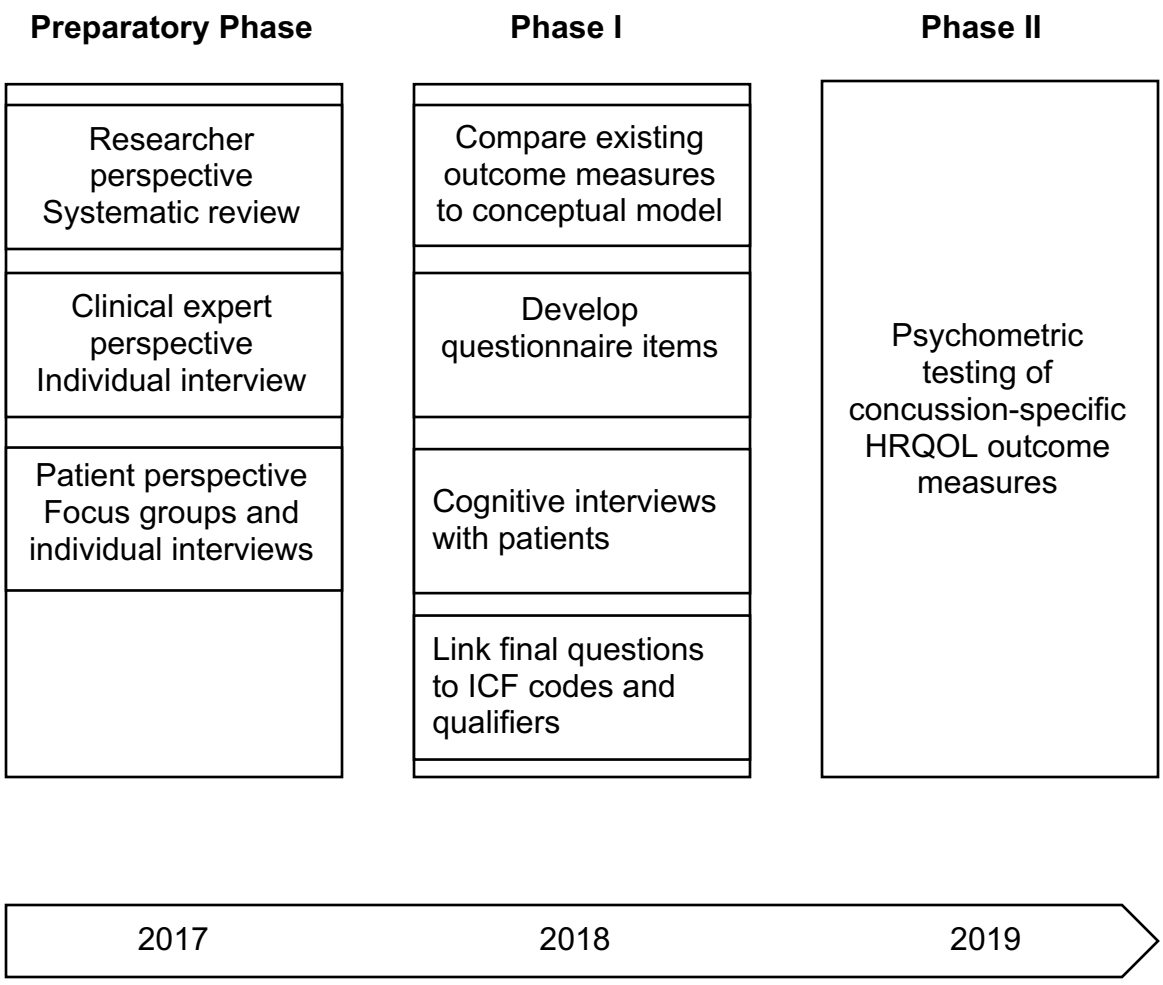

Figure 2.1. Mixed-method development process of a Concussion-Specific Health-Related Quality of Life Outcome Measure based on the ICF for a multistage project started in 2017, with a projected completion date of 2019. The preparatory phase describes the development of a conceptual model of HRQOL; Phase I describes the development of a HRQOL questionnaire based on the conceptual model; Phase II refers to the assessment of questionnaire's test-retest reliability and construct validity with the WHOQOL-BREF and QOLIBRI in a concussion population. Embedded boxes within each phase represent the distinct steps required to complete each phase in successive order. Abbrevations: ICF, International Classification of Functioning, Disability and Health; HRQOL, Health-related quality of life; WHOQOL-BREF, World Health Organization Quality of Life – Brief; QOLIBRI, Quality of Life after Brain Injury.

2.3 Methods

Patient and public involvement.

Patient involvement will be a keystone in the development of a concussion-specific questionnaire. Within the overarching construct of quality of life, patients will be specifically asked to identify those issues that are greatest importance to them, and what issues they would like addressed in a questionnaire based on their lived experience with PPCS. Additionally, their input is being sought in the design of the questionnaire formatting. Clinician input will also be sought to identify issues that may have relevance to patients with PPCS. This will be an iterative process, such that patient preferences and clinician feedback will be reviewed in subsequent discussions to ensure that the views of the patients and clinicians are well represented in the questionnaire. Finally, the working questionnaire will be brought back to a sample of patients to confirm that their priorities and preferences have been adequately captured. Upon completion of the study, patients and clinicians who have participated in the study will be provided with an electronic copy of the final questionnaire.

The development of a concussion-specific HRQOL outcome measure involves 3 distinct phases: a preparatory phase, phase I, and phase II). The preparatory phase involves the development of a conceptual model, which will form the framework for the concepts to be included in the questionnaire. In Phase I, the identified concepts will be transformed into a concussion-specific HRQOL questionnaire. Phase II involves the psychometric testing of the questionnaire in patients with PPCS.

Preparatory phase – development of a conceptual model.

Within the preparatory phase, a systematic review has already been performed to develop a *working* conceptual model consisting of broad domains that have been linked to the ICF. Qualitative interviews with clinicians and patient focus groups will identify the specific concepts within each domain that are impacted by concussion in order to further develop and refine the working conceptual model. The *final* conceptual model will be developed through content analysis of the qualitative data.

Researcher perspective: systematic review.

A systematic review was undertaken to identify the HRQOL outcome measures used in concussion-specific research since the introduction of the ICD-10 code for concussion in 1992. The specific objectives of the review were i) to identify the concepts contained in the measures using the ICF as a reference (Cieza et al., 2002; Cieza, Fayed, Bickenbach, & Prodinger, 2016) ii) to describe the breadth and depth of concepts; and iii) to develop a working conceptual model of HRQOL in individuals with PPCS based on the concepts identified. Eight electronic databases were searched from 1 January 1992 to 12 March 2017, including Medline (OVID), Embase (OVID), PsycINFO (OVID), Cumulative Index to Nursing and Allied Health Literature (CINAHL) (EBSCO), SCOPUS, the Cochrane Database for Systematic Reviews, Prospero and Patient-Reported Outcome and Quality of Life Database (PROQOLID; http://www.qolid.org). Grey literature was searched, reference lists scanned, and relevant journals hand-searched. Search terms included database subject headings and keywords for

the concepts: ‘concussion’, ‘traumatic brain injury’, and ‘quality of life’ using a Boolean strategy, and adapted for each database.

Studies were eligible if they involved primary qualitative or quantitative research exploring the impact of PPCS on HRQOL in adults aged 18-65 years with a diagnosis of concussion. Studies were excluded if they included the results of a moderate-severe TBI sample not differentiated from the concussion sample, or patients presented with evidence of structural injury or intracranial bleeding on diagnostic imaging.

Content analysis was performed on individual questions within identified outcome measures by linking concepts to 2nd level ICF categories according to established linkage rules (Cieza et al., 2016, 2005). Concepts were then organized into domains at the ICF component level. A working conceptual model of HRQOL post-concussion was proposed based on these results to inform the content of semi-structured interviews with clinicians and patient focus groups. This systematic review has been registered with PROSPERO (CRD42017068241).

Clinician perspective: individual interviews.

The importance of clinician interviews in the development of an HRQOL outcome measure is two-fold. First, clinicians will improve content validity by identifying clinically important domains that should be considered in the conceptual model. Additionally, clinicians in this study will be asked to identify perceived facilitators and barriers to the use of a concussion-specific HRQOL outcome measure in their clinical practice.

Clinicians will be purposively sampled to represent the diverse healthcare provider groups who treat the key domains from which PPCS are comprised. Eligibility includes a minimum of 3 years of clinical experience working with concussion patients, and will include at least one representative from each of the following groups: physicians, neuropsychologists, physiotherapists, occupational therapists, neuro-optometrists, and speech-language pathologists. These clinicians will be chosen based on their recognition as national experts in the management of post-concussion symptoms, as evidenced by their membership in national concussion guidelines working groups. Written informed consent is required prior to participation.

Concepts perceived by clinicians to have an impact on the HRQOL of patients with PPCS will be identified through semi-structured interviews and linked to 2nd level ICF categories. Feedback from clinicians on the use of an HRQOL outcome measure will be incorporated into the design of the questionnaire to facilitate the implementation of the final questionnaire in clinical practice.

Patient perspective: focus groups.

A comprehensive list of HRQOL concepts that are relevant to patients with PPCS will be collected using focus groups and linked to 2nd level ICF categories using content analysis.

Patients will be recruited from the Acquired Brain Injury Outpatient Clinic at the Ottawa Hospital Rehabilitation Centre (TOHRC) and from community-

based medical clinics throughout Ottawa with known concussion management programs.

Patients will be considered eligible for inclusion if they are English speakers between the ages of 18-65 years, and have experienced persistent symptoms for at least 3 months following a diagnosed concussion sustained between 2008 and 2018. Patients will be excluded if they have a diagnosis of moderate-severe TBI, if they were receiving treatment for a pre-existing mental health disorder or addiction at the time of injury, or if there is evidence of post-traumatic structural injury or intracranial bleeding on diagnostic imaging, if available. Written informed consent is required from all patients prior to participating in the study.

We estimate that a minimum of 30 patients will be sufficient to reach data saturation. The patient perspective will be used to expand upon and refine the working conceptual model and identify the most relevant emerging concepts.

Patients will be asked to identify how their concussion has impacted their HRQOL through open-ended questions and review of existing questionnaires, guided by the working conceptual model. Concepts derived from patient focus group discussions will be extracted using content analysis and linked to 2nd level ICF categories. Concepts will then be deductively coded into the domains of the working conceptual model. An inductive approach will also be used to add additional domains as needed to reflect emerging concepts from the data. Data collection and linking will be conducted iteratively during multiple rounds of focus group discussions so that patients in subsequent groups can confirm the

relevance and importance of concepts that have emerged from earlier discussions. Two independent researchers will review the domains established through coding to agree upon the final conceptual model. Discrepancies will be resolved through discussion with a third researcher.

Inter-coder reliability between the researchers will be determined by using the kappa statistic for inter-rater reliability on a select sample of transcripts. A kappa of >0.7 will be considered acceptable for inter-coder reliability.

Phase I Development of a concussion-specific HRQOL questionnaire.

Systematic review.

A systematic review will be conducted to determine if existing generic and TBI-specific HRQOL outcome measures possess sufficient content validity to evaluate outcomes in concussion research. The specific objectives of the review are: i) to identify existing generic and TBI-specific outcome measures currently being used to evaluate HRQOL in patients post-concussion; ii) to compare the content of existing outcome measures with the concussion-specific conceptual model of HRQOL; and iii) to assess whether questions in existing measures reflect domains in the conceptual model (content relevance), and whether all the domains in the conceptual model are represented appropriately (content representativeness) by questions in the identified measures. It is hypothesized that existing HRQOL outcome measures contain both questions that are relevant to concussion patients, such as cognitive abilities, and questions not identified by patients as relevant to their HRQOL post-concussion, such as satisfaction with

bodily appearance. More importantly, it is hypothesized that some concussion-specific domains identified by the conceptual model will be under-represented or absent from existing questionnaires, such as social isolation, sense of identity, uncertainty of prognosis, or the stigma of an invisible injury.

Eight electronic databases will be searched from 1 January 1992 onwards, including Medline (OVID), Embase (OVID), PsycINFO (OVID), Cumulative Index to Nursing and Allied Health Literature (CINAHL) (EBSCO), SCOPUS, the Cochrane Database for Systematic Reviews, Prospero and Patient-Reported Outcome and Quality of Life Database (PROQOLID; http://www.qolid.org). Grey literature will be searched, reference lists scanned, and relevant journals hand-searched. Search terms will include database subject headings and keywords for the concepts: 'concussion', 'traumatic brain injury', and 'quality of life' using a Boolean strategy, and adapted for each database.

Studies will be included if they assess self-reported HRQOL in adults aged 18-65 years with persistent symptoms 1 month or more following a diagnosed concussion. Studies using proxy measures, single-item rating scales, or involving concussion sustained in conjunction with multiple trauma will be excluded.

Specific questions from existing outcome measures will be linked to 2nd level ICF categories to facilitate content comparison between existing outcome measures and the concussion-specific conceptual model (Laxe et al., 2012). This will provide a comprehensive understanding of the conceptual basis of what is being measured by each of the outcome measures, and identify any potential

gaps in assessment tools. Content validity will be assessed with respect to content relevance and representativeness. Within each outcome measure, individual questions will be considered to possess content relevance if they can be linked to 2nd level ICF categories of the concussion-specific conceptual model. Content representativeness will be assessed to determine the extent to which the relevant domains within each outcome measure may be over-represented, under-represented, or excluded. If the balance is wrong, the outcome measure will lack content validity. Consistent with previous studies, existing HRQOL outcome measures will be considered to possess acceptable content validity if 75% or more of the questions demonstrate both content relevance and content representativeness[24]. Psychometric properties, including reliability, and responsiveness in a concussion population, will be extracted and analyzed from published reports for any existing measures that meet the above criteria. Outcome measures will be considered suitable for use in a concussion population if they demonstrate a minimum threshold of a kappa statistic of 0.7 for intra-rater reliability, and at least a moderate effect size of 0.5 for responsiveness, to indicate the ability to measure clinically important change in patients with PPCS[25,26]. Support for a new concussion-specific HRQOL outcome measure will be established if existing outcome measures do not meet the above criteria.

This systematic review has been registered with PROSPERO (CRD42017075588).

Pilot-questionnaire development.

Concepts from the final conceptual model will be transformed from 2nd level ICF codes into a comprehensive list of subjective questions for a pilot concussion-specific HRQOL outcome measure, hereafter referred to as the CONcussion Quality of Life (CONQOL). The CONQOL will be constructed as a self-administered questionnaire that evaluates the *impact* of each concept on HRQOL, as opposed to how *satisfied* or *bothered* a patient is by the concept identified in the question; for example, "How much does the stigma of an invisible injury impact your health-related quality of life?". Framing the questions from the perspective of how much each concept *impacts* HRQOL more directly measures the extent of the problem; whereas HRQOL questions traditionally framed as satisfaction or bother may be confusing for patients to disentangle the magnitude of functional limitations or activity restrictions from their ability to cope with the problem.

Patients will be asked to quantify the magnitude of time or severity of each concept within the past week. This interval was chosen to minimize the risk of recall bias and respondent burden, while balancing sufficient time for the participant to provide a reliable estimate of the impact of PPCS on their HRQOL. Additionally, the persistent nature of PPCS makes natural healing effects unlikely within the specified timeline. The magnitude or severity of each question will be rated on a 5-point Likert scale with both descriptive and numerical anchor points for each response (0 = No problem 0-4%; 1 = MILD problem 5-24%; 2 = MODERATE problem 25-49%; 3 = SEVERE problem 50-95%; 4 = COMPLETE

problem 96-100%) consistent with the generic qualifiers used to classify ICF codes (see Table 2.1) (World Health Organization, 2001) .

Table 2.1. Proposed response scale consistent with the ICF qualifiers

Response options	Descriptor	Scaling
0	No problem	0-4% of the time.
1	Mild problem	5-24% of the time
2	Moderate problem	25-49% of the time
3	Severe problem	50-95% of the time
4	Complete problem	96-100% of the time

Note. Adapted from "International Classification of Functioning, Disability and Health: ICF", by World Health Organization, *World Health Organization*, 2001.
ICF, International Classification of Functioning, Disability and Health

Respondents will then be required to rank the top three concerns identified on the questionnaire. Finally, the CONQOL will enable the respondent to identify in an open-ended qualitative format up to three goals they wish to accomplish with treatment that would have a positive impact on their HRQOL. For each goal, the respondent will be prompted to rate both how important the goal is, and to what extent they have achieved it on a 10-point Likert scale (1 = Not at all; 10 = Extremely/Completely). The addition of patient-reported goals is intended to facilitate clinician-patient communication and identify priorities for interventions. The CONQOL will be scored as an index, with scores generated for each sub-domain, and an overall summative score. Each subdomain will be grouped to represent functional domains identified in standardized concussion guidelines,

such as cognitive, emotional, and vestibular domains, where appropriate. Grouping questions by functional domains will allow clinicians to identify areas that need to be assessed in more detail through further probing of symptoms and standardized outcome measures. This will streamline the clinical assessment based on those domains that have the greatest impact on the patients' HRQOL.

Finally, the CONQOL will include a section that prompts clinicians to provide patients with relevant concussion-specific resources, such as external organizations that provide educational modules, websites, informative handouts, and standardized guidelines. Thus, the CONQOL will function to evaluate HRQOL, guide clinical decision-making, and provide patient education.

Cognitive interviewing

The CONQOL will then be pretested using face-to-face cognitive interviewing to identify any problems with the questionnaire items, formatting, or administration. The purpose is to ensure patient understanding, appropriateness of response options and recall period, level of readability, and completeness of the concepts contained in the questions (C. Gorecki, Lamping, Nixon, Brown, & Cano, 2012; US Food and Drug Administration, 2009). This process is necessary to improve the design of the CONQOL by informing revision decisions and providing evidence of content validity. Cognitive interviews will be performed using the "think-aloud" technique to describe the patients' thought process as they read each question, followed by "verbal probing" if necessary to clarify any sources of confusion (Peterson, Peterson, & Powell, 2017).

This process will be an iterative approach with multiple rounds of interviewing and item revision. Consistent with published recommendations, a minimum sample size of 15 will be sought to increase the probability of detecting problems with the pilot questionnaire (Peterson et al., 2017). Initial interviews will explore major conceptual problems and global issues with the CONQOL, with an emphasis on conceptual clarity, content coverage, and respondent burden. Subsequent interviews will focus on structural or logical problems with the CONQOL such as unclear wording, grouping of questions, formatting issues, and appropriateness of questions. Varying perspectives will be elicited by selecting patients across a broad representation of demographics, mechanism of injury, previous history of concussion, employment characteristics, and time since injury. Written informed consent will be obtained.

Questionnaire refinement

Following each round of interviewing, the questionnaire development team will identify problems on an item-by-item basis using the Question Appraisal System (QAS-99) (Willis & Lessler, 1999). Similar to the qualitative research approach to identify issues of importance during the item generation phase, problems with content or construction will be extracted and coded. The questionnaire development team will discuss and resolve identified problems after each round of interviews. Consensus will be required in order to retain, revise, delete, or add additional questions, or make structural changes to the questionnaire. Careful attention will be paid to ensure that questions pertaining to each domain of the conceptual model are retained.

Phase II psychometric testing.

Psychometric testing in phase II will involve a cross-sectional multi-centre study to assess the test-retest reliability and construct validity of the CONQOL. Eligibility criteria for patient recruitment will be consistent with those used for during the qualitative phase of item development.

Test-retest reliability.

The CONQOL will be assessed for test-retest reliability at two time points, separated by two weeks. Based on clinical experience and the chronicity of PPCS, a two-week repeat-measures study is an appropriate timeframe to minimize changes in HRQOL due to either recall bias or physiological recovery. Sample size will be calculated to be able to estimate test-retest correlations with a 95% confidence interval (±0.1), and will follow the recommendation of five to ten subjects per question on a newly developed outcome measure (Claudia Gorecki et al., 2013). The minimum requirement for test-retest reliability will be set at a kappa statistic of ≥0.7.

Internal consistency.

Outcome measures that assess a single construct, such as anxiety, contain questions that reflect the effect of the construct (Streiner, 2003). Because these *effect indicators* are correlated, the outcome measure is assumed to have a high degree of internal consistency (Streiner, 2003). The theoretical nature of HRQOL is such that it may be influenced by many different unrelated concepts. These concepts, called *causal indicators*, are responsible for causing changes in HRQOL, rather than HRQOL affecting the concepts (Streiner, 2003).

Correlations between causal indicators may be deliberately low in order for questions to represent a broad set of concepts. For example, if patients with PPCS experience a reduction in their post-traumatic headaches because of a new medication, their HRQOL will improve, even though there has been no change in their exercise tolerance, speed of thinking, level of fatigue, or return to work status. Because a patient can endorse one concept (e.g. improvement in headache) without that implying that they would necessarily endorse another (e.g. level of fatigue), the concepts would not be expected to necessarily correlate with each other. Therefore, it would be inappropriate to use statistics based on the assumption of homogeneity, such as internal consistency, inter-item correlations, or factor analysis to assess the construct of HRQOL, as this might lead to false assumptions about reliability or usefulness of the CONQOL (Streiner, 2003). Therefore, concepts will be allocated to subdomains based on their classification according to ICF chapters. This highlights the importance of significant input from patients with PPCS in the development of the questionnaire in order to ensure a high level of content validation.

Content validation.

Evidence for the extent to which the CONQOL measures the important concepts of HRQOL in patients with PPCS will be provided through the rigorous development of the questionnaire based on a concussion-specific conceptual model. Cognitive interviewing with patients will then further confirm evidence of content validation by demonstrating that the questions influence HRQOL, no important concepts were missed, and the response options, recall period, and

questionnaire design are appropriate, comprehensive and understandable (Patrick et al., 2011). This will ensure that each question on the CONQOL relates to one of the domains of the conceptual model (content relevance), and that each domain of the conceptual model is represented with appropriate importance by at least one question (content representativeness).

Construct validation.

Construct validation of the CONQOL will be performed against the generic measure WHOQOL-BREF and TBI-specific measure QOLIBRI to provide support that the CONQOL measures what it intends to measure. It is hypothesized that the CONQOL will demonstrate moderate to high correlations with these existing measures that evaluate the same construct of HRQOL. Spearman's rank correlation will be used to assess the strength of association between similar subdomains on the outcome measures.

Criterion validation.

Health-related quality of life is an unobservable construct that cannot be measured directly. It can only be inferred by how well questions on an outcome measure fit the underlying theory. Since there is no "gold standard" against which a newly developed HRQOL outcome measure can be compared, testing for criterion validation is not applicable.

2.4 Significance of study

The strength of the CONQOL to evaluate change in patients with PPCS will be evidenced by the substantial patient input in the development of the outcome measure, thus providing support for a high level of content validation.

This concussion-specific HRQOL outcome measure would meet the specific needs of patients with PPCS by prompting clinicians to ask relevant probing questions, identify concerns, perform appropriate standardized tests, set meaningful patient-directed intervention goals, facilitate referrals to specialists, and evaluate change.

The proposed design of the CONQOL to provide clinicians with recommendations for a more focused assessment and educational resources that match patient-identified problems would be a novel use of an HRQOL outcome measure to facilitate patient-centred care.

Ethics and dissemination.

No personal health information will be collected during this research, and no personal identifying information will be accessed from records or databases. Only names, telephone number, and emails of participants will be available to the research team for the purpose of screening for eligibility and scheduling. Written informed consent will be obtained from all participants prior to taking part in the study. Participants will be assigned a respondent number, and data collected will be de-identified. Data will be processed anonymously and presented as aggregate results.

Within the preparatory phase, no ethical approval is required to perform either systematic review or to develop the pilot questionnaire. Ethical approval was granted by the Ottawa Health Science Network Research Ethics Board (Protocol #20170720-01H) on October 31, 2017 to conduct the patient and clinical expert interviews. Ethical approval for psychometric testing of the

outcome measure will be sought by the Ottawa Health Science Network Research Ethics Board in Phase II, after the development of the final HRQOL questionnaire.

The results of this project will be distributed to professional groups through peer-reviewed publications and presentations. Additionally, the results of the study will be disseminated to clinicians at conferences and strategic meetings.

Author's contributions.

J.v.I., H.S., and S.M. contributed to the conception and design of the study protocol. J.v.I. was responsible reviewing the literature and drafting of this manuscript. H.S. and S.M. supervised the work, reviewed, and edited the manuscript critically. All authors read and approved the final manuscript.

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Competing interests

The authors report no conflicts of interest.

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Chapter 3: Identifying the concepts contained within health-related quality of life outcome measures in concussion research using the International Classification of Functioning, Disability, and Health as a reference- a systematic review

The work in this chapter has been published in *Quality of life research* and is reproduced in its entirety with permission. The published article is presented in Appendix B. The final publication is available at link.springer.com. Ethics approval was not required for this study.

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3.1 Introduction

While most concussions resolve entirely within days to months post-injury [1], a minority of patients will go on to develop persistent postconcussion symptoms (PPCS) such as headache, balance deficits, mood disorders, and difficulty concentrating, which may persist for many months or years. The long-term consequences of physical, emotional, and cognitive dysfunction may be associated with functional limitations, difficulty in returning to school or work, and an increased risk of depression and anxiety [1,2], adversely influencing a patient's health-related quality of life (HRQOL).

Health-related quality of life is defined as a multidimensional construct that reflects the impact of physical, emotional, and social well-being on an individual's health status [3]. Increasingly, patient-reported HRQOL is being recognized as an important consideration in the evaluation and treatment of patients with chronic health problems, including PPCS. The ability to evaluate those issues that are of greatest importance to a patient based on their priorities is especially relevant to those with PPCS in which symptoms may persist for months, or years, and for which recovery may, ultimately, be incomplete. HRQOL measures may be used to supplement traditional objective clinical or laboratory measures of disease, to form the framework for future research designed to improve patient HRQOL, assess the effectiveness of interventions, distinguish populations, identify priorities of intervention based on patient relevance, set patient goals, and develop treatment plans using a patient centered approach. It is essential then, that HRQOL outcome measures in a PPCS population accurately assess the

construct they are intended to measure. Although HRQOL measurement is emerging within the field of concussion, existing generic outcome measures currently being employed may be inadequate for evaluating the specific issues of concern to patients suffering from PPCS.

Despite the increasing interest in HRQOL over recent years, many knowledge gaps remain concerning what health-related quality of life concepts are relevant to adults with PPCS. A larger project has been established to develop a self-report measure of HRQOL in patients with PPCS for use in clinical trials, epidemiological studies, and clinical practice. An essential step in the development of a concussion-specific HRQOL outcome measure is ensuring content validity by identifying those concepts most relevant to the population.

In May 2001, the World Health Organization (WHO) approved the use of the International Classification of Functioning, Disability and Health (ICF) as a standard language and framework for the description of health and health-related states [4]. As such, the ICF can help identify, quantify and compare concepts contained within different outcome measures to assess their suitability for use in various populations and across various conditions.

The objective of this systematic review was to explore how HRQOL is being measured in concussion-specific research with existing outcome measures. The specific aims were i) to identify the concepts contained in the outcome measures using the ICF as a reference; ii) to describe the breadth and depth of concepts between outcome measures; iii) to develop a working

conceptual model of HRQOL in individuals with PPCS based on the concepts identified.

3.2 Methods

This systematic review was performed in accordance with guidelines established by Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) [5], and involved four steps: step one, selection of studies; step two, identification of outcome measures; step three, linkage of concepts contained in the outcome measures to ICF categories; step four, schematic representation of concepts as a conceptual model of HRQOL in individuals with PPCS. A detailed protocol was registered on Prospero prior to data collection (CRD42017068241).

Databases and Search Terms.

In step one, the study objective guided the identification and selection of relevant studies. The literature was searched for studies that reported HRQOL in patients post-concussion, including symptoms, function, activities, participation, and the environment as outlined in the ICF [6]. An overview of the study selection process is presented as a PRISMA flow diagram in Figure 3.1.

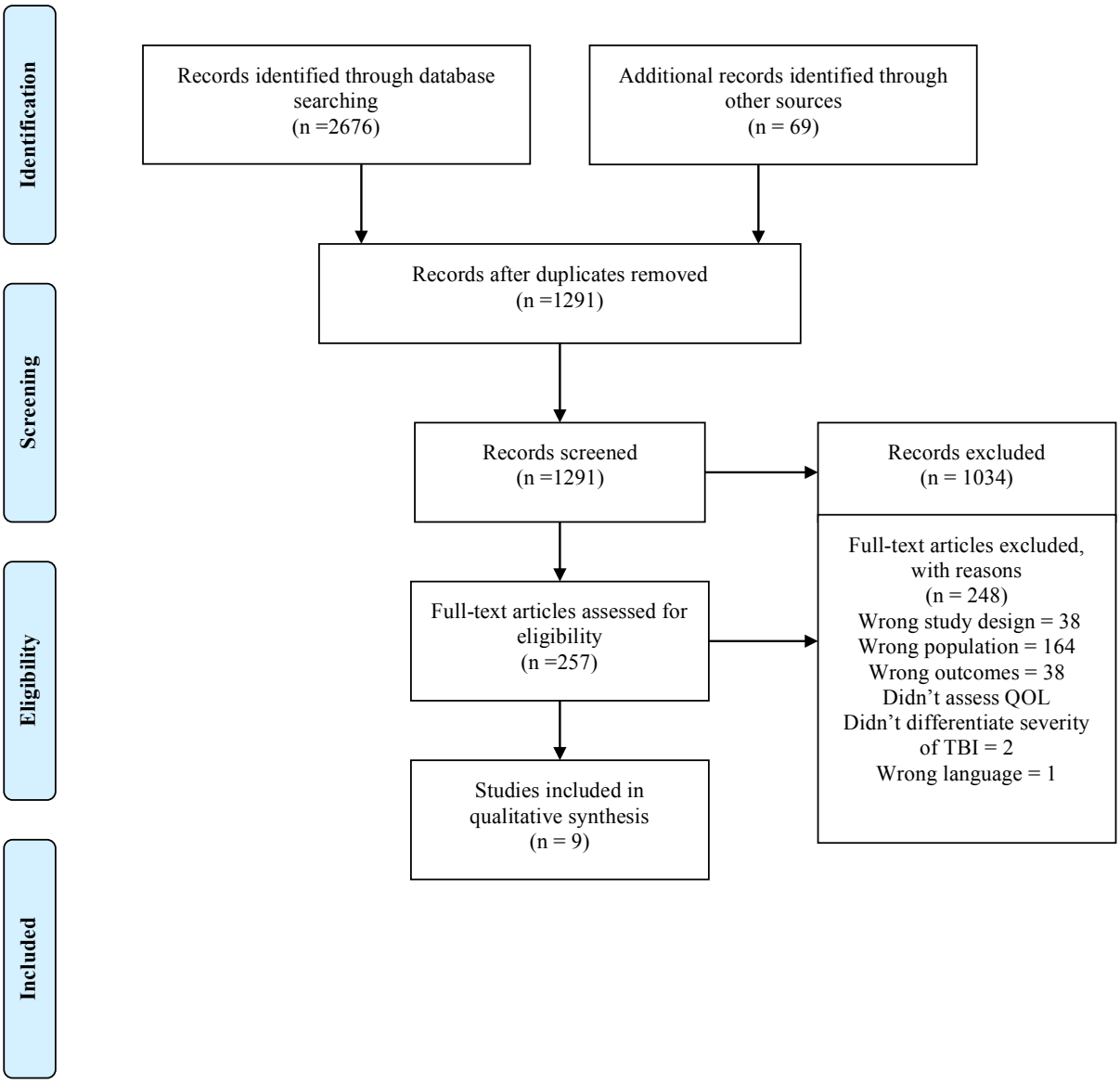

Figure 3.1. PRISMA flow diagram as follows: Records after duplicates removed (1291); records screened (1291), and records excluded (1282).

Eight electronic databases were searched from 1 January 1992 to 12 March 2017, including Medline (OVID), Embase (OVID), PsycINFO (OVID), Cumulative Index to Nursing and Allied Health Literature (CINAHL) (EBSCO), SCOPUS, the Cochrane Database for Systematic Reviews, Prospero and Patient-Reported Outcome and Quality of Life Database (PROQOLID;

http://www.qolid.org). Given that the diagnostic criteria for concussion continue to evolve, studies were restricted prior to 1992 to reflect the most currently accepted criteria based on the date of introduction of the ICD-10 code for concussion with loss of consciousness less than 30 minutes [7]. Studies published prior to this date may include subjects with more severe injuries whose recovery is not consistent with persistent post-concussion symptoms.

Search terms included “concussion”, “post-concussion”, “traumatic brain injury”, “TBI”, “mild head injury”, “quality of life”, and “health-related quality of life”. Keywords were matched to database-specific subject headings. Complete search strategies for each database can be found in Appendix #1. Additionally, reference lists from included studies were scanned for potentially pertinent studies using a snowballing technique, and relevant journals were hand-searched for appropriate studies, including Brain Injury, Journal of Neurotrauma, Journal of Head Trauma Rehabilitation, and Archives of Physical Medicine and Rehabilitation. A grey literature search was performed for reports, discussion papers, conference proceedings, academic and organizational reports using “Grey Matters, A Practical Search Tool for Evidence-Based Medicine” [8] and Physiotherapy Evidence Database, in addition to ProQuest Theses and Dissertations Global. Assistance was sought from an expert medical librarian, experienced in systematic reviews, to develop a comprehensive and inclusive search strategy for all relevant sources.

Eligibility Criteria.

The citation screening and data extraction tool Covidence (www.covidence.org) was used to screen titles and abstracts for eligibility criteria, identify discrepancies between reviewers, and to document a single reason for article exclusion. Studies that were clearly not relevant to the review (e.g. pediatric population) were deemed ineligible and excluded from further review. Full-text articles were retrieved for all abstracts deemed potentially relevant and evaluated against *a priori* eligibility criteria. Studies that meet the eligibility criteria and were deemed acceptable were included for review (Figure 3.1). Studies that failed to meet eligibility criteria were excluded from further consideration. Agreement for inclusion was made through consensus between the two independent reviewers. Unresolved discrepancies were to be resolved through discussion with a third reviewer, however this was unnecessary as there was complete agreement between the two independent reviewers.

Studies were eligible for inclusion if they involved primary research; explored the impact of PPCS on HRQOL, including symptoms, function, activities, participation, and the environment, as either a primary or secondary end point; either qualitative or quantitative data were reported; subjects were adults aged 18-65 years from any healthcare setting; subjects had received a diagnosis of concussion according to the ICD-10 criteria since 1992, and were published in English or French.

Studies were deemed ineligible if HRQOL outcomes were not reported; the study included a moderate-severe traumatic brain injury (TBI) sample not

differentiated from the concussion sample; patients presented with evidence of structural injury or intracranial bleeding on diagnostic imaging if available; if an article was unobtainable or missing data could not be obtained from authors. No limit on methodology was imposed. Additionally, no critical appraisal of methodological quality of included studies was performed since the objective of the study was how HRQOL is being measured in concussion-specific research in order to increase our understanding of the phenomenon without an interpretation of the key findings or theory development. All included studies then passed on to step two of the review.

Data Extraction.

In step two, HRQOL outcome measures contained within the included studies were identified and labeled as TBI-specific or generic.

In step three, content analysis was performed on the identified outcome measures using the taxonomy of the ICF as the framework for coding and organizing concepts. The ICF is a biopsychosocial model that classifies functioning and disability within its components of *body functions*, *body structures*, and *activities and participation*, along with contextual factors that incorporate *environmental factors* and *personal factors* (See Figure 3.2) [4].

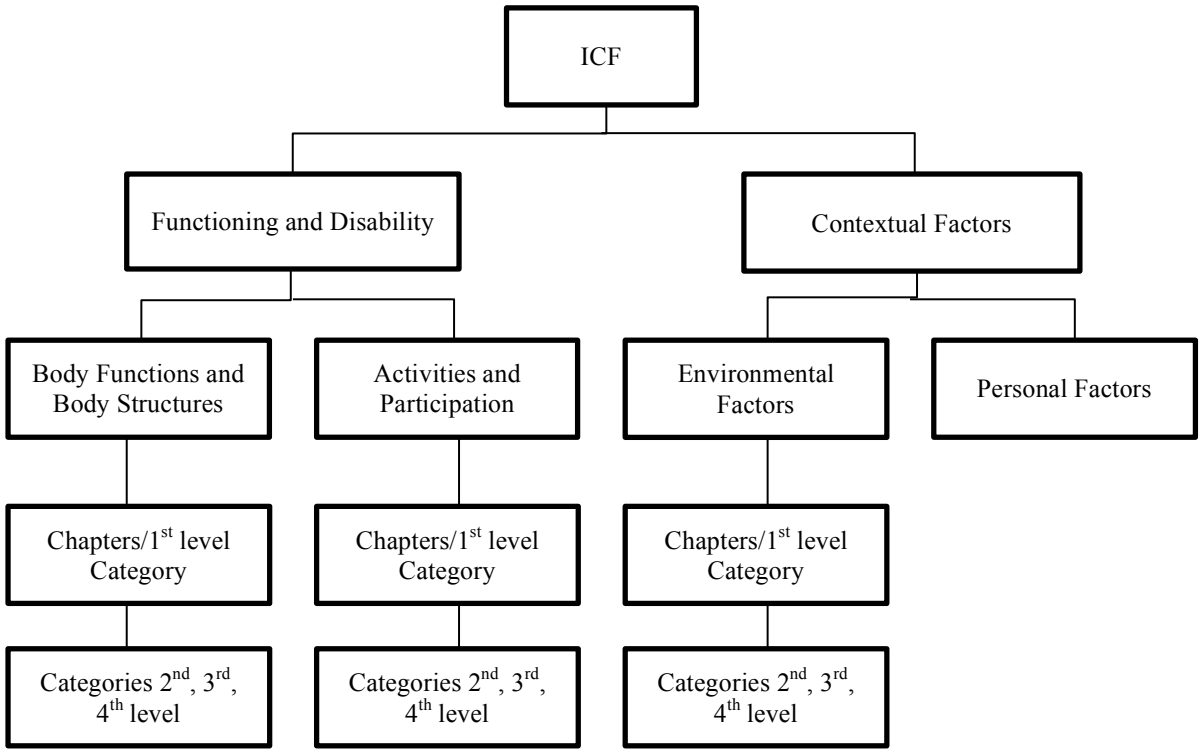

Figure 3.2. Structure of the ICF
ICF, International Classification of Functioning, Disability and Health; Parts: Functioning and Disability, and Contextual Factors; Components: Body Functions, Body Structures, Activities and Participation; Environmental Factors, and Personal Factors; Chapters: 1st level Categories; Categories: 2nd-4th level.

As a universally accepted reference system, the ICF describes functioning, disability and health as a hierarchical structure using an exhaustive list of alphanumeric codes to categorize components and environmental factors into more detailed levels. The first level of the hierarchy is classified as chapters (1st level categories). Chapters are comprised of 2nd level categories, which are then further described in more detail in 3rd and 4th level categories. Table 3.1 provides an example how a question on the QOLIBRI, "How bothered are you by pain, including headaches?", would be linked to different levels of the ICF.

Table 3.1. Example of linking the question "How bothered are you by pain, including headaches?" (F.3. QOLIBRI [15]) to the ICF.

ICF Level	Application in study	Example	Coding
Component	Domain	Body Functions	b
Chapter	Subdomain	Sensory functions and pain	b2
2nd-level category	Concept	Sensation of pain	b280
3rd-level category	Not applied	Pain in body part	b2801
4th-level category	Not applied	Pain in head and neck	b28010

ICF, International Classification of Functioning, Disability and Health; QOLIBRI, Quality of Life after Brain Injury

Concepts from identified outcome measures were linked to the ICF using established rules for health status measures [9,10] in a two-step process: i) identification all meaningful concepts; and ii) linking each concept to an alphanumeric ICF code. Where questionnaire items contained more than one concept, each concept was extracted separately and linked accordingly. The hierarchical structure of the ICF was then used to map the concepts at the level of corresponding 2nd level categories, using pre-prepared data extraction tables derived from the ICF Core Set for TBI. If a concept could be linked to a 3rd or 4th level category, it was coded to the corresponding 2nd level category. Concepts were then further organized into higher-level subdomains at the ICF chapter level, and domains at the ICF component level. Questionnaire concepts that lay within the framework of the ICF, but were not covered by the ICF Core Set for TBI were linked appropriately and identified. If a meaningful concept identified during the linkage process had insufficient detail to assign the most precise ICF category, the information was documented as 'not definable' (linking rule nine) [9].

Several key concepts not represented by the ICF emerged in the content analysis. These were coded as 'not covered', according to linking rule ten [9].

In step four, the concepts extracted from the outcome measures were used to create the framework for a working conceptual model of HRQOL in individuals with PPCS, as currently measured with existing tools (Figure 3.3). The conceptual model depicts the complex relationship between the construct of HRQOL and the domains of Body Function, Activities, and Participation. The contextual factors of Personal Factors and Environment modify these domains, which further influence HRQOL. Subdomains provide a more detailed description of the concepts within each domain and contextual factor.

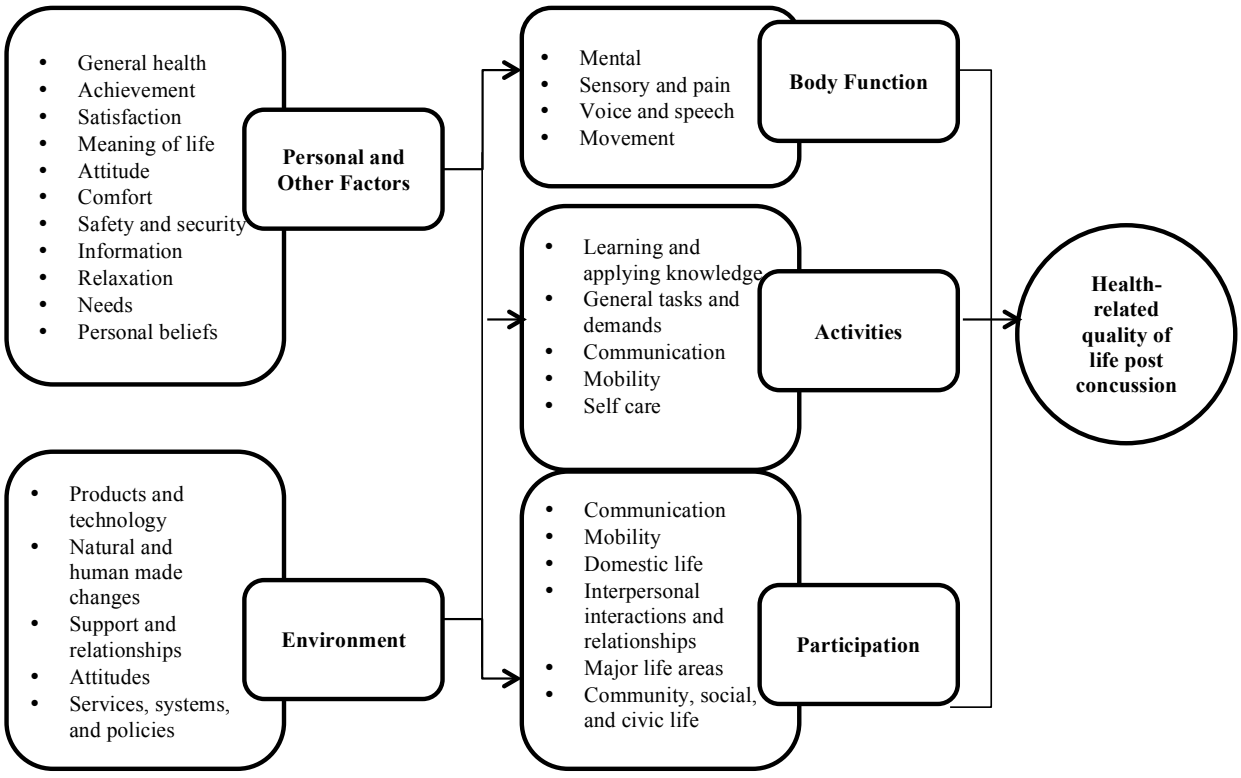

Figure 3.3. Working conceptual model of health-related quality of life (HRQOL) for individuals with persistent post-concussion symptoms (PPCS) based on the international classification of functioning, disability, and health (ICF).

The domains of body function, activities, and participation act to influence the construct of HRQOL. Contextual factors modify domains, and include Personal Factors and Environment. Subdomains provide a more detailed description of concepts within each domain and contextual factor.

3.3 Results

The literature search retrieved 2676 citations; after removal of duplicates, 1291 articles underwent review of title and abstract. A further 1034 studies did not meet inclusion and exclusion criteria and were excluded. A total of 257 full-text articles were assessed for eligibility, of which 248 were excluded. Nine quantitative studies met review eligibility criteria and were included in the review. No qualitative studies met eligibility criteria for inclusion in the review (Figure 1). Characteristics of the included studies are summarized in Table 3.2.

Table 3.2. Characteristics of included studies assessing HRQOL post-concussion.

Author, yr	Study design	Age (yrs)	Sample size	Time post-injury (mo.)	HRQOL outcome measure used
Kleffelgaard [11], 2016	PCS	24-45	Concussed: 2 F; 2 M	9-30 mo.	Secondary outcome: QOLIBRI
Scholten [12], 2015	PCS	28-57; x=45	Concussed: 298 F; 499 M Other: 70 F; 129 M	6 mo.; 12 mo.	Secondary outcome: PQOL
Azulay [13], 2013	PCS	18-62	Concussed: 11 F; 11 M	7-12 mo. (n=4) 13-36 mo. (n=15) >36 mo. (n=1)	Primary outcome: PQOL
Boussi-Gross [14], 2013	RCT	21-66; x=44	Concussed: 32 F; 24 M	12-72 mo.; x=33 mo.	Secondary outcomes:EQ-5D, VAS
Fourtassi [15], 2011	CS	34.4 ±15.5; x=29.4	Concussed: 42	12 mo.	Secondary outcome: VAS
King [16], 2011	CS	30-64; x=44.7	Concussed:12 F; 12 M; Control: 29 F; 47 M	24-202; x=83.7	Secondary outcome: WHOQOL-100
Polusny [17], 2011	PCS	31; SD=8	Concussed: 2 F; 58 M Other: 68 F; 809 M	12 mo.	Secondary outcome: WHOQOL-BREF
Bazarian [18], 2007	PCS	18-31; x=21.7	Concussed: 6; Control 6 4 F; 8 M	1 mo.	Secondary outcome: EQ-5D
Chiu [19], 2006	CS	45.4 ±20.3	Concussed: 71 F; 128 M	12 mo; ±8.4 mo.	Primary outcome: WHOQOL-BREF

Author indicates last name of first author. Year refers to year of publication. Study design coded as follows: CS, clinical series; PCS, prospective cohort study; RCT, randomized controlled trial. Age is coded as follows: years, yrs; x, mean, SD, standard deviation. Sample size coded as follows: F, female; M, male; list both if applies. Time post-injury is coded as follows: mo., months; x, mean; n, number of studies. HRQOL outcome measures: PQOL, Perceived Quality of Life Scale; VAS, visual analogue scale.

Five outcome measures were identified in the studies that met the inclusion criteria, including the Perceived Quality of Life Scale (PQOL), EuroQoL-5 Dimensions (EQ-5D), Quality of Life after Brain Injury (QOLIBRI), WHOQOL-100, and WHOQOL-BREF. These included one TBI-specific HRQOL tool (QOLIBRI), and four generic HRQOL tools. Additionally, one study assessed the deterioration of HRQOL as measured by a visual analogue scale. Since the visual analogue scale assessed deterioration of HRQOL as a global concept, it was unable to be linked to any concepts within the ICF, and was therefore considered 'not covered'.

The PQOL is a 19-item self-report measure that measures a patient's satisfaction with their functioning in 3 domains (physical, cognitive, and social) [20]. One single global item measures overall happiness as a comparison. Responses are scored on an 11-point Likert scale ranging from extremely dissatisfied (0) to extremely satisfied (10). The mean score of the 19 items is calculated, with a PQOL <7.5 considered "dissatisfied", and a PQOL >7.5 considered "satisfied" [20]. The PQOL has been used to measure life satisfaction in a TBI population, with an internal reliability of 0.89 reported [21,22].

The EQ-5D is a generic measure of HRQOL that provides a simple descriptive profile and single index value [23]. Five domains of mobility, self-care, usual activities, pain/discomfort, and anxiety/depression are measured on a 3-point scale, ranging from no problem, to some problem, to extreme problem/unable to perform. Higher scores are associated with poorer self-reported health.

The QOLIBRI is a TBI-specific measure of HRQOL that consists of 37 items across 6 domain [24,25]. Four subscales measure satisfaction across the domains of “cognition”, “self”, “daily life and autonomy”, and “social relationships”. Two subscales measure how bothered respondent feel by “emotions” and “physical problems”. Responses are reported as “not at all”, “slightly”, “moderate”, “quite”, or “very”, and provide both a profile and a total index score. Psychometric properties are good with an internal consistency of α=0.81-0.91 and test-re-test reliability of r=0.68-0.87.

The WHOQOL-BREF is a short form of the generic WHOQOL-100 that contains 26 questions representing one from each of the 24 facets within the comprehensive WHOQOL-100, in addition to 2 overall quality of life and general health questions. The WHOQOL-100 is recommended for a more comprehensive assessment in epidemiological research, whereas the WHOQOL-BREF is more appropriate in clinical practice, due to its brevity [26]. Since one of the aims was to identify the concepts contained in the outcome measures, data was only extracted from the more comprehensive WHOQOL-100, since it encompassed all the questions in the WHOQOL-BREF, thereby not losing information. The WHOQOL-100 is a self-report outcome measure that measures HRQOL across 6 domains: physical, psychological, spiritual, environmental, independence, and social [27]. Four additional items pertain to global QOL and general health. All items are scored on a 5-point Likert scale from 1 to 5 using the descriptives “not at all”, “a little”, “moderately”, “mostly”, and “completely”. The WHOQOL-100, and its short form WHOQOL-BREF, have been used in a

TBI population to measure HRQOL, and have demonstrated good internal consistency (0.75-0.89) and test-retest reliability (0.74-0.95) [27].

All concepts from the remaining four outcome measures were then extracted and linked to the ICF where possible. A total of 365 concepts were extracted from the PQOL, EQ-5D, QOLIBRI, and WHOQOL-100. Descriptive statistics were used to assess the frequency of ICF categories contained within each outcome measure (Table 3.3). Two-hundred nineteen (60.0%) of the concepts were linked to the ICF, 12 (3.3%) contained insufficient information to assign the concept to the most precise ICF and were coded as “not definable”, three (0.8%) concepts were linked to personal factors, and 131 (35.9%) lay outside the framework of the ICF and were coded as “not covered”. The vast majority of concepts that were unable to be linked related to questions such as “satisfaction with” or “bothered by” other assignable concepts.

Table 3.3. Frequency of ICF categories linked to concepts contained in HRQOL outcome measures.

			TBI-specific	Generic-measure		
ICF code	ICF category	All	QOLIBRI	PQOL	EQ-5D	WHOQOL
Component: Body Functions						
Chapter 1 Mental functions						
b126	Temperament and personality functions	3				3
b130	Energy and drive functions	6	2			4
b134	Sleep functions	6		2		4
b140	Attention functions	2	1			1
b144	Memory functions	3	1	1		1
b147	Psychomotor functions	1	1			
b152	Emotional functions	23	8	1	2	12
b156	Perceptual functions	1	1			
b160	Thought functions	3	1	1		1
b180*	Experience of self and time functions	8	4			4
Chapter 2 Sensory functions and pain						
b210	Seeing functions	1	1			
b230*	Hearing functions	3	1	1		1
b280	Sensation of pain	9	2		1	6
b289*	Sensation of pain, other specified and unspecified	1			1	
Chapter 3 Voice and speech functions						
b399*	Voice and speech functions, unspecified	1		1		
Chapter 7 Neuromusculoskeletal and movement-related functions						
b760	Control of voluntary movement functions	1	1			
Total Body Functions Concepts		72	24	7	4	37
Component: Activities and participation						
Chapter 1 Learning and applying knowledge						
d155	Acquiring skills	3				3
d166	Reading	1	1			
d175	Solving problems	1	1			
d177	Making decisions	2	1			1
Chapter 2 General tasks and demands						
d230	Carrying out daily routine	9			1	8
Chapter 3 Communication						
d330	Speaking	1		1		

Table 3.3 continued

ICF code	ICF category	All	TBI-specific	Generic-measure		
			QOLIBRI	PQOL	EQ-5D	WHOQOL
Chapter 4 Mobility						
d450	Walking	2		1	1	
d460*	Moving around in different locations	3	1	2		
d470	Using transportation	1		1		
d475	Driving	1		1		
d489	Moving around using transportation, unspecified	2				2
d499*	Mobility, unspecified	5			1	4
Chapter 5 Self-care						
d510	Washing oneself	2		1	1	
d540	Dressing	1			1	
d599*	Self-care, unspecified	1		1		
Chapter 6 Domestic life						
d620	Acquisition of goods and services	1		1		
d630	Preparing meals	2	1	1		
d640	Doing housework	1			1	
d649	Household tasks, unspecified	1	1			
d660	Assisting others	4		2		2
Chapter 7 Interpersonal interactions and relationships						
d750	Informal social relationships	4	2	2		
d760	Family relationships	5	2	2		1
d770	Intimate relationships	9	3	2		4
d799*	Interpersonal interactions and relationships, unspecified	2	1			1
Chapter 8 Major life areas						
d839*	Education, other specified and unspecified	2	1		1	
d850	Remunerative employment	7	1	2	1	3
d860	Basic economic transactions	1	1			
d865	Complex economic transactions	1	1			
Chapter 9 Community, social and civic life						
d910	Community life	4		4		
d920	Recreation and leisure	10	4	4	1	1
d930	Religion and spirituality	1		1		
d999*	Community, social and civic life, unspecified	2				2
Total Activities and Participation concepts		96	25	30	9	32

Table 3.3 continued

ICF code	ICF category	All	TBI-specific QOLIBRI	Generic-measure PQOL	EQ-5D	WHOQOL
Component: Environmental factors						
Chapter 1 Products and technology						
e110	Products or substances for personal consumption	6		2		4
e155	Design, construction and building products and technology of buildings for private use	1				1
e165	Assets	4		1		3
e199*	Products and technology, unspecified	3				3
Chapter 2 Natural environment and human-made changes to environment						
e225*	Climate	2				2
e235*	Human-caused events	1				1
e250	Sound	2				2
e298*	Natural environment and human-made changes to environment, other specified	2				2
e299*	Natural environment and human-made changes to environment, unspecified	6				6
Chapter 3 Support and relationships						
e310	Immediate family	5		4		1
e315	Extended family	5		4		1
e320	Friends	6		4		2
e355	Health professionals	1				1
e399*	Support and relationships, unspecified	2	1			1
Chapter 4 Attitudes						
e499*	Attitudes, unspecified	2	1	1		
Chapter 5 Services, systems and policies						
e575	General social support services, systems and policies	2				2
e580	Health services, systems and policies	1				1
Total Environmental factors concepts		51	2	16	0	33
Total Concepts		219	51	53	13	102

ICF, International Classification of Functioning, Disability and Health; HRQOL, health-related quality of life; TBI, traumatic brain injury; QOLIBRI, Quality of Life after Brain Injury; PQOL, Perceived Quality of Life; EQ-5D, EuroQOL-5 Dimensions; WHOQOL-100, World Health Organization Quality of Life.
*Linked to ICF, not included in the ICF Comprehensive TBI Core Set

Concepts contained within the identified outcome measures were then compared at the 2nd-level category of the ICF. Of the 219 assignable concepts, 72 were linked to the component *body functions*, 96 concepts were linked to the component *activities and participation*, and 51 concepts to the contextual factor *environmental factors*. No questions in any of the outcome measures referred to the assessment of *body structure (0%)*. The 219 concepts contained within the outcome measures were linked to 67 different 2nd-level categories. Concepts that were extracted at a greater specification of detail at the 3rd or 4th level were reported at the 2nd level category.

The majority of the questions were linked to the domain of *activities and participation* (n = 34, 50.7%). Another 16 questions (23.9%) referred to *body functions*, and 17 questions (25.4%) were related to the *environment*. The number of meaningful constructs identified in the four QOL measures and their distribution across the major components of the ICF is outlined in Figure 3.4.

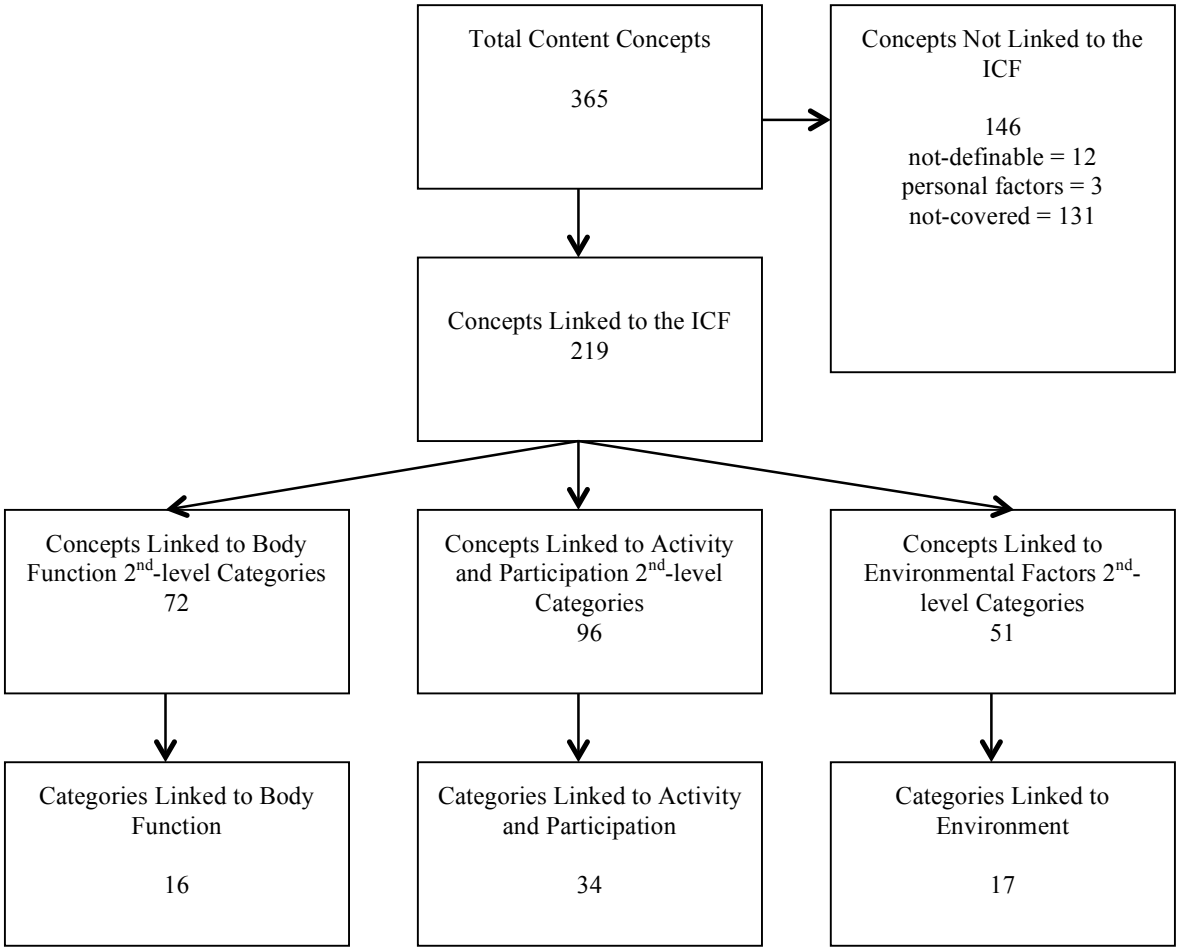

Figure 3.4. Number of meaningful constructs identified in the 4 QOL measures and their distribution across the major components of the ICF.
The component *body structures* is not part of the figure, because none of the measures contained concepts that were linked to this component.

A comparison of concepts contained within the identified outcome measures is summarized at the 2nd-level category of the ICF in Table 3.3. The difference in subdomain coverage between the outcome measures at the chapter level is presented in Figure 3.5.

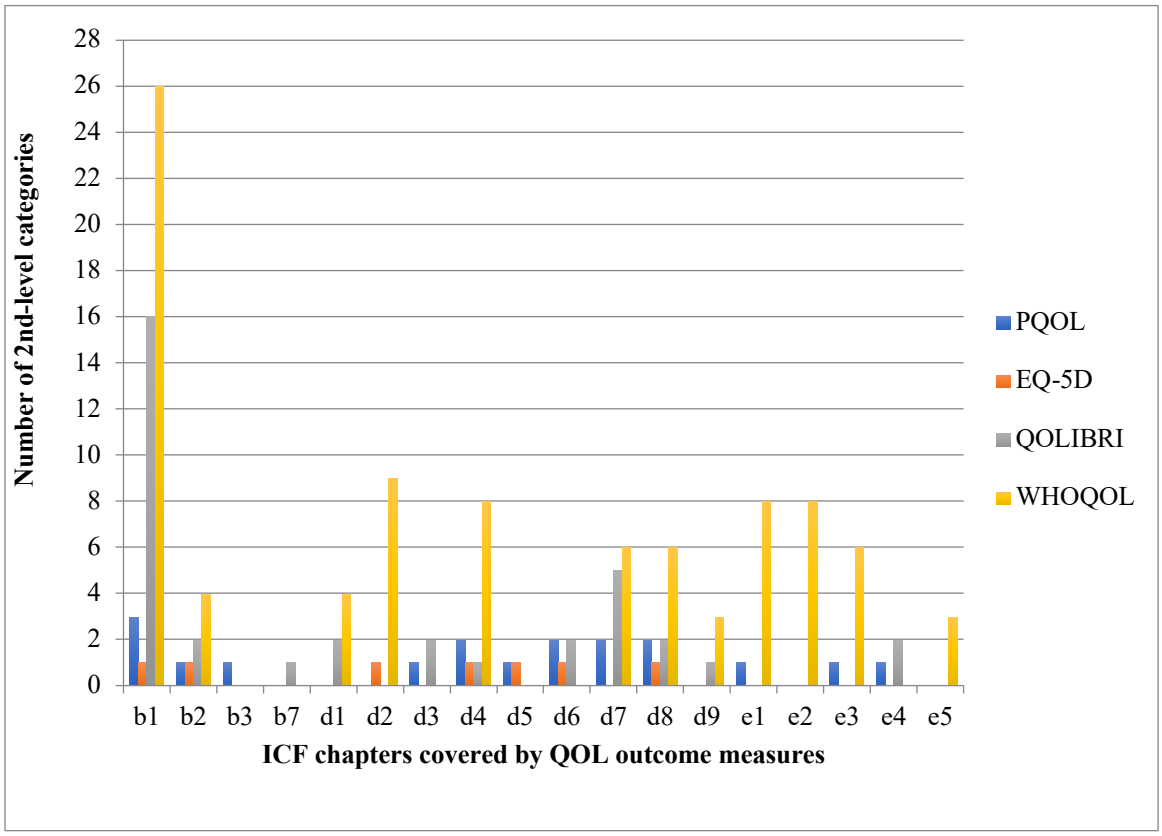

Figure 3.5. QOL outcome measures linked to the ICF at the chapter level. Results demonstrate depth and breadth of outcome measures. b1, Mental functions; b2, Sensory functions and pain; b3, Voice and speech functions; b7, Neuromusculoskeletal and movement related functions; d1, Learning and applying knowledge; d2, General tasks and demands; d3, Communication; d4, Mobility; d5, Self-care; d6, Domestic life; d7, Interpersonal interactions and relations; d8, Major life areas; d9, Community, social and civic life; e1, Products and technology; e2, Natural environment and human-made changes to environment; e3, Support and relationships; e4, Attitudes e5, Services, systems, and policies. ICF, International Classification of Functioning, Disability and Health; QOL, Quality of Life; QOLIBRI, Quality of Life after Brain Injury; PQOL, Perceived Quality of Life; EQ-5D, EuroQol – 5 Dimensions; WHOQOL, World Health Organization Quality of Life.

HRQOL Themes linked to the ICF TBI Core Set – Body Functions.

Mental functions.

Overall impact of mental functions on quality of life (QOL) was the most commonly explored theme by all questionnaires. Global mental function was evaluated primarily by questions asking about patients' level of energy, feeling tired, fatigued and level of motivation. Satisfaction with amount or quality of sleep and the impact on QOL was frequently asked. Concerns with attention functions were identified by questions regarding the ability to concentrate. Changes in memory function were represented by questions such as how well respondents remember everyday things or rate their memory. A key concept identified by all questionnaires was the consequence of emotional functions on QOL. Questions were heavily weighted in favour of evaluating the impact of negative feelings such as anxiety, depression, loneliness, sadness, boredom, anger, aggressiveness, or despair, over positive feelings such as happiness. Experience of thought functions such as speed of thinking, and the ability to understand difficulties in life was only represented in two questionnaires. A single question on higher-level cognitive functions was identified as satisfaction with decision-making.

Sensory functions and pain.

Questions relating to sensory functions and pain were included in all identified QOL questionnaires. Of these, the experience of pain and discomfort was frequently assessed. The consequence of these symptoms was identified by numerous evaluative, affective, and functional questions. Evaluative questions

were posed in terms of severity and frequency of pain or discomfort, including headaches. Affective questions included emotional feelings about how bothered or worried one is about the pain experience. Functionally, patients were asked to express their difficulty in handling the symptoms, and to what extent suffering prevents them from doing what they need to do. Additionally, patients were asked to report on any change in their quality of life resulting from problems with seeing.

Voice and speech functions.

A single question regarding voice and speech functions was reported as the ability to speak clearly and be understood.

Neuromusculoskeletal and movement-related functions.

Clumsiness of movement represented the only question investigating neuromusculoskeletal and movement-related functions.

HRQOL Themes linked to the ICF TBI Core Set – Body Structures.

No themes were identified in any of the included questionnaires related to Body Structures.

HRQOL Themes linked to the ICF TBI Core Set – Activities and Participation.

Learning and applying knowledge.

The significance of learning and applying knowledge was represented by four concepts: acquiring skills, reading, solving problems, and making decisions. Each concept was explored with one only question, and reported in terms of

satisfaction with the ability to read, problem-solve everyday practical problems, learning new information, and the ability to make decisions.

General tasks and demands.

The implication of general tasks and demands on QOL was evaluated from varying perspectives. Patients were asked to report concerns about any limitations in their everyday activities; to what extent they were having difficulty carrying out these activities; how much they were bothered by these limitations; and if their daily activities were affected by negative feelings.

***Communication*.**

Questions pertaining to communication were assessed as limitations at the level of activities and participation. Key concerns addressed were satisfaction with the ability to speak clearly, carry on and keep track of a conversation, and the ability to understand.

Mobility.

Questions of mobility were expressed in terms of both the individual moving within their environment, and moving around using transportation. Significance of walking and the ability to get around was reported in terms of the satisfaction with ability to get out, general mobility difficulties, and the impact on the respondent's way of life. Transportation problems were identified as the ability to adequately access transportation, level of satisfaction, and how those difficulties restrict the respondent's life.

Self-care.

The contribution of self-care to quality of life was evaluated non-uniformly across questionnaires at the level of an individual activity limitation. Patients were asked to report satisfaction with their level of independence, and their ability to perform basic daily living skills, including bathing, and dressing, and general self-care.

Domestic life.

Questions pertaining to impact of domestic activities explored three basic concepts, acquisition of necessities, household tasks, and assisting others. Significance of everyday actions and tasks was assessed as difficulties or satisfaction with the ability to shop, prepare meals, perform housework, or give help to family and others.

Interpersonal interactions and relationships.

Most questionnaires addressed the significance of interpersonal relationships on a patient's quality of life. The impact of these relationships was assessed with questions related to satisfaction with frequency of interaction, amount of support provided, and general happiness with friends, family, and intimate partners. At an intimate level, patients were asked to express their satisfaction with their level of sexual activity, sexual fulfillment, any perceived difficulties, amount of support provided, and their general happiness with the relationship.

Major life areas.

Questions related to the impact of major life areas, such as education, work, and economic life were well represented across all questionnaires. The impact of education was evaluated by questions about problems and satisfaction with

participation in education. Work questions included asking patients about their capacity for work, how much, and whether they are satisfied with their ability to work. In terms of economic life, patients were asked to report on their ability to run personal finances, their worry about money, and any financial difficulties.

Community, social, and civic life.

Social impact was represented across all QOL questionnaires in terms of community life, religious participation, recreation and leisure, sports, and hobbies. Questions asked patients to report on their satisfaction with both their contribution to the community, and opportunities to be able to participate social activities. Two general questions summarized the topic, asking how much respondents are satisfied with and enjoy their free time.

HRQOL Themes linked to the ICF TBI Core Set – Environmental Factors.

Products and technology.

A rudimentary exploration of the impact of products on individuals post-concussion was identified in only two questionnaires, with broad ranging questions. From a personal consumption perspective, individuals were asked to report their satisfaction with the kind and amount of food they eat. From an overall quality of life perspective, individuals were asked to report on the use of medical substance or aids, including how much medication is needed to function in daily life. Patients were also asked to report on their satisfaction with their home, its level of comfort, and whether it met their needs. A single question assessed the patient's satisfaction with their financial situation.

Natural environment and human-made changes to environment.

The extent to which patients consider noise where they live to be a concern represented a unique contribution of the environment to quality of life. No questions regarding environmental facilitators were posed in any of the questionnaires identified.

Support and relationships.

The impact of support and relationships were divided along the contribution of family and friends, or health care providers. Questions regarding the support of family and friends were posed in terms of the amount and satisfaction with the help provided to an individual. The role of health professionals was reported as both how much medical treatment is necessary to function, and the ability to access it.

Attitudes.

The influence of others' attitudes towards the patient was explored generically at both an interpersonal and societal level. Patient satisfaction with the level of respect and attitude of others towards them did not specify the relationship between individuals, leaving the questions open to interpretation.

Services, systems and policies.

Consequences of the quality and accessibility of services, such health and social care services, was assessed in only one questionnaire, in both its long and short form.

Personal factors.

Three meaningful concepts identified were coded as 'personal factors (pf) as they clearly pertained to individual traits acknowledged to influence health, but not codified by the ICF. The significance of personal beliefs in terms of giving meaning to life, and the strength to face and understand difficulties was explored.

Linked to ICF, not included in the ICF Comprehensive TBI Core Set.

Several questions were identified on both the generic and TBI-specific QOL outcome measures that were not included in the ICF Comprehensive TBI Core Set. These questions covered a total of four categories across the components of *body functions*, *activities and participation*, and *environmental factors*. *Body functions* questions regarding *experience of self and time functions* were posed in terms of both appearance and sense of worth. Satisfaction with appearance was explored with respect to self-perception and body image; whereas satisfaction with one's sense of value and self-esteem dealt with the contribution of sense of worth to quality of life. A single question dealing with changes in quality of life resulting from problems with hearing represented the *sensory functions and pain* chapter. Within the component *activities and participation*, several non-specific questions were posed within the chapters of *mobility*, *self-care*, *interpersonal interactions and relationships*, *major life areas*, and *community, social and civic life* that broadly encompassed second-level categories within the ICF Comprehensive TBI Core Set. These were linked to 2nd-level categories otherwise identified within the outcome measures, or as unspecified. One question assessing satisfaction with the ability to repair things

represented the only unique contribution to the *activities and participation* component. The consequence of the *natural environment & human-made changes to environment* on quality of life was investigated by both long and brief versions of one questionnaire only. General questions regarding satisfaction with the health, comfort, appeal, and safety and security of where one lived conceptualized the global impact of the physical environment. Concern regarding climate, pollution, noise, and living conditions represented specific questions of environmental factors. Several questions clearly dealt with the contribution of *environmental factors* to quality of life, however there was insufficient information to assign them to a precise category.

HRQOL Themes linked to the ICF TBI Core Set – Other.

Not definable.

From a general health perspective patients were asked to report on how bothered they were by the effects of the brain injury and other injuries sustained at the same time in addition to their overall satisfaction with health. Clarification was only provided by one question to distinguish between the impact of injury on physical versus mental health. Likewise, no specific physical or mental health condition questions were identified amongst the questionnaires. The significance of perceived productivity was evaluated in terms of level of satisfaction with their abilities, their ability to do what they need to do, and what they have achieved since the brain injury.

Not covered.

Questions not covered by the ICF tapped into the broader concepts of life, well-being, experiences, information, and quality of life. Satisfaction with the extent the patient perceived the meaning and purpose of life, along with variety in life, were evaluated in two separate questionnaires. The concept of well-being was assessed in terms of the ability to relax and enjoy life, feelings of safety and security, and attitude about the future. Experiential questions included comfort of living conditions; the way patients saw their future; perceived needs, and the extent to which they feel in charge of their own life. The significance of both the availability and opportunities to acquire day-to-day information was also evaluated. Additionally, patients were asked to report on their overall quality of life with respect to its deterioration post-injury and an overall rating of satisfaction.

3.4 Discussion

The primary objective of this study was to explore how HRQOL is being measured in concussion-specific research with existing outcome measures. The large number of concepts extracted from existing outcomes supports the complexity and challenge of measuring HRQOL post-concussion. Likewise, the wide variance in breadth and depth of concepts between outcome measures highlights the inconsistency with which the construct of HRQOL is defined and measured across studies. The working conceptual model developed from these concepts provides an emerging framework for future qualitative investigation of

those issues that post-concussion patients identify as being most relevant to their HRQOL.

While the ICF is not a substitute for an outcome measure, it is useful to understand *what* is being measured [28]. List of agreed upon ICF categories thought to be relevant to TBI patients have been developed through collaborative efforts between the WHO and several international organizations [29]. These ICF Core Sets for TBI have been developed using the same linking guidelines applied in this study. This standardized terminology of the ICF have been recommended as a means of comparing the content validity of health status measures, and as the foundation for the development of new outcome measures [29].

The application of the ICF in this systematic review as a standard reference to link concepts to 2nd-level categories provides deeper insight into the content of the HRQOL outcome measures currently being used in concussion research. Most of the concepts linked to the ICF at the 2nd-level category. Only twelve concepts were considered to have insufficient detail to assign them to a specific chapter, and were coded as 'not-definable'. These concepts included general health, as well as global concepts of ability and duties. Approximately one-third of concepts did not fall within the biopsychosocial framework of the ICF and were considered "not covered". These included more existential questions such as the meaning and purpose of life, life satisfaction, attitudes about the future, and general safety and security. Although these concepts were unable to be linked to the ICF, they were maintained and integrated into the working

conceptual model of HRQOL for individuals with PPCS. The large number of questions not covered by the ICF support the notion that HRQOL is a multifaceted construct determined by concepts other than just limitations in functioning and disability. This highlights the need for a concussion-specific HRQOL measure that taps into concepts not covered by measures of health status.

This systematic review identified a large number of categories across the different components of *body function*, *activities and participation*, *environment*, and *personal factors* regarded as most relevant to assess. The absence of any concepts linked to the component *body structure* is consistent with our current understanding of concussion as a functional disturbance, not a structural injury to the brain induced by biomechanical forces [30]. No pharmaceutical or physical therapies have been demonstrated to cause a structural change correlated to an improvement in recovery; therefore it seems reasonable not to assess *body structure* in relation to HRQOL.

Most questionnaire items were related to the ICF component *activities and participation*. Collectively, all nine chapters were represented in this review, although the breadth and depth of subcategory coverage differed between outcome measures. The QOLIBRI covered the most chapters within *activities and participation*, with seven out of nine. This is unsurprising, as the QOLIBRI is the only TBI-specific HRQOL outcome measure suitable for use in clinical settings and research studies. Chapters four (*mobility*), six (domestic life), eight (*major life areas*), and nine (community, social and civic life) were covered by all

four outcome measures. The WHOQOL-100 covered six of the chapters in the greatest detail, especially problems associated with d230 *carrying out daily routine*, d470 *transportation*, and d770 *interpersonal relationships*. This reflects the generic nature of the instrument and its ability to cover a breadth of issues due to the large number of questions.

By far the most frequent category examined within the component *body functions* was b152 emotional functions, followed remotely by b280 *sensation of pain.* No question on higher-level cognitive functions (b164), a common concern amongst individuals with PPCS, was identified in any of the outcome measures. Within *body functions*, chapter four (functions of the cardiovascular, immunological and respiratory systems), chapter five (functions of the digestive, metabolic and endocrine systems), and chapter six (functions of the genitourinary and reproductive systems) were not represented by any of the identified outcome measures. This is unremarkable given the generic nature of the HRQOL outcome measures. Furthermore, limitations in these domains remain outside the scope of commonly reported issues post-concussion.

The ICF contextual factors *environment* and *personal factors* were poorly represented amongst the included outcome measures, despite their potential to have an impact on HRQOL. A content comparison revealed little overlap between outcome measures, with none of chapters being covered by more than two different outcome measures. No single outcome measure was linked to all five chapters within the *environmental factors*. The *environmental factors* covered in the greatest detail were e299 *natural environment and human-made changes*

to environment and e399 *support and relationships, unspecified*. These categories were linked to concepts such as 'where one lives', and 'support received from others' which were assessed in terms of satisfaction.

Each outcome measure was used only once or twice, with none being applied in the majority of the included studies. The QOLIBRI, the only TBI-specific HRQOL outcome measure, was only included in one recently published study, as was the WHOQOL-100. The PQOL, EQ-5D, and WHOQOL-BREF were each only used in two out of the nine included studies. This demonstrates the lack of a universally accepted HRQOL outcome measure for patients with PPCS, suggesting that current measures may not meet the specific needs of this population.

HRQOL is a complex construct represented by a heterogeneous constellation of concepts, including, but not limited to functioning, disability and health. Existing outcome measures tap into these concepts to varying degrees. For example, general concepts contained within the 37-item QOLIBRI include cognitive abilities, emotional health, daily functional activities, social relationships, and physical health [31]. These concepts have been linked to 42 2nd-level ICF categories in a study carried out by two independent researchers using established linking rules [10,32]. Individuals with PPCS may present with some of the concepts, but not others, and the concepts endorsed by different individuals may vary, since they aren't necessarily related to one another. Using a clinical example, one individual may report that the cognitive impairments due to their concussion, such as poor memory and concentration, have a negative impact on

their HRQOL. Another individual may report that their inability to ride a bicycle due to post-concussion balance impairments negatively impacts their HRQOL. However, one can have cognitive impairments without balance impairments after a concussion, and vice versa. This has several significant implications. First, concepts assessed by the ICF *cause* changes in HRQOL, rather than being affected by it [33]. Therefore, within the hierarchical taxonomy of the ICF, HRQOL should be considered a higher-level construct determined by a composite of the components *body functions*, *body structures*, *activities and participation*, *environment*, and *personal factors*, rather than being a subset of any of them. Second, because the concepts affect HRQOL, rather than being affected by it, they are not necessarily causally related. If the concepts are not correlated, concepts included on outcome measures will not cover relevant concepts that have been omitted [34]. Practically, this means that outcome measures need to possess high content validity to ensure that they adequately represent the construct of HRQOL. This study describes the concepts contained in existing outcome measures being used to assess HRQOL in patients with PPCS. While these concepts represent current best-thought, the extent of the items' content validity has yet to be confirmed in this population. Furthermore, it is unclear whether additional concepts need to be identified that are relevant to individuals with PPCS. Comprehensive content validity, as evidenced by PPCS patient involvement in the generation of questionnaire items, as well as the evaluation of patient understanding through cognitive interviewing, is lacking in existing outcome measures [35]. A qualitative study using patient focus groups is

necessary to elicit concepts relevant to individuals with PPCS in order to prevent any missing, redundant, or irrelevant concepts, and identify any gaps in existing outcome measures in order to understand what *needs* to be measured. Support for the development of a concussion-specific HRQOL outcome measure would be provided if concepts identified by individuals with PPCS were not well represented by existing outcome measures.

Study Limitations.

While all attempts were made to be comprehensive by including a number of different electronic databases and grey literature search, the possibility exists that some studies were not identified by the search strategy employed. Additionally, studies were limited to those published in English or French. Only one study was excluded during the abstract review for failing to meet this criterion, so although the chances are low that significant data loss occurred due to this stringent language criteria, the possibility must be acknowledged. Decisions on study relevance were unblinded, raising the possibility of reviewer bias in the selection of included studies. Furthermore, concepts contained within the outcome measures were linked to 2nd-level ICF categories by a single researcher. Data extraction performed by two independent reviewers may have yielded different results.

Lastly, the results are only as valid as the content validity of the tools that were used to assess the construct of HRQOL in individuals with PPCS. The lack of direct patient input into the development of any of these tools in a concussion-specific population underscores the need to substantiate the relevance of these

concepts. The working conceptual model developed from these concepts should be considered an emerging framework for an iterative process to validate these concepts and identify additional concepts through future qualitative studies with patients and clinical experts.

3.5 Conclusions

Previous studies have examined the concepts contained within a sample of various outcome measures using the ICF as a framework, without differentiating between severities of TBI or specifying HRQOL[36,37]. This systematic review identified and quantified concepts of HRQOL used in concussion-specific research, using the ICF as a standard reference. The ICF provides a practical tool to identify limitations in health from an objective perspective. Where it is limited is in its ability to assess non-health related concepts that contribute to HRQOL, or to assess whether functional limitations and disability are relevant to the subjective patient experience. The wide breadth of coverage identified in this review reflects the complexity of concussion and the heterogenic constellation of problems associated with prolonged recovery. The wide range of concepts covered by different outcome measures also demonstrates a lack of universal agreement in terms of what should be measured in this population. The results of this study provide a framework for a working conceptual model of HRQOL in individuals with PPCS. A qualitative study exploring the patient's subjective perspective is necessary to ensure robust content validity of the identified concepts. Further work is needed to build upon this study and deepen our

understanding of whether the concepts identified are relevant to patients with PPCS.

Compliance with ethical standards.

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Conflict of Interest.

The authors declare no conflict of interest with respect to the research, authorship and/or publication of this article.

Ethical Approval.

For this type of study ethical approval is not required.

Informed Consent.

For this type of study informed consent is not required.

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Appendix 1

Search Strategy for systematic review

Database: Medline (Ovid)
Database update: 1946 to present
Date search: 26 August 2016

1 Brain Injuries/
2 Brain Concussion/
3 Post-Concussion Syndrome/
4 Traumatic brain injur*.mp.
5 mild head injur*.mp.
6 concussion*.mp.
7 tbi.mp.
8 mtbi.mp.
9 post-concussion syndrome*.mp
10 postconcussion syndrome*.mp
11 post-concussion symptom*.mp
12 postconcussion symptom*.mp
13 1 or 2 or 3 or 4 or 5 or 6 or 7 or 8 or 9 or 10 or 11 or 12
14 “Quality of Life”/
15 ‘quality of life’.mp.
16 QOL.mp.
17 ‘health-related quality of life’.mp.
18 HRQOL.mp.
19 HRQL.mp.
20 14 or 15 or 16 or 17 or 18 or 19
21 13 and 20

Database: Embase (Ovid)
Database update: 1974 to 2016 August 19
Date search: 26 August 2016

1 Brain Injuries/
2 Brain Concussion/
3 Post-Concussion Syndrome/
4 traumatic brain injur$.mp.
5 mild head injur$.mp.
6 concussion.mp.
7 ?tbi.mp.
8 (((post or persistent or prolonged) adj3 (concuss$ or ?tbi or mild head injur$)) or postconcuss$).mp.
9 1 or 2 or 3 or 4 or 5 or 6 or 7 or 8
10 “Quality of Life”/
11 quality of life.mp.
12 health-related quality of life.mp.
13 QOL.mp.
14 HRQ?L.mp.
15 10 or 11 or 12 or 13 or 14
16 9 and 15

Database: PsychInfo (Ovid)
Database update: 1806 to August Week 3 2016
Date search: 26 August 2016

1 Traumatic Brain Injury/
2 Brain Concussion/
3 Head Injuries/
4 traumatic brain injur$.mp.
5 concuss$.mp.
6 mild head injur$.mp.
7 post?concuss$.mp.
8 ?tbi.mp.
9 1 or 2 or 3 or 4 or 5 or 6 or 7 or 8
10 “Quality of Life”/
11 quality of life.mp.
12 QOL.mp.
13 HRQ?L.mp.
14 10 or 11 or 12 or 13
15 9 and 14

Database: CINAHL (EBSCO)
Database update: 1981 to 01 November 2016
Date search: 01 November 2016

1 “Brain Injuries” (MH)
2 “Brain Concussion” (MH)
3 “Postconcussion Syndrome” (MH)
4 “mild head injur*”
5 “traumatic brain injur*”
6 “concussion”
7 “tbi”
8 “mtbi”
9 “post*concussion syndrome”
10 “post*concussion symptom”
11 S1 or S2 or S3 or S4 or S5 or S6 or S7 or S8 or S9 or S10
12 “Quality of Life” (MH)
13 “quality of life”
14 “QOL”
15 “health-related quality of life”
16 “HRQ*L”
17 S12 OR S13 OR S14 OR S15 OR S16
18 S11 AND S17

Database: Cochrane Library
Database update: 1999 to present
Date search: 07 November 2016

1 “concussion”
2 Post?concuss* NEXT (syndrome or disorder or symptom?)
3 “traumatic brain injur$”
4 “mild head injur$”
5 #1 or #2 or #3 or #4

Database: ProQuest (Theses and Dissertations Global)
Database update: 1997 to present
Date search: 07 November 2016

1 ti(concussion*) OR ab(concussion*)
2 ti("mild traumatic brain injur*) OR ab("mild traumatic brain injur*)
3 ti("mild head injur*) OR ab("mild head injur*)
4 ti(post-concuss* NEAR (syndrome OR disorder OR symptoms*)) OR ab(post-concuss* NEAR (syndrome OR disorder OR symptoms*))
5 ti("quality of life") OR ab("quality of life")
6 ti(QOL) OR ab(QOL)
7 (ti(concussion*) OR ab(concussion*)) OR (ti("mild traumatic brain injur*) OR ab("mild traumatic brain injur*)) OR (ti(mild head injur*) OR ab("mild head injur*)) OR (ti(post-concuss* NEAR/4 (syndrome OR disorder OR disorder OR symptoms*)) OR ab(post-concuss* NEAR/4 (syndrome OR disorder OR symptoms*)))
8 (ti("quality of life") OR ab("quality of life")) OR (ti(QOL) OR ab(QOL))
9 ((ti(concussion*) OR ab(concussion*)) OR (ti("mild traumatic brain injur*) OR ab("mild traumatic brain injur*)) OR (ti(mild head injur*) OR ab("mild head injur*)) OR (ti(post-concuss* NEAR/4 (syndrome OR disorder OR disorder OR symptoms*)) OR ab(post-concuss* NEAR/4 (syndrome OR disorder OR symptoms*)))) AND ((ti("quality of life") OR ab("quality of life")) OR (ti(QOL) OR ab(QOL)))

Chapter 4: A qualitative study of persons with persistent postconcussion symptoms and clinicians with concussion expertise to inform the development of a concussion-specific questionnaire

The work in this chapter has been submitted for publication in *Disability and Rehabilitation*. Ethics approval for this study was granted by Ottawa Hospital Health Science Network Research Ethics Board (20170720-01H) and the University of Ottawa Research Ethics Board (A11-17-03).

4.1 Abstract

Purpose: To explore the experiences of adults with persistent postconcussion symptoms and clinicians to inform the development of a concussion-specific questionnaire.

Methods:

Using a qualitative descriptive design, we conducted 10 focus groups with persons with persistent post-concussion symptoms (n=35; female 66%; age range 19.0-65.1 years) and semi-structured interviews with clinicians with concussion expertise (n=16; female 81%). Thematic analysis was used to identify themes within their narratives. The International Classification of Functioning, Disability and Health provided a standardized language for coding.

Results:

Three overarching themes emerged from the data: *Functioning*, *Environmental* and *Personal Factors*, and *Capacity*. *Functioning* mapped closely onto Activities and Participation within the International Classification of Functioning, Disability and Health. Contextual factors, both *Environmental* and *Personal*, had a significant influence on functioning following concussion. *Capacity* was a unique finding that described how long a person is able to engage in a task before the onset or worsening of symptoms.

Conclusion:

Capacity is fundamental to measuring limitations in functioning based on symptom threshold and time to recovery. The impact of contextual factors on

functioning needs to be considered on a continuum from barrier to facilitator. These findings provide the basis for the development of a concussion-specific questionnaire.

Key Words: Concussion; Qualitative Research; International Classification of Functioning, Disability and Health

Implications for Rehabilitation

- Concussion can cause a significant limitation across all areas of functioning in persons who experience prolonged recovery.
- Support and relationships, attitudes of others, access to affordable and high-quality healthcare, coping strategies, and a patient's own knowledge of concussion appear to influence functioning, and should be addressed in rehabilitation.
- Current guidelines recommend a symptom-based approach to concussion management, whereas persons with concussion emphasize the importance of measuring function using a time-based approach to symptom threshold and recovery.
- Currently, no concussion-specific measure of functioning exists.

4.2 Introduction

Concussion is a complex injury that presents not only as a heterogeneous constellation of symptoms, but also as various functional limitations and restrictions in social, athletic, educational and work participation, which may negatively impact a person's quality of life. Problematically, there is no consensus on the definition of concussion among clinical practice guidelines and position statements, which introduces bias into clinical studies (1,2). Concussion is commonly considered a form mild traumatic brain injury (mTBI), and the terms are often used interchangeably in the literature (1,3). Diagnostic criteria typically include the Glasgow Coma Scale, although considerable differences exist regarding the presence of loss of consciousness, posttraumatic amnesia, acute or delayed onset of symptoms, balance deficits, behavioural changes, neurocognitive impairments, and sleep disturbances (4–6). No single test can accurately diagnose concussion (2,6). Most persons who have sustained a concussion are expected to make a full recovery and return to work and other pre-injury activities within days to months (7,8). However, 10-15% will go on to develop persistent postconcussion symptoms (PPCS), which may persist for months or years (9,10). The etiology of these symptoms is controversial, as evidence suggests that prolonged recovery may be attributable to factors other than biological injury, such as gender, lack of a social support system, pre-existing psychiatric problems, prior history of concussion, financial compensation, and concurrent post-traumatic stress disorder (9,11). Since no evidence-based treatments have been shown to promote recovery following concussion (12), much of the rehabilitation literature focuses on the management of symptoms or specific domains, such as fatigue, sleep, anxiety, or executive function (8,13).

Relatively few studies focus on the consequences of those symptoms from the person perspective (14–16), or what factors influence person's ability to participate in society (17).

In a recent qualitative study by Snell et al. (14), the authors presented a conceptual model of the recovery pathway experienced by persons with concussion. The model depicts the need for persons with concussion to understand their injury, feel validated and reassured, and the importance of social support to assist their recovery process. Preliminary evidence of the clinician experience with problems of functioning and contextual factors in persons with different severities of traumatic brain injury (TBI) was recently captured in an international survey of multidisciplinary healthcare professionals (18). The findings revealed a large variety of sequelae that impaired functioning across a broad spectrum of health categories. While these studies provided a unique insight into the injury and recovery experience, *how* the impact of concussion on functioning should be measured was not described. It is clear that persons are negatively affected by concussion, however which specific aspects of functioning should be included in a concussion-specific outcome measure is less clear. The few studies investigating the impact of concussion on functioning have used generic measures of participation as secondary endpoints (e.g. Mayo-Portland Adaptability Inventory-4; Participation Assessment with Recombined Tools-Objective) (19,20). Currently, there is no agreed-upon outcome measure that assesses global functioning postconcussion (18). Although recent psychometric evaluation of the generic World Health Organization Disability Schedule-12 item (21) in an mTBI population has provided preliminary evidence of whether items are related to each other (internal consistency) or to similar

constructs, such as depression (construct validation), this is insufficient evidence of content validity. Content validity, whether the measure samples all the most relevant concepts to persons with PPCS, needs to be assured through item development using qualitative methods with those persons with lived experience of the condition (22,23). The heterogenic constellation of functional limitations following a concussion suggests a measure with high internal consistency would not be tapping the diverse range of concepts associated with PPCS. Thus, there is a potential for disconnect between what is currently being measured in terms of functioning and the lived experience of persons with PPCS and clinicians. It is essential to understand the lived experience to inform the choice of outcome measures that best assess recovery. This may have particular salience following concussion, given the non-specific nature of PPCS (8,10).

A diagnosis of concussion is insufficient to describe the level of functioning and recovery of a person with PPCS. Having a standardized language with which to discuss problems in functioning from a comprehensive perspective would allow different professionals to compare and coordinate patient care. The International Classification of Functioning, Disability and Health (ICF) has been shown to be effective at describing a diverse array of problems associated with TBI (24,25). A few studies have used the ICF to develop new outcome measures that focus on participation (26).

The ICF provides a biopsychosocial framework with which to understand the health consequences associated with concussion (27). The ICF is a hierarchical structure that describes Functioning and Disability, and Contextual Factors. Functioning and Disability, contains the domains *Body Functions* and *Structures*, and *Activities* and *Participation*. *Body Functions* refer to the physiological functions of the body, whereas

Body Structures refer to the anatomical parts of the body. Conceptually, the ICF describes *Activities* as the performance of an action at level of the individual, and *Participation* as a person's involvement in society. Practically speaking, the categories which describe *Activities* and *Participation* may be operationalized as distinct or separate, depending on the need of the user. Contextual Factors include the domains *Environmental Factors* and *Personal Factors*. *Environmental Factors* represent factors external to the person, including the physical, social and attitudinal environment in which they live. *Personal Factors* are unique characteristics of a person that are not part of their health condition and have not yet been classified. Both *Environmental* and *Personal Factors* can interact with and impact upon Functioning and Disability (Figure 4.1).

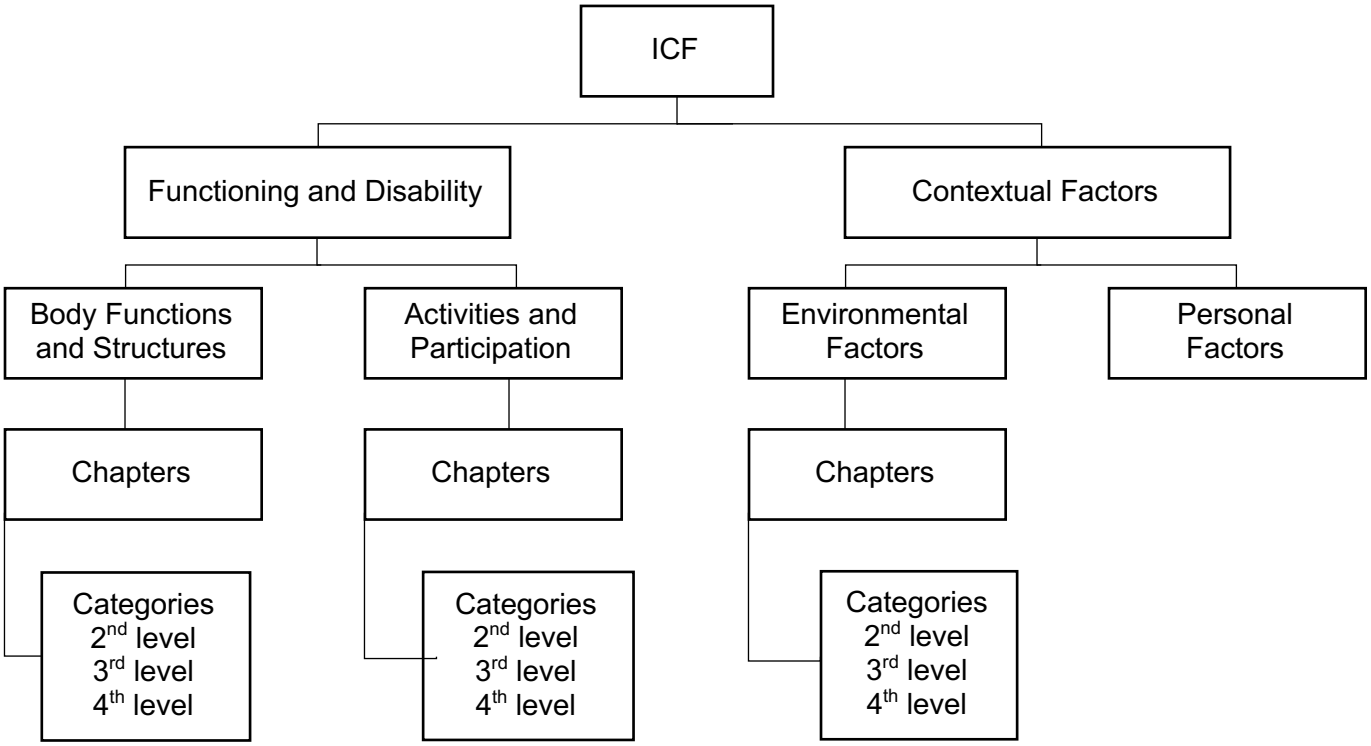

Figure 4.1. Structure of the ICF (World Health Organization, 2001)
ICF, International Classification of Functioning, Disability and Health
The ICF is organized in a hierarchical structure with two parts. Part 1: Functioning and Disability contains the components (1) Body Functions and Structures; and (2) Activities and Participation. Part 2: Contextual Factors contains the components (1) Environmental Factors; and (2) Personal Factors. Each component is made up of chapters which contain a total of 1454 categories. Personal Factors have not yet been classified.

Qualitative research has provided a rich understanding of the lived experience in a TBI population (15,28). More recently, qualitative studies focusing exclusively on a postconcussion population have illustrated the impact of this invisible injury on recovery, interpersonal relationships, and quality of life (14,29,30). Qualitative research describing the lived experience with concussion using the standardized language of the ICF would provide a more comprehensive understanding of functioning in persons with PPCS. Qualitative evidence is essential to establish content validity in the development of a

patient-reported outcome measure (23). Such a measure would have important implications for rehabilitation assessment, intervention strategies, and the development of policies (15,16).

Study aim.

Our aim was to explore the impact of PPCS on adults in order to inform the development of a concussion-specific questionnaire for use in clinical decision-making. We had 3 specific questions:

1. What was the experience of persons with PPCS and clinicians with concussion expertise regarding the consequences of concussion?
2. What influenced recovery following a concussion?
3. How do persons with PPCS and clinicians think the consequences of concussion should best be measured on a concussion-specific patient-reported questionnaire?

4.3 Methods

We were guided by philosophical pragmatism as it enabled us to focus on the practical application of our research using sampling techniques, data collection, and an analytic approach best suited to answer our research questions (31). This approach was underpinned by ontological critical realism and epistemological constructionism. Our methodological framework was qualitative descriptive commonly used in healthcare research (32), whereby the emphasis was on understanding and describing the consequences of concussion using straightforward language that stayed close to our data (33,34). Data sets from focus groups with persons with PPCS and semi-structured interviews with clinicians with concussion expertise were analyzed using thematic

analysis and combined to provide multiple perspectives of the same concepts. Eliciting participant perspectives through open-ended questions allowed us to generate data-driven concepts that were confirmed through direct probing in later focus groups. Theoretically, the ICF was used as a standard language for coding emerging concepts according to established linking rules (35–37). New codes were developed inductively for concepts that could not be coded to the ICF.

Ethical considerations.

After enrolling in the study, all participants were informed of the overall aim of the larger project (i.e. develop a concussion-specific questionnaire), that participation was voluntary, potential benefits and adverse effects of participation, who would have access to the findings, and how the data would be stored. Written informed consent was obtained from all participants prior to participating in the study. Participants used unique numbers to identify themselves when speaking to ensure their identities remained anonymous throughout the data collection and analysis phases. All focus group members were asked to maintain the confidentiality of other members of the group outside of the study.

Ethical approval was obtained from the Ottawa Hospital Health Science Network Research Ethics Board (20170720-01H) and the University of Ottawa Research Ethics Board (A11-17-03).

Participants.

Study participants included both persons with PPCS and clinicians. English speaking adults aged 18 to 65 years who had experienced PPCS lasting more than one month following injury were purposively sampled from concussion clinics and support

programs in a large urban centre. Exclusion criteria included a diagnosis of moderate to severe TBI, uncontrolled pre-existing mental health disorder or addiction at the time of injury, and structural injury or intracranial bleeding on diagnostic imaging if available.

Participants were recruited through recruitment flyers at local concussion clinics and through a support group email list through the Brain Injury Association of the Ottawa Valley. Interested persons were requested to contact the research team directly via email or telephone. Participant eligibility was based on the diagnostic criteria for postconcussion syndrome by the *International Statistical Classification of Diseases and Related Health Problems, Tenth Revision (ICD-10)* (38), and was confirmed by JV during the screening process using a standardized telephone interview.

Clinicians were purposively sampled to represent the diverse healthcare professional groups, such as physicians, psychologists, physical therapists, and occupations therapists, whose scope of practice includes managing PPCS (39). Representatives were chosen as experts in the management of concussion, as recognized by their authorship on national concussion guidelines.

Data collection.

Focus groups were conducted in a community setting between December 13, 2017 and October 30, 2018 and lasted approximately 2 hours each. One person with PPCS was unable to attend the scheduled focus group and was interviewed over the telephone. Focus groups were conducted by two PhD candidates (JV and JO), both of whom were physiotherapists with significant clinical experience interviewing persons with PPCS and had a good knowledge of the ICF and guided by a working conceptual model developed from a systematic review of the literature (40). At the beginning of each focus group,

the ground rules were laid out. This was followed by open-ended questions designed to encourage participants to talk freely about the impact of concussion on their life (Table 4.1). The key questions were revised in an iterative process as new concepts were identified from the data. These concepts were incorporated into focused questions during the second half of subsequent focus groups in order to further explore them with subsequent participants and confirm their importance. The note-taker (JO) took extensive field notes to capture non-verbal behaviours, synthesize observations, and to prevent loss of data. Clinician interviews lasted 30 minutes and were conducted over the telephone, with one face-to-face interview, between December 5, 2017 and May 14, 2018. Clinicians were asked to describe the impact of concussion on persons with PPCS, and what questions they wanted addressed in a concussion-specific questionnaire. All focus group discussions and clinician interviews were audio-recorded and transcribed verbatim by JV.

Table 4.1. Interview questions

Patients
1. What is the impact of PPCS on your life? *(Probes – physically, mentally, emotionally, socially, at work, at school?)*
2. What has influenced your recovery? (Probes – what has made it easier/harder?)
3. What are your limitations or challenges? *(Probes – how is your life different than before?)*
4. What are your symptom triggers? *(Probes – is there anything you're avoiding due to symptoms?)*

5. What do you want us to ask you on a questionnaire? *(Probes – what is missing/not well asked on other questionnaires you have answered before?)*
6. How do you want us to frame a questionnaire? *(Probes – over what time period should we ask? How do we best measure your concerns – satisfaction/difficulty/how often?)*
7. Is there anything else important you would like to share with us?

Clinicians

8. 1. What is the impact of PPCS on a patient's life? *(Probes – physically, mentally, emotionally, socially, at work, at school?)*

2. What challenges do patients with PPCS face? *(Probes – how is their life different since their concussion?)*

3. Do you use any patient-reported outcome measures with concussion patients? *(Probes - which? Why? What do you want to know about to help you direct treatment?*

3. What should be asked on a concussion-specific questionnaire? *(Probes – what is missing/not well asked on other questionnaires you have answered before?)*

4. How can we design the questionnaire to improve your likelihood of using it clinically? (Probes – content/format?)

5. Is there anything else important you would like to share with us?

Note. This was an iterative process, and questions were modified throughout the study to further explore emerging themes and confirm the relevance of previous responses.

Data coding and analysis.

We deductively coded the transcript using the 6-step process of thematic analysis endorsed by Braun and Clarke (41) to develop a coherent understanding of participant experiences. Since the aim of the study was to explore the lived and clinical experience of participants, the ICF was used only as a codebook to give a name to emerging concepts and did not guide questions. Therefore, not all aspects of the ICF were represented. JV read and then re-read each transcript in its entirety while listening to the audio recording to confirm the accuracy of the transcription and to become familiarized with the data. Key concepts were identified from specific text segments. JV and JO independently coded identified concepts from the first focus group transcript by linking them to 2nd-level ICF categories, compared results, and came to a consensus on how to code the subsequent data to the ICF. Concepts were assigned multiple codes where appropriate. The two researchers then independently coded concepts manually from subsequent focus groups using the language of the ICF, resolving discrepancies until they were in complete agreement. Concepts were grouped together into higher order subthemes and themes using the hierarchical taxonomy of the ICF. Concepts described by similar 2nd-level ICF categories were grouped into subthemes that corresponded to ICF chapters. Subthemes were then grouped under higher-order themes represented by the ICF components *Activities* and *Participation*, *Environmental Factors*, and *Personal Factors*. Any concepts that could not be linked to an ICF code were inductively coded into new categories according to predefined linking rules (35,36). Data collection continued until no new concepts were identified in the thematic analysis at the ICF 2nd level from additional focus groups, as we considered them the

most important source of data (23). No new information was obtained in the 10th focus group (n=35), so we stopped collecting data. This suggests that saturation was reached after conducting 9 focus groups (n=33). Even though data saturation from clinician interviews was reached by 13 interviews, we continued to conduct clinician interviews to include the perspectives of a diverse sample of professions. This qualitative approach is an important early step in the development of a relevant, meaningful, and socially valid concussion-specific patient-reported outcome measure.

Trustworthiness.

Several measures were used to ensure our findings are credible, transferable, dependable, and confirmable. First, our interviews were guided by a systematic review and triangulated with qualitative data collected from persons with PPCS and clinicians with concussion expertise. Two independent researchers made data coding, analysis and interpretation decisions that were then presented back to participants for feedback. Second, detailed descriptions of the participants are provided for readers to judge transferability to their own context. Third, we reflected regularly on how our experience as clinicians might influence the research process and an audit trail was maintained to support our decisions and to allow others to replicate our findings. Fourth, our findings are supported by ample quotes that allow readers to judge our interpretations.

4.4 Results

Participants.

Thirty-five (median age, 46.1years [range 19.0-65.1 years]; 66% female) persons with concussion participated in 10 focus groups, with group sizes ranging from 2-6 persons with concussion (Table 4.2). One of the 35 participants was unable to attend the

scheduled focus group and was interviewed over the phone. Six persons contacted the research team, but declined to participate for scheduling reasons. Median number of previous concussions was 1 (range 0-5) with a median of 25 (range 5-90) months since the most recent concussion. Most common cause was a motor vehicle accident (n=12, 34%)

Table 4.2. Demographic characteristics of persons with concussion (n=35)

Participant No.	Sex	Age (years)	No. of previous concussions	Mechanism of injury	Months since last concussion
P1	F	57	0	MVA	70
P2	F	55	0	Fall	59
P3	F	46	0	SRC	83
P4	F	53	4	Other	34
P5	F	58	5	Other	60
P6	F	42	4	Other	46
P7	F	46	0	MVA	36
P8	F	48	1	Other	26
P9	F	54	0	MVA	50
P10	F	55	0	MVA	36
P11	F	50	0	SRC	18
P12	F	31	1	Other	16
P13	F	57	2	Other	60
P14	F	35	4	Other	14
P15	F	55	1	SRC	6
P16	F	45	0	Other	5
P17	M	48	1	SRC	78
P18	M	56	0	Fall	64
P19	M	35	0	MVA	6
P20	F	56	1	Fall	25
P21	F	47	0	Fall	5
P22	F	34	0	MVA	6
P23	M	33	0	MVA	22
P24	F	42	0	MVA	5
P25	M	25	0	MVA	7
P26	F	31	3	SRC	38
P27	M	65	0	MVA	90
P28	F	47	2	MVA	23
P29	M	19	4	SRC	23
P30	F	41	0	Other	22
P31	M	missing	missing	SRC	missing
P32	M	47	0	SRC	22
P33	M	35	1	MVA	84
P34	M	45	2	SRC	8
P35	M	23	3	SRC	10

Abbreviations: F, female; M, male; MVA, motor vehicle accident; SRC, sport-related concussion

Sixteen [13 (81%), female] clinicians with a median 11 (range 6-34) years of clinical experience participated in individual semi-structured interviews (Table 4.3). Eleven different professional groups were represented, including 1 (6%) Neurosurgeon, 2 (13%) Physiatrists, 2 (13%) Sport Medicine Physicians, 2 (13%) Clinical Psychologists, 1 (6%) Chiropractor, 1 (6%) Physical Therapist, 1 (6%) Occupational Therapist, 2 (13%) Speech Language Pathologists, 1 (6%) Registered Nurse, 2 (13%) Optometrists, and 1 (6%) Social Worker. Participant verbatim comments are referred to in the text as "P" for person with PPCS or "C" for clinician, combined with their study number.

Table 4.3. Demographic characteristics of clinicians with concussion expertise (n=16)

Participant	Sex	Profession	Years of clinical concussion experience
C1	M	Sport Medicine Physician	34
C2	F	Speech Language Pathologist, PhD	7
C3	M	Physiatrist	20
C4	F	Optometrist	7
C5	M	Neurosurgeon	6
C6	F	Occupational Therapist	20
C7	F	Physiotherapist, PhD	8
C8	F	Social Worker	missing
C9	F	Registered Nurse, PhD	7
C10	F	Psychologist	21
C11	F	Psychologist	6
C12	F	Optometrist	11
C13	F	Sport Medicine Physician	14
C14	F	Chiropractor, PhD	10
C15	F	Speech Language Pathologist	10
C16	F	Physiatrist	13

Abbreviations: F, female; M, male

Qualitative findings.

Three overarching themes encapsulated the impact of PPCS on a person's life: 1) functioning; 2) barriers and facilitators; and 3) capacity. The first two themes mapped closely onto the components of *Activities and Participation* and *Contextual Factors* of the ICF (Figure 1). A minority of concepts were identified that didn't possess enough

detail to be coded or were not contained within the language of the ICF. They were coded as either 'not definable' (nd) (e.g. physical health, mental health, symptoms) or 'not covered' (nc) (e.g. comparison to preinjury, invisible injury, uncertainty, and quality of life), respectively. With the exception of "sense of loss and grief", "choice" and "personal grooming", persons with PPCS and clinicians expressed the same perspectives regarding the impact of concussion. No concepts were unique to clinicians.

Theme 1: Functioning.

The primary theme that emerged was the overriding importance of functioning. Functioning was conceptualized as the ability to participate in activities and social situations within the limits imposed by symptoms. Limitations in functioning stretched across the subthemes of learning and applying knowledge; general tasks and demands; communication; mobility; self-care; domestic life; interpersonal interactions; major life areas; and community, social and civic life. These subthemes are described in detail below with the exception of self-care, which was raised by only one person with PPCS.

> "I think you're going to see more positive improvement from a functional point of view than you will from a symptomatic point of view." (P34, male, 45 years)

Learning and applying knowledge. Challenges with thinking fundamentally impacted the ability for persons with PPCS to perform basic daily activities such as reading and writing. The invisibility of these cognitive difficulties was highly distressing to persons with PPCS, and often the limiting factor in returning to their preinjury activities.

> “The cognitive impacts, which I’ll just throw in for the record, have been the most devastating to my career, and my relationships, and just about everything else.” (P5, female, 58 years)

> “I cannot read a book. I mean, I don't know why this is, but I will read something, and I'll get to the end of the sentence or the end of the paragraph and I can't remember what was at the beginning. It doesn't hang together; it doesn't gel properly.” (P27, male, 65 years)

> “Being able to text or being able to e-mail or as they write. I don't think that gets asked and that's a lot of what keeps people from getting back to life, work school.” (C15, female, speech language pathologist)

> “We have to walk them through, you know, attention, comprehension, memory, verbal expression, reading, writing, problem solving, social skills and these are all things that really impact students’ ability to return to school successfully.” (C15, female, speech language pathologist)

Persons with PPCS described being ill-equipped to make their own personal and healthcare decisions, and the lack of assistance in the medical system to help them navigate their own care.

> “Decision making is an extremely common problem postconcussion. And every single one of these questions is a huge decision. I can't emphasize that enough.” (P5, female, 58 years)

General tasks and demands. Persons with PPCS and clinicians identified challenges associated with undertaking multiple tasks and carrying out daily routines as major limiting factors in the ability to engage in everyday activities. Needing to modify their environment and limit their social interactions in order to be able to concentrate on one task at a time was a frequent source of frustration for persons with PPCS who tired of explaining to others how to behave around them.

> “I can't cook supper and have music on in the background. I can't have someone, if I'm working on the computer, talk to me.” (P20, female, 56 years)

> “Complaining a lot of trouble multitasking.” (C13, female, sport medicine physician)

Persons with PPCS described carefully planning out every aspect of how to carry out their day in an effort to prevent symptoms from coming on or getting worse. Clinicians had concerns about persons’ ability to self-pace their activities.

> “You're very much planning how many activities you can do in a week when an activity for us is an appointment, or in some cases a shower. And how many days do you need of just complete rest.” (P21, female, 47 years)

> “Patients are pushing themselves too hard and then they don't get better because they're doing too much, right?” (C6, female occupational therapist)

Communication. Problems with communication often presented as difficulty expressing oneself in writing or keeping up with a conversation. Being unable to communicate effectively was seen as a barrier to getting back to life roles such as work, school, and social interactions.

> “And being unable to keep up in conversations, that alone, if that was my only symptom, that would be hell.” (P5, female, 58 years)

> “I hear patients describing formulation, getting to my point, in addition to finding my words, and then understanding, like comprehension. So being able to follow and process.” (C15, female, speech language pathologist)

Mobility. Persons with PPCS described their world shrinking, because they were unable to wander far from their home. Being unable to walk or drive due to fatigue, balance issues, anxiety, or visual problems was highly limiting and incompatible with the active lifestyles enjoyed by many before their concussion.

"I used to walk to work, it was a half hour walk each way, and now I can barely walk to the mailbox. Sometimes I can't walk at all, like I can't even, I'm too tired to go get the mail." (P9, female, 54 years)

"'I can't walk straight.' That's a big one actually, walking, ambulation." (C12, female, optometrist)

"I have a lot of postconcussion patients who really struggle with driving. Sometimes that can be related to anxiety issues around driving, because their concussion was a result of a motor vehicle accident. And sometimes it has nothing to do with that it; it has to do with visual motion sensitivity." (C4, female, optometrist)

Domestic Life. The ability to go grocery shopping, prepare meals, or do housework was frequently linked to fatigue, dizziness, and anxiety, and often required multiple strategies to minimize symptom reproduction in order to complete the task. Persons with PPCS described feeling a loss of independence and shift in family relationships as a result.

"I walked into a grocery store and all these people, and all sounds, and this noise, and all these products, and I could not handle it. And the only way I've learned how to handle it is I go shopping, like, at eight o'clock in the morning

> when the store opens, and there's nobody in the store. And I can handle it okay. But I cannot go into a crowded 5 o'clock in the afternoon when everybody is struggling to get their stuff. I can't handle it." (P27, male, 65 years)

> "There can be a lot of disabilities from work and also in activities of living and home life etcetera, caregiving, you know, the whole, the whole nine yards." (C16, female, physiatrist)

Persons with PPCS raised concerns about changes in their ability to care for other family members, particularly their own children, and felt guilty that they couldn't take care of their family the way they used to.

> "I should have been looking after him, but I was asleep on the sofa for, like, three hours every afternoon, every day. And he just had to do quiet activities to not wake me up and disturb me. Instead of me being able to look after him." (P21, female, 47 years)

Interpersonal interactions and relationships. The impact of concussion on the lives of persons with PPCS was clearly articulated as having broad negative consequences on relationships with family, friends, and peers. Persons with PPCS highlighted the emotional repercussions of the stress put on relationships and resultant social isolation. Connections were made between relationships, the invisibility of their injury, and how well others understood their limitations.

> “The isolation is phenomenal.” (P13, female, 57 years)

> “My social network is vastly reduced, because I'm just not able to go out and attend and participate in activities the way most people take for granted.” (P18, male, 56 years)

> “Sorry, Mommy can't do that. So, I feel like I'm disappointing my kids in a lot of ways too.” (P21, female, 47 years)

Clinicians expressed concern that too high a priority was often placed on returning to work and other life roles, leaving persons with PPCS unable to put enough energy into their relationships.

> “People, they tend to put (relationships) on sort of the backburner as opposed to, like you know, return to work or some of these other activities that they think they HAVE to do, but it's their relationships that suffer as a result.” (C10, female, psychologist)

Major life areas. Being unable to fulfil all of the life roles and obligations at a pre-injury level was a common theme. Return to work was repeatedly cited as a goal by both persons with PPCS and clinicians. This was discussed in terms of job performance, return to work timing, being rushed back before full recovery, the desire to return to an

engaging and self-fulfilling life role, and the basic financial need to survive. Employment was closely associated with emotional well-being and sense of identity. Persons with PPCS were often determined to return to work, despite significant symptoms, and expressed dismay at the being labelled ‘a little lazy’ or ‘making this up’ (P5) when they were unable to.

> “When they lose their employment. It can also affect their sense of what they are contributing to, like, the community or to the world, which then affects depression, anxiety, etcetera, sense of self.” (C4, female, optometrist)

Unique to the perspective of persons with PPCS was the feeling of a profound sense of loss and grief wrapped up with abruptly losing who they were and what they can no longer do compared with their old self.

> “I haven't been back at work since. So that's a *huge* loss for me. I'm still not admitting to myself that I'm never going to go back to work. Because I really loved my career. It was a big sense of who I was and I was good at it.” (P20, female, 56 years)

Community, social and civic life. Engagement in recreation and leisure activities, including exercise, was viewed by both participant groups as fundamental to enjoying life. Whereas clinicians focused on resumption of pre-injury activities, persons with PPCS emphasized the importance of modifying their environment in order to minimize

symptoms and be able to participate at any level. When that wasn't feasible, persons with PPCS described needing to choose between avoiding overstimulating situations such as crowded, visually busy spaces, movie theatres, sporting events, holiday parties, and restaurants, or paying the consequences. The cost of participating in these activities was high, ranging from hours to weeks to recover from symptoms. Again, connections were made between a diminished social life and feelings of isolation, anxiety, and depression.

> The decision to go to the movies is an impossibility for me right now. I still can't do it at 3 years. it's going to throw me way over the edge and I'm going to have a setback, and I'm going to be in bed for the next 2 weeks, and it's just not worth it. (P7, female, 46 years)

> "People will invite you out to things, because they feel that you are isolated, but you can't; you have to optimize every environment to go into." (P14, female, 35 years)

> "Often people are withdrawing from social, leisure stuff just because of, potentially because of other symptoms, noise sensitivity, light sensitivity, fatigue, that kind of thing." (C11, female, psychologist)

Theme 2: Barriers and Facilitators.

A second theme that emerged from the data was the significant influence of *Environmental* and *Personal Factors* on functioning. Environmental sub-themes were identified (products and technology; natural environment and human-made changes to the environment; support and relationships; attitudes; services, systems and policies) that acted on a continuum from barrier to facilitator, thus making it harder or easier to function. Comparing functioning to preinjury, wrestling with uncertainty about long-term prognosis, the invisibility of the injury, and quality of life emerged as subthemes outside the language of the ICF. When coping skills or knowledge of concussion were limited, persons with PPCS described feeling less able to function.

Products and technology. Universally, the visual stimulation and overload from computer, tablet, or smartphone screens was cited as a trigger for symptoms and a major barrier to engaging in many activities or resuming life roles. Persons with PPCS struggled with reducing their exposure to screens given its ubiquitous presence at home and work to send emails, texts, and access the internet. Furthermore, computer use was considered an essential skill for many jobs that integrate technology, and limited screen tolerance was commonly cited as the reason behind being unable to return to work.

> "I can't look at a screen. So, I work in IT. I need to look at a screen." (P21, female, 47 years)

> “Screen times, we’re very screen focused. I can do it for, it's all limits. I can do it for 20 minutes and then symptoms start. And they get worse. And do I stop at 20 minutes? No, because I still want to do certain things. But then I pay the price. I pay the price. I just sit down afterwards and zone out, or I go for a walk, or I try not to run into people I know. And I just try to zone out.” (P20, female, 56 years)

> “Periods of trying to use computers and reading can be significantly shortened by concussions. I've had some patients who can't read more than a sentence at a time.” (C4, female, optometrist)

Natural environment and human-made changes to the environment. Persons with PPCS emphasized barriers imposed by bright or fluorescent lights and noise within their environment. Commonly identified strategies to mitigate their effect such as adjusting indoor lighting, wearing sunglasses, reducing speaker volume, or wearing ear plugs appeared only minimally helpful.

> “Noise and light sensitivity, all of these things are all amplified.” (P3, female, 46 years)

Support and relationships. Persons with PPCS and clinicians were in agreement that receiving support at home was central to helping with recovery. Persons with PPCS elaborated that they felt physicians should ask what supports persons with PPCS have in place and seek out their help.

> “If you live on your own, you have no support, you will not get better. There’s a direct relationship there.” (P7, female, 46 years)

> “I think those reassurances are really, really important.” (C15, female, speech language pathologist)

Persons with PPCS described leaning on friends and peers to help them out with domestic tasks, with financial assistance, to understand their injury, to provide emotional assistance, and to navigate the healthcare system.

> “I was relying my friends would bring me [meals] sometimes.” (P6, female, 42 years)

> “Being able to connect with other people who have the same experience and share ideas is enormously helpful.” (P16, female, 45 years)

Having an employer that was supportive, understood a person’s needs, and was willing to accommodate them was considered integral in returning to work.

> “I feel a big issue was the lack of support with returning to work.” (P6, female, 42 years)

> "And I think the other barriers are, which are improving, but workplace accommodation and integration. It's interesting to me that there's no problem with a fracture to the leg, at least being offered 6-8 weeks to return. But often we're advising a patient with concussion, and often with significant symptoms ongoing, to return after one week or longer, shorter periods of time." (C3, male physiatrist)

However, many persons with PPCS described waning support over time. They attributed this to the prolonged nature of recovery, uncertainty of prognosis, lack of understanding by others, and the invisibility of their injury. They felt that other people didn't understand why they needed support and accommodations when they looked fine.

> "People get fed up with giving you support. And so, you know, it's the 'everyone is sick of this'. Those people aren't willing to do that anymore. (P8, female, 48 years)

Attitudes. Strong connections were made between the stigma of dealing with an invisible injury and emotional health. Persons with PPCS described being able to cope better when they felt others validated their symptoms.

> "They just don't understand how debilitated I actually am." (P9, female, 54 years)

This was particularly poignant when dealing with insurance companies.

> "It invalidates how it impacts on your self-esteem. You're working hard to get people to understand how this has affected your life, and then you've got these big people with all this power saying 'no'. And then your spouse or your friend says, 'oh well, if your insurance company says you're not disabled then maybe, you know, you're not'." (P13, female, 57 years)

Services, Systems and Policies. Quality of care was one of the top issues identified by both persons with PPCS and clinicians. Persons with PPCS also expressed frustration that the healthcare system wasn't set up to help them navigate their own care, as they were not in the best position to make their own decisions.

> "Lack of clinics, lack of knowledge among primary care physicians to know which, you know, clinics are ones that people should be sending to. And probably the worst is just people practicing outside their scope of practice and offering, you know, non-evidence-based therapies to, you know, to this vulnerable patient population." (C5, male, neurosurgeon)

Persons with PPCS also felt the fundamental lack of knowledge about concussion management on the part of some primary care physicians fostered a sense of disbelief in the extent of disability persons with PPCS experienced.

> “There seems to be a whole body of physicians or persons on the periphery of this kind of injury who deny that it actually exists, and therefore it's not a problem, and it's all in somebody's head. And they're out of touch with reality, to be quite honest.” (P27, male, 65 years)

Persons with PPCS often relied on word-of-mouth from people with similar experiences to find care. When they were able to find care, they were frustrated by long waitlists and high financial costs to treatment. Persons with PPCS discussed at length the challenges in being able to access and afford appropriate care and the relationship between finding care and recovery.

> “It was 27 months before I got in to see Dr. M. So, I'm frustrated that there was this first year where I was just literally debilitated by symptoms, suffering and not really able to do and not really getting any of the help that I feel now that I might have benefited from early on.” (P18, male 56 years)

> “To be able to afford that care is a huge, access, well, access to care is a big issue in determining recovery.” (P25, male, 25 years)

Not covered. Key concepts not covered by the ICF included the importance of comparing participation to preinjury levels, uncertainty about long-term prognosis, the invisibility of the injury, and quality of life. Persons with PPCS strongly articulated the adverse effect of uncertainty regarding the fluctuating nature of symptoms, effective treatment options, recovery expectations, long-term complications, ability to work, and resumption of usual social and life activities. This was highly distressing for many individuals and intertwined with anxiety about the future.

> "I don't think that there are other conditions where you are so facing uncertainty as in a concussion. In postconcussion syndrome. You never know. And that's part of the condition." (P10, female, 55 years)

One of the more salient concepts was the invisible nature of the injury made it difficult for people to understand and empathize their struggles, and ultimately led to compassion fatigue.

> "With an invisible injury like this, it's so hard to communicate what's going on for you and it's really challenging trying to express the struggles you're going through." (P17, male, 48 years)

> "I think that's one of the barriers that patients kind of encounter is that often people can't tell that they're disabled based on the way that they look.

> Concussion tends to be something that, you know, where the patient looks normal. (C4, female optometrist)

Although quality of life was indisputably diminished following concussion, comparing participation to preinjury rather than satisfaction with life was considered fundamental to measuring recovery.

> "For those who don't (recover) or who are delayed, their quality of life is significantly compromised, and I think it's very important." (C2, female, speech language pathologist)

> "If (the questionnaire) is actually trying to get at the injury, and how it's impacted your life, the "satisfied" I don't think is that helpful. Because then it measures your resilience, or your ability to cope as opposed to what your life is objectively like." (P2, female, 55 years)

> "The idea of comparing things to preinjury should be absolutely front and centre." (P5, female, 58 years)

Personal Factors. Coping strategies and persons with PPCS's own knowledge of concussion seemed to percolate up regularly as strong influencers of participation. Coping strategies varied from adjusting expectations, to limiting exposure to

environmental stimuli, limiting social interactions, planning and pacing efforts, and managing symptoms with stress-reduction strategies.

> "I try to manage my symptoms by managing my activities. So, I manage them by restricting access to people, which is very hard for an extrovert. Because I was extremely extroverted. And now I'm extremely introverted. Because people cause me pain." (P20, female, 56 years)

> "I was treated in an ER situation and released. And there was no information. There was no paperwork. There was nothing that I went home with. And I think that directly had an impact on my quality of life and the fact that then I went on to experience postconcussion syndrome." (P11, female, 50 years)

> "They have to pull away after a while and they have to just go and withdraw and remove themselves from all the stimuli and then they feel better and then they may be able to come back later." (C16, female, physiatrist)

Theme 3: Capacity.

Capacity emerged verbatim from participant descriptions as a strongly resonant expression of how much one was able to function, defined as the length of time one could perform a task before symptom onset, primarily fatigue. Persons with PPCS emphasized needing to choose between activities in order to manage symptoms and the length of time it took to recover from those symptoms as key subthemes of capacity.

When capacity was low, this reduced the ability to engage in individual activities or participate in life situations.

Capacity weaved through individual storylines, describing how persons with PPCS needed to choose where to spend their limited energy in order to engage in family, leisure, social, and work activities. This was further complicated by the issue of staying below their symptom threshold in terms of needing to choose how long they could perform a task before symptom onset, and the number of tasks they could perform in a given day. In some cases, persons with PPCS were able to consistently identify how long they were able to perform a certain activity before their symptoms started or worsened. In others, the relationship was more variable and inconsistent. Clinicians recognized persons with PPCS had lowered capacity endorsed planning and pacing strategies as a means of staying below the symptom threshold.

> "How long can you do it? Does it trigger symptoms? How long does it take you to recover? And what's your level of functioning in that domain compared to before?" (P6, female, 42 years)

> "You learn to pace yourself before you start feeling foggy like, you need to change the stimuli or decrease the stimuli, do something different, etc." (C16, female, physiatrist)

Persons with PPCS explicitly used the term “choice” to describe needing to choose between activities in order to conserve energy and minimize symptoms. They considered this idea of “choice” as fundamental to any measure of participation, and not captured on any questionnaires they had completed to date. Equally important was being able to document how long it took them to recover from symptoms if they had been aggravated. Recovery was an important concept, with the majority of persons with PPCS emphasizing the limitations imposed by needing significant periods of rest in between activities to be able to function. Choice and recovery were deemed essential to measuring the impact of injury and being able to articulate the consequences of concussion to others. This was a unique finding that did not emerge from the clinician perspective.

> “There’s an issue of sustain that is not caught by many surveys. And it’s not just “can I sustain that activity”, it’s, “I have to choose that activity and nothing else”. So, there are questions that ask, “Can you grocery shop?”. And I actually can, but I’ll have many symptoms, I have to have many strategies, and I’ll do nothing else for the day. And I have to go on an off-peak time, and not take a cart, and I have to know the store, and it can’t have loud music, etc. So, but if I do that, I can’t do something else.” (P2, female, 55 years)

> “I have to choose what I’m going to do that day. I have to choose am I going to read, am I going to talk to someone, am I going to do my taxes? Am I going to prepare a meal? What am I going to choose to do? ‘Cause it’s always a question

> of choices and figuring out how I can get that activity done with the least symptoms possible. Whereas I never thought about that before. It was how can I cram as much stuff in a day." (P20, female, 56 years)

Persons with PPCS expressed frustration that commonly used clinical measures of symptoms or fatigue didn't take into account the issue of "choice" in terms of needing to choose between how many activities they were able to participate in before reaching their symptom threshold. Clinicians shared concerns that existing questionnaires did not fully meet the needs of persons with PPCS.

> "Our own discipline has had this sort of question about utility of some of the existing questionnaires and things that are out there and that it doesn't seem to capture some of the complaints our patients have." (C15, female, speech language pathologist)
>
> "(Questionnaires) don't seem to take into consideration that one has such diminished cognitive and perhaps physical energy, that while one *could* do that on a given day, one *can't* do all of those things in combination. So, I feel that these things can give a very distorted view of your capacities." (P18, male, 56 years)

The variability in symptoms on a daily basis was felt to be confusing to family, friends, and employers who couldn't understand why they felt good and could do more on one

day, but not the next. This was very discouraging to persons with PPCS and acknowledged by clinicians as a barrier to recovery.

4.5 Discussion

This study captures the experiences of persons with PPCS and clinicians with concussion expertise and fills a gap in the literature about the functional consequences of concussion. This knowledge is the groundwork needed for the development of a concussion-specific outcome measure that measures functioning, by informing its content and structure, and ultimately its content validity (23).

Functioning, barriers and facilitators, and capacity emerged as the three main themes. It is important to note that symptom reporting in this study was emphasized in the context of how symptoms limited functioning, rather than as the problem itself. Our findings suggest that persons with PPCS often manage their symptoms by reducing their activities. Hence, a low score on a symptom scale may be less reflective of recovery, and more likely represent reduced engagement in life activities. This can result in a recovery paradox, whereby persons with PPCS may appear to be improving when only symptoms are measured without taking capacity into consideration. While this strategy may reduce symptoms associated with concussion, it also leads to reduced social participation and a decreased quality of life for the person. The resulting sense of isolation resonated deeply with persons with PPCS and contributed to a sense of loss and depression. This has implications for clinical assessment, as symptom improvement may reflect withdrawal from participation, rather than true recovery. Recent Canadian guidelines for concussion/mild traumatic brain injury and PPCS recommend a symptom-based approach to treatment, however little guidance is given

to measure if symptom reduction results in changes in participation (13). These findings highlight the need to carefully consider a person's symptoms in the context of their full participation in individual activities and their role in society. Assessment that takes into consideration how long a person is able to engage in activities before they develop symptoms, how many activities they can do in a given day, and how long it takes them to recover appears useful. This is in contrast with current recommendations that typically target the management of symptoms (13).

Clinical assessments may well be complemented by measuring barriers and facilitators to participation to get a clearer picture of recovery. Participants in our study described a diverse array of environmental and personal factors that influenced individual and social participation. These findings mirror those of Snell et al. (14), in which persons with PPCS identified the importance of being treated with compassion and understanding by health providers, family, friends, employers, and insurance companies as having a strong influence on recovery. We found similar issues with persons with PPCS in our study clearly feeling distressed when they perceived others disbelieved they were suffering. They attributed this to the invisible nature of their injury and others' lack of knowledge regarding PPCS. Similar to Snell et al. (2017) (14), this sense of disbelief was described as being incredibly invalidating, with education perceived as being key to enabling clinicians to support them through their recovery. Uncertainty is a key component in other disability models when prognosis and recovery are unpredictable (42,43). As with Snell et al. (2018) (29), we found the uncertainty of recovery compounded feelings of anxiety and invalidation that was not captured by the

ICF, suggesting the framework may not capture all relevant concepts following concussion.

Capacity was a new theme identified in this study and emphasized by persons with PPCS as essential measures of recovery along with the concept of choice that has implications for clinical practice and highlights the importance of using outcome measures that have the most relevance for end users. These findings suggest that a concussion-specific questionnaire should assess functioning in terms of how long a person can perform an activity before the onset or worsening of symptoms, how many of these activities they can do in a typical day, and how long it takes the symptoms to return to baseline once aggravated. This novel approach would help quantify functional capacity in a meaningful time-based manner and allow decisions on participation to be made to ensure persons with PPCS stay below their symptom threshold. This is important for clinicians to be able to recommend criteria-based planning and pacing strategies, and to substantiate return to work recommendations to employers and insurance companies.

This study adds to the existing body of research by providing evidence of the complex relationship between how concussion symptoms limit participation, and how this is influenced by social and environmental factors, and personal characteristics (7,44). A comprehensive understanding of the consequences of concussion is essential to guide our clinical management of this injury.

Limitations.

Persistent postconcussion symptoms are non-specific to concussion and may evolve over time, owing to the interplay between psychosocial factors, environmental

influences, and the development of secondary conditions (13). Study eligibility was confirmed in participants recruited from a regional hospital-based concussion clinic that used American Congress of Rehabilitation Medicine diagnostic criteria for concussion (45), however we relied on a standardized eligibility screening interview for 3 participants recruited through a support group.

While this study used the ICD-10 diagnostic criteria for postconcussion syndrome as symptoms lasting longer than one-month following concussion, time since injury ranged from 5 to 90 months among our participants, which includes the longer duration symptom requirement of the DSM-IV. Therefore, these findings should be considered transferable in the context of PPCS and may differ in persons with acute symptoms following concussion. Interviewing persons at earlier time points following concussion and over time might improve our understanding of how functioning varies over time.

The analysis was performed by two physiotherapists with experience treating persons with PPCS. It may be argued that our previous knowledge and experience helped shape our questioning and interpretation of findings, however confirmation of our interpretations through cognitive interviews suggests we stayed true to the experiences of the participants. Additionally, our use of predefined ICF codes may have introduced unconscious bias into our analysis. We attempted to control for any possible bias by asking open-ended questions, coding the qualitative data independently, and asking participants to provide feedback on concepts identified from previous focus groups to check if they reflected a common experience (46).

4.6 Conclusion

Our study provides evidence of the complex consequences of concussion and, has implications for clinical management. Current guidelines recommend a symptom-based approach to concussion management, [6] however this was not echoed by persons with PPCS in this study who emphasized the need to capture the impact of symptoms on functioning, rather than focus on the symptoms themselves. Environmental and personal factors appear to play an important role in recovery, and interventions directed at addressing some of these barriers might improve functioning. Additionally, capacity appears fundamental to capturing limitations in functioning based on symptom threshold and time to recovery. Finally, and not least, current questionnaires appear not to capture the pervasive impact of concussion, thus supporting the development of a new concussion-specific measure that would address issues most relevant to persons with PPCS.

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Chapter 5: The Concussion Recovery Questionnaire (CORE-Q): Conceptual model development and item generation of a concussion-specific measure of functional status

The work in this chapter has been submitted for publication in *Brain Injury*. Ethical approval for the cognitive interviews was granted by the Ottawa Hospital Health Science Network Research Ethics Board (20170720-01H) and the University of Ottawa Research Ethics Board (A11-17-03).

5.1 Abstract

Introduction: Defining and measuring limitations in functional status post-concussion has been challenging, as generic measures do not accurately reflect issues most relevant to adults with persistent post-concussion symptoms.

Purpose: To develop a new concussion-specific measure of functional status for use in clinical practice and intervention trials.

Method: We developed a conceptual model of functioning based on concepts identified from a previous qualitative study with persons with concussion and clinicians. An initial set of questionnaire items was generated from the concepts, codes, and conceptual model. Items were refined using cognitive interviews elicit feedback on their relevance and acceptability.

Results: We developed an initial set of 145 items categorized by concepts that was reduced to 50. Our final item set resulted in the *CO*ncussion *RE*covery Questionnaire, which contains a total of 53 items split into 3 separate scales: the Post-Concussion Functional Scale, Concussion Modifiers Scale, and Global Functional Recovery Scale.

Conclusion: The new Concussion Recovery Questionnaire is a self-reported measure of functional status for monitoring outcomes in clinical practice and in clinical intervention trials following concussion. Further studies are necessary to provide evidence of the measure's psychometric properties and to determine the questionnaire's ability to facilitate clinical decision-making.

Key words

Conceptual Model; Concussion; Functioning; Patient-Reported Outcome Measure

5.2 Introduction

Most adults fully recover following concussion, although 10-15% continue to experience persistent post-concussion symptoms (PPCS) beyond the expected period of recovery (1,2). While 67% of those with PPCS will recover within the first year, those with symptoms beyond 3 years do not recover, resulting in significant disability(3). Given the prevalence of PPCS, it is important to be able to measure the burden of concussion on those affected.

Although numerous studies have examined the prevalence of symptoms following concussion, few studies have focused on the impact of those symptoms on functioning (4–7). This limits our ability to measure meaningful change in recovery and identify potentially modifiable factors that influence functioning following concussion. Functional status is particularly important and relevant in concussion, where interventions often result in functional change despite minimal improvement in symptoms. Importantly, functioning necessarily takes place in the context of a person's abilities, participation within the community, and environmental barriers (8). Mallinson and Hammel (2010) refer to this as the intersection of the person-task-environment (9). How the environment interacts with functioning following concussion is poorly understood. Examining the relationship between functioning and the environment, including physical, social and attitudinal supports; barriers to functional capacity; and social and community participation following concussion may prove valuable in setting rehabilitation goals (10).

Currently, no concussion-specific measure of functional status exists. This limits our ability to measure injury burden and environmental contribution to functioning, evaluate effectiveness of treatment interventions, and plan health policy. Such a measure is urgently needed.

We conceptualized functional status to be an assessment of functioning, and defined by Leidy (1994), as "a multidimensional concept characterizing one's ability to provide for the necessities of life; that is, those activities people do in the normal course of their lives to meet basic needs, fulfill usual roles, and maintain their health and well-being" (11). Those necessities include physical, cognitive, psychological, social, and spiritual needs. In order to understand how functioning was being measured post-concussion, we conducted a systematic review of concepts contained within existing outcome measures used in concussion research (12). We compiled a wide range of concepts that demonstrated the complexity of recovery post-concussion, and classified them according to the International Classification of Functioning, Disability and Health (ICF) (13). In preparation for the development of a new measure, we then conducted an initial qualitative study to explore which of those concepts were most impacted following concussion through focus groups with 35 persons with concussion and semi-structured interviews with 16 clinicians. We deemed this an adequate sample size based on recommendations by Guest et al. (2006) to be able confident we had reached sufficient data saturation to ensure content validity (14). Findings from the qualitative interviews were also grounded in the language of the ICF. Results of the qualitative study laid the groundwork for the current study and are being prepared separately for publication.

The purpose of this study then, was to develop a self-report measure of functional status for adults with PPCS that could be used in clinical practice and intervention trials. Our goal was to make the measure brief enough to be included in a battery of assessment tools, yet provide a comprehensive evaluation across multiple domains. Our specific objectives were to:

1. Develop a conceptual model of functioning post-concussion;
2. Develop questionnaire items based on concepts, codes, and the conceptual model;
3. Refine questionnaire items based on cognitive interviews with persons with concussion and clinicians with concussion expertise.

5.3 Methods

Phase I: Development of a conceptual model functioning postconcussion.

Early on, we made the decision to increase the practical application of the questionnaire by transforming the concepts elicited during the initial qualitative study into a conceptual model framed by clinical domains instead of ICF codes.

The primary purpose of the conceptual model was to guide the development of the questionnaire by informing our decision about what concepts to measure, how to measure them, and the relationships amongst the concepts. The conceptual model was developed from themes and concepts that aligned with the construct of functioning elicited during the initial qualitative interviews with 35 persons with concussion who were a median of 25 months post-injury and 16 clinicians who had a median of 11 years of concussion experience. Two researchers (JV and JO), developed a conceptual model, discussed the concepts contained within it, reviewed the structure, and revised

the graphical representation through an iterative process until they agreed that it was a good representation of the relationships between the 3 major themes of the qualitative study: functioning, barriers and facilitators, and capacity.

Phase II: Item generation.

Questionnaire items were generated from concepts and codes elicited from the initial qualitative interviews, and categorized together (binned) according to the conceptual model. For example, “Mobility” became a bin within the Physical Activity Tolerance domain. This allowed us to identify the best potential items and avoid redundancy (15). The goal was to ensure adequate content coverage within each bin from which to select items that best represented the meaning of each bin (16).

Those items from each bin that best represented the domain definition were retained. Predetermined criteria were used to reduce the number of items (winnowing): (1) inconsistency with domain definition; (2) item content similar to other retained items; (3) lack of relevancy to concussion; and (4) item was confusing(16). For example, concepts related to symptoms were identified, binned, and removed from further consideration, because symptoms did not meet our definition of functioning. Careful consideration was given to ensure item stems were clear, concise, and were consistent with the response options for each scale. A limited number of items that were common within the same bin were retained as examples within the stem of a question to clarify its meaning.

Phase III: Item refinement.

Cognitive interviews.

A subset of 8 persons with concussion and 5 clinicians from our initial qualitative study were subsequently approached for a follow up study and invited to provide feedback on the pilot questionnaire. All agreed to participate. This involved 4 rounds of interviews, each round comprising 2 to 5 individual interviews with participants, resulting in a total of 13 interviews by the end of the 4th round. This was done to confirm our interpretation of concepts generated in the qualitative study and assess problems with cognitive processing of the questions. Participants who had sustained a concussion were purposively selected to represent varying experiences across a broad range of mechanism of injury, presence of persistent symptoms, previous history of concussion, and time since injury. Clinicians were purposively selected to represent diverse healthcare professional groups commonly involved in concussion care. Expert recommendations suggest that 5 to 15 cognitive interviews are sufficient to elicit feedback when developing questionnaire items (17,18). Clinicians were identified based on their expertise in concussion management (as demonstrated by significant publications in the field and/or authorship in national concussion guidelines). Winnowed items were then tested through face-to-face cognitive interviews with both groups to elicit feedback on participant understanding, relevance of items, appropriateness of response options and recall period, level of readability, and completeness of the concepts contained in the questions (19,20). Interviews were performed over multiple iterative rounds until all major problems were identified. All participants provided written informed consent prior to participation. Ethical approval for the cognitive interviews was

obtained from the Ottawa Hospital Health Science Network Research Ethics Board (20170720-01H) and the University of Ottawa Research Ethics Board (A11-17-03).

Using the “think –aloud” technique, participants were asked to describe their thought process as they read each question. This was followed by verbal probing to ensure items were easily understood, that the meaning of the items reflected the underlying construct, and to identify any content gaps (17,21). Each item was reviewed by all participants. Following item-level inquiry, participants were asked to provide feedback on the questionnaire in its entirety to evaluate content coverage, and identify any problems with formatting or administration. The interviewer took extensive notes throughout each interview, highlighting problem questions and identifying areas of misinterpretation or confusion. Interviews lasted 30-60 minutes each. After each round, the principal investigator reviewed participant responses, extracted key phrases or statements that were relevant to item interpretation, identified problems, and clustered them into categories to decide on necessary revisions. Criteria for revision or deletion included two or more negative comments, such as difficulty with comprehension, mismatch between participant interpretation and item intent, or lack of relevance to personal experience with concussion. New items were added where gaps in content were identified.

Reading level analysis.

Although the new questionnaire was designed as a self-report outcome measure using participants words and phrases taken from transcripts wherever possible, it was important to ensure the comprehensibility of the questionnaire. Therefore, we assessed the reading level of each item according to the Flesch-Kincaid Grade Level and

reworded items that were above a sixth grade reading level (22). This was considered especially important in this population to make the questionnaire accessible to persons with cognitive problems and mental fatigue post-concussion.

Design of assessment form.

We were guided by the need to keep the format visually clean given the frequent visual problems experienced by persons with concussion. This meant avoiding word wrap within text boxes, maximizing the use of white space, using larger font size, minimizing the number of words through clear and concise instructions, creating visual anchors with the use of italics or bold fonts, organizing similar concepts into tables, and repeating headings at the top of new tables. The intent was to maximize the readability to improve completion of the questionnaire.

5.4 Results

Participants.

Results for Phase I and Phase II were drawn from data from our initial qualitative study that included 35 persons with concussion (23 females [66%]; age range 19.0-65.1 years) and 16 clinicians (13 females [81%]) with a median of 11 years concussion experience. Persons with concussion had a median of 1 (range 0-5) previous concussions and were a median of 25 months post-injury. Clinicians included 1 (6%) Neurosurgeon, 2 (13%) Physiatrists, 2 (13%) Sport Medicine Physicians, 2 (13%) Clinical Psychologists, 1 (6%) Chiropractor, 1 (6%) Physical Therapist, 1 (6%) Occupational Therapist, 2 (13%) Speech Language Pathologists, 1 (6%) Registered Nurse, 2 (13%) Optometrists, and 1 (6%) Social Worker. A subset of these participants were enrolled in the follow-up Phase III study. A total of 8 persons with concussion

(median age 52.8 years; 7 females [88%]) and 5 clinicians with expertise in concussion (median 13 years of experience) participated in the cognitive interviews. The majority of the persons with concussion had no previous history of concussion (75%). Although 88% had completed some postsecondary education, only 13% had returned to work an average of 4.2 years following injury. Approximately one-third of the concussions were sustained from a motor vehicle accident (38%), another 25% were sports-related, with one-third split between falls, accidents, and other. Clinicians included 2 Physiatrists, 1 Neuropsychologist, 1 Speech Language Pathologist, and 1 Nurse (4 females [80%]).

Phase I Conceptual model.

Our conceptual model (Figure 5.1) captures the functional consequences of PPCS across 5 major life domains: (1) sensory tolerance; (2) physical activity tolerance; (3) mental activities; (4) life activities; (5) and social participation. These domains are commonly occurring, but are not necessarily interrelated. For example, sensory tolerance may be unrelated to physical activity tolerance, such that a person may have difficulty looking at a screen, but be able to tolerate light amounts of physical activity such as walking or climbing stairs, or vice versa. Recovery of functioning is influenced by multiple factors at an individual level (e.g. physical health, emotional health, cognitive function), a social level (e.g. relationships with friends and family, attitude of others), and at an environmental level (e.g. financial security, access to healthcare, and support in the community).

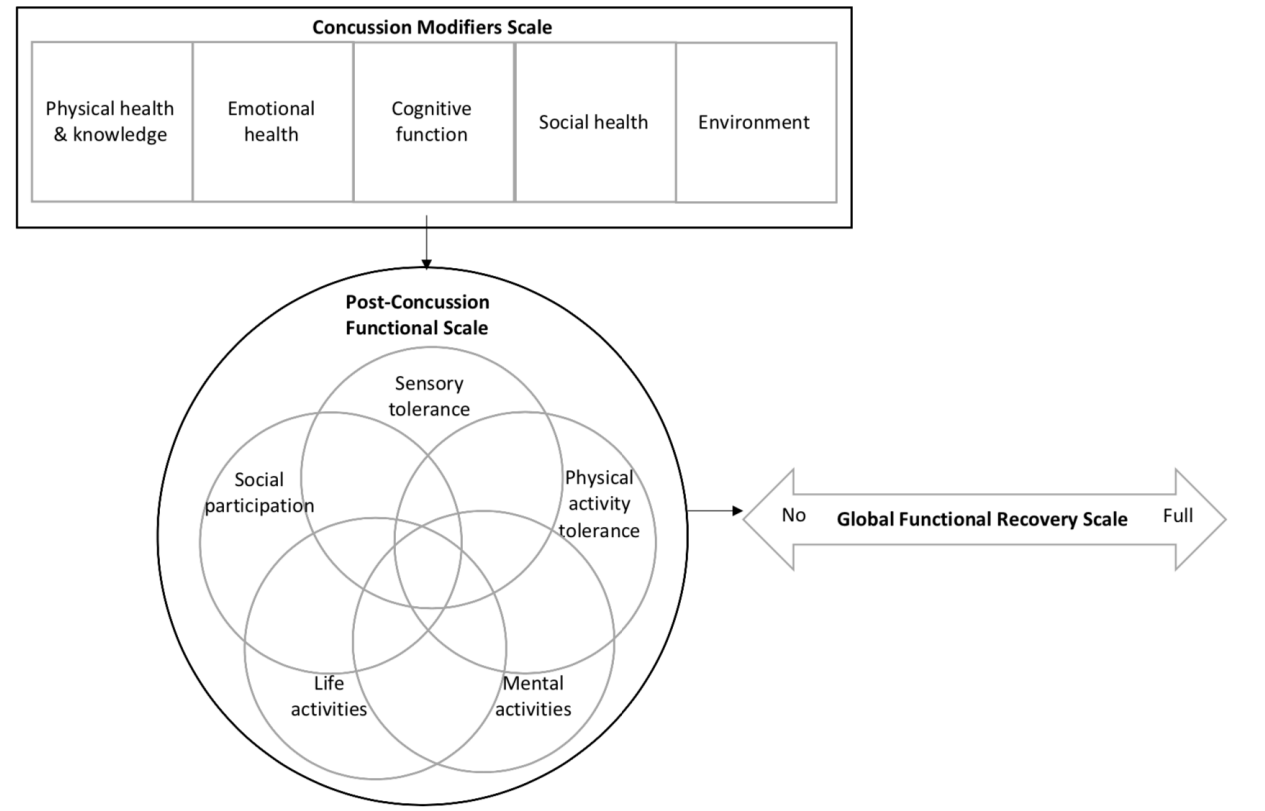


Figure 5.1. Conceptual model of functioning post-concussion
The large rectangle represents the Concussion Modifiers Scale. Each subscale is represented by one of the smaller squares inside the rectangle. Each factor can influence functioning independently or in combination with other factors. The large circle represents the Post-Concussion Functional Scale. Each subscale is represented by one of the smaller circles inside the large circle. Functional activities within each subscale may be related to other functional subscales. The large bidirectional arrow indicates functional recovery may be experienced on a scale from “no recovery” to “full recovery”, as measured by the Global Functional Recovery Scale.

These factors likely work concurrently and over time. For example, Eliyahu (2016) showed that providing patients with education regarding typical concussion symptoms, prognosis, and expected recovery time can reduce the anxiety over acute symptoms, and reduce the risk of PPCS (23).

Furthermore, the conceptual model illustrates concussion modifiers. The relationship between these individual, social, environmental factors, and level of

functioning is likely interactive. For example, lack of support with the return to work process may reduce a person's capacity to perform activities of daily living in the household, causing tension within family relationships, and influencing mental health.

In our model, these modifiers act on a continuum from being a big problem to a big help. Being a problem is characterized by lowering a person's capacity to perform individual activities and participate in society. In contrast, being a help is characterized by increasing capacity. Capacity encapsulates how *long* one can do an activity before symptoms start or worsen, how *many* activities can be performed in a typical day before symptoms start or worsen, and how *long* would it typically take for symptoms to go back to usual once aggravated. Increasing capacity is critical to improving functional status, and represents a key measure of recovery post-concussion. Based on our model, interventions, modifications, accommodations, and education targeted directly at concussion modifiers have the potential to increase capacity post-concussion.

Phases II and III-Item development and refinement.

Drawing from our concepts, codes, and conceptual model, we compiled an initial pool of 145 items that we categorized by concept into 11 different bins. These would later form the foundation for each subscale of the questionnaire. Following the winnowing process, we reduced the number of items by approximately two-thirds to 50 representative items (Table 5.1).

Table 5.1. Concepts and item counts

Concept	Binned Items	Items remaining after winnowing	Item counts after 1st round of cognitive interviews	Final item count
Activities and Participation				
Learning and applying knowledge	12	3	3	3
General tasks and demands	7	2	2	3
Communication	6	2	2	3
Mobility	11	2	4	4
Self-care	1	0	0	1
Domestic life	6	5	6	5
Interpersonal interactions and relationships	6	1	1	1
Major life areas	5	2	2	3
Community, social and civic life	7	6	6	6
Environmental Factors				
Products and technology	7	4	3	3
Natural environment and human-made changes to environment	4	3	3	3
Support and relationships	10	4	3	3
Attitudes	10	2	1	1
Services, systems and policies	14	3	2	2
Personal Factors				
Not coded	8	2	2	2
Not covered				
Not coded	31	9	9	10
Total	**145**	**50**	**49**	**53**

Note: Concepts categorized under ICF chapters.

Using the decision process outlined above, problem categories identified in all 13 cognitive interviews were compared. As a result, instructions were clarified, response options were modified, recall period was determined, additional examples were provided for some of the items, and item content was revised. Following the 4th round of interviewing (N=13), consensus was reached on all items, and so we considered content coverage to be saturated and scale design to be acceptable. Four rounds of interviewing have also been found to be sufficient to detect and address major problems

(24). As a result of cognitive interviewing, 18 questions were reworded, the PCFS response time was modified, 2 instructions were added for clarification, 1 question was deleted, 3 questions merged as examples into a single question, and multiple formatting changes (e.g. bolding text, use of italics, enlarged font size) were made during round 1. During round 2, concepts from categorized bins were added as examples to 20 questions, the response scale was further modified, 1 question was added to the CMS, and 1 duplicate question was deleted. The 3rd round resulted in 1 question being modified in both the PCFS and CMS, clarification of 2 headings, the addition of 1 question to the CMS and a helpline resource, and 1 duplicate concept deleted. The 4th and final round resulted in the clarification of 1 subheading and 1 instruction, and the use of italics and bolding. At this stage, revisions were minor, and we deemed the final draft of the questionnaire to be complete.

Tables 5.2 and 5.3 provide a sample of items and formatting that were revised, added, or deleted based on participant feedback.

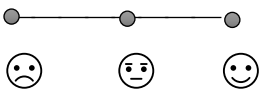
Table 5.2. Examples of revisions to items or additions of items after cognitive interviews

Scale	**Item stem (before cognitive interviews)**	**Reason for revision**	**Final item**
Post-Concussion Functional Scale	Please tell us how much of a problem the following activities are as a result of your concussion	Original instruction assumed there was a problem. Rewritten with neutral wording.	*Revised:* How much do the following things affect your functional recovery?
	Exercise	Clarify intent of question.	*Revised:* Physical Activity Tolerance
	Bright lights (e.g. sunshine, fluorescent lights)	Persons with concussion described problems all levels of lighting, not just bright lights.	*Revised:* See lights (e.g. sun, fluorescent, headlights)
	Read (e.g. book email, text)	Persons with concussion wanted to differentiate between cognitive and visual difficulties with reading.	*Revised:* Read words on paper (e.g. book, newspaper) *Added:* Look at screen (e.g. TV, tablet, computer)
	…	A range of intensities better captures level of physical activity tolerance	*Added:* Vigorous physical activity
	…	Improve ability of persons with concussion to self-report problems.	*Added:* Other difficulties.
Concussion Modifier scale	…	Need to capture subtleties of household administration.	*Added:* Your ability to manage the household (e.g. schedule chores, plan activities, arrange childcare)

Table 5.2. continued.

Scale	Item stem (before cognitive interviews)	Reason for revision	Final item
	…	Provide resources to individuals who need help.	*Added:* If you are struggling with the above, the following resource may be helpful: Ontario Brain Injury Association www.obia.ca 1-800-263-5404
	Legal claim over injury	Content too similar to question about insurance claims	*Deleted*
Global Functional Recovery Scale	Overall, how functional are you compared to before your concussion?	Question lacks clarity.	*Revised:* Overall, how much do you feel you've recovered from your concussion?
	…	Clinician feedback suggests recovery expectations of persons with concussion important to explore resiliency and self-efficacy.	*Added:* How much do you expect to recover?

Table 5.3. Examples of revisions to formatting after cognitive interviews

Scale	Initial version	Reason for revision	Final version
Post-Concussion Functional Scale	Less than 5 min | 5-15 min |15-30 min | 30-45 min | 45-60 min | More than 60 min | n/a	Too many response options; participants preferred longer time intervals; persons with concussion stressed need to identify immediate onset of symptoms (0-5 min).	*Revision:* 0-5 min | 6-30 min | 31-60 min | 61-90 min | 90-120 min | n/a
Concussion Modifier Scale	|——————|	Clarify response options.	

Finally, the retained items were collated to form the *CO*ncussion *RE*covery *Q*uestionnaire (CORE-Q) (Appendix 1), which contains a total of 53 items split into 3 separate scales that are complimentary: Post-Concussion Functional Scale (PCFS),

Concussion Modifiers Scale (CMS) and Global Functional Recovery Scale (GFRS). This was done to reflect the differences in underlying constructs behind each scale, differences in rating scales, and to keep each scale a manageable length to complete given higher levels of fatigue post-concussion. The corresponding ICF codes for the item on each scale are presented for reference to permit future comparisons with other measures (Tables 5.4-5.6).

Table 5.4. Post-Concussion Functional Scale domains and items linked to the International Classification of Functioning, Disability and Health (ICF) codes

Domain	Item	ICF code
Sensory tolerance	**Over the *past week*, on average, *how long* can you do the following activities before your symptoms *start or worsen*?**	
1	Look at a screen	d360 Using communication devices; d110 Watching; e125 Products and technology for communication
2	Use smartphone	d360 Using communication devices; d166 Reading; d170 Writing
3	See lights	d110 Watching; e240 Light
4	Listen to noises	d115 Listening; e250 Sound
Physical activity tolerance	**Over the *past week*, on average, *how long* can you do the following activities before your symptoms *start or worsen*?**	
5	Light physical activity	d430 Carrying; d450 Walking; d455 Moving around
6	Moderate physical activity	d4 Mobility
7	Vigorous physical activity	d920 Recreation and leisure
Mental activities	**Over the *past week*, on average, *how long* can you do the following activities before your symptoms *start or worsen*?**	
8	Learn something new	d1 Learning and applying knowledge
9	Read words on paper	d166 Reading
10	Write ideas down	d170 Writing
11	Do more than one task at a time	d220 Multi-tasking; d160 Focusing attention
12	Converse with 1 person	d350 Conversation
13	Converse with a group of people	d350 Conversation; d160 Focusing attention
Life activities	**Over the *past week*, on average, *how long* can you do the following activities before your symptoms *start or worsen*?**	
14	Take care of yourself	d5 Self-care
15	Take care of others	d660 Assisting others
16	Take care of pets	d650 Caring for household objects
17	Prepare meals	d630 Preparing meals
18	Do housework	d640 Doing housework
19	Drive	d475 Driving
20	Ride public transit	d470 Using transportation
21	Grocery shop	d620 Acquisition of goods and services
22	Do your usual work/school tasks	d850 Remunerative employment; d830 Higher education; d160 Focusing attention
23	Other difficulties	
24	How many of the activities above can you do in a typical day before your symptoms *start* or *worsen*?	Not covered (capacity question)
25	If you did too much in a day and your symptoms got worse, how long would it typically take for symptoms to go back to usual?	Not covered (capacity question)
Social participation	**Over the *past week*, on average, *how long* can you do the following activities before your symptoms *start or worsen*?**	
26	Go to a restaurant	d920 Recreation and leisure
27	Go to the movies	d920 Recreation and leisure
28	Go to a small social event	d9 Community, social and civic life
29	Go to a large social event	d9 Community, social and civic life
30	Attend a crowded event	d9 Community, social and civic life

Table 5.5. Concussion Modifier Scale domains and items linked to the International Classification of Functioning, Disability and Health (ICF) codes

Domain	Item	ICF code
Health and knowledge	**How much do the following things affect your functional recovery?**	
31	Your physical health	Not defined (physical health)
32	Your current knowledge of concussion	Personal factor
Emotional health	**How much do the following things affect your functional recovery?**	
33	Your mental health	Not defined (mental health)
34	Accepting your new sense of self since your concussion	Personal factor
35	Your ability to cope with day-to-day frustrations	d240 Handling stress and other psychological demands
36	Your ability to cope with a stressful event	d240 Handling stress and other psychological demands
Cognitive health	**How much do the following things affect your functional recovery?**	
37	Your ability to manage the household	d230 Carrying out daily routine
38	Your ability to work or study at your previous level of quality	d850 Remunerative employment; d830 Higher education
39	Your ability to manage money and personal finances	d865 Complex economic transactions
Social health	**How much do the following things affect your functional recovery?**	
40	Relationships with family and friends	d760 Family relationships; d770 Intimate relationships; d750 Informal social relationships
41	Attitude of family and friends	e410 Attitudes of immediate family; e415 attitudes of extended family; e420 Attitudes of friends
42	Using social media	e125 Products and technology for communication
Environment	**How much do the following things affect your functional recovery?**	
43	Having enough money to meet your needs	e165 Assets
44	Access to healthcare	e580 Health services, systems and policies
45	Level of support you're getting at home	e310 Support from immediate family; e315 Support from extended family
46	Level of support from friends, colleagues, support groups	e320 Support from friends; e325 Support from acquaintances, peers, colleagues, neighbours and community
47	Level of support at work or school	e330 Support from people in authority
48	Feeling safe	Not covered
49	Spending time outdoors	e2 Natural environment and human-made changes to environment
50	Dealing with insurance company	e570 Social security services, systems and policies

Table 5.6. Global Functional Recovery Scale linked to the International Classification of Functioning, Disability and Health (ICF) codes

Domain	Item	ICF code
51	Overall, how much do you feel like you've recovered from your concussion?	Not covered
52	How much do you expect to recover?	Not covered
53	What are the 3 biggest issues for you?	Not covered

Scale 1: Post-Concussion Functional Scale.

The PCFS consists of 30 questions in 5 subscales corresponding to the domains of sensory tolerance, physical activity tolerance, mental activities, life activities, and social participation.

Scale 2: Concussion Modifiers Scale.

The CMS contains 20 questions across 5 domains that correspond to physical health, emotional health, cognitive health, social health, and environment.

Scale 3: Global Functional Recovery Scale.

The GFRS is a global measure of recovery following concussion. Two general questions ask persons with concussion how they feel compared to pre-injury and how much they expect to recover. Additionally, persons with concussion are asked to indicate their 3 biggest issues.

Response options.

Scale 1: Post-Concussion Functional Scale.

We had initially considered rating the severity of problem with each item on a five-point Likert scale to be consistent with the generic qualifiers used to classify ICF codes (13). During qualitative interviews with persons with concussion, it became clear that the use of percentages would present an unnecessary cognitive burden, contribute to poor reliability due to discrepancies in interpreting subjective responses, and yield less

clinically useful information. Other studies have shown reliability using ICF qualifiers to be low, and recommended adopting qualifiers best suited to clinical use (25). All participants in this study strongly endorsed an objective measure of functioning over more subjective options such as level of severity, satisfaction with abilities, or ranking. Moreover, since the purpose of the PCFS is to assess functioning in order to measure recovery and make treatment recommendations, a time-based approach seemed most appropriate. As such, we arrived at the decision to measure functional capacity as time before the onset or worsening of symptoms with the view to using individualized responses to create planning and pacing treatment recommendations.

Based on feedback from persons with concussion and clinicians, we decided that dividing response options into 30-minute increments would capture clinically significant changes in function. Dividing response options into smaller increments of time would likely present more cognitive burden on respondents, and provide little additional clinical benefit. Furthermore, we selected 'more than 2 hours' as the maximum time for a response category, since most functional tasks can reasonably be expected to be performed within this time-frame. Persons with concussion may continue to experience disability beyond 2 hours; however, the findings of this study and our clinical experience suggest this represents a minority of persons with concussion with higher levels of functioning often not seen in rehabilitation. Persons with concussion felt it was also important to capture whether symptom burden was high almost immediately, which would reflect an inability to perform functional activities in a meaningful time-frame. As such, we selected 6 response levels, including unable, 1-30 minutes, 31-60 minutes, 61-90 minutes, 91-120 minutes, and more than 2 hours. An additional 'have not tried'

category was included in case one of the response options does not apply to the respondent. This is consistent with the literature, which recommends between 4 and 6 response categories as being ideal to adequately assess an item (16,26). Two additional functional capacity questions were included to measure how many activities can be done in a typical day before symptoms start or worse, and how long it takes to recover once symptoms have been aggravated.

Importantly, we chose to measure time in minutes before the onset or worsening of symptoms. This decision aligns with the definition of the ICF qualifier *capacity*, which describes what a person can do in a standardized environment. This is in contrast to the qualifier *performance*, which describes what a person does in his or her current environment. This distinction acknowledges the challenges of a person with concussion in their actual day-to-day-experiences (capacity) versus the highest level of functioning they could achieve with modifications and accommodations to their environment (performance).

Scale 2: Concussion Modifiers Scale.

Concussion modifiers are measured on a 4-point ordinal scale with descriptive and graphic anchor points at both ends. This was done for a more relevant assignment of response options, as 'time to symptom onset' was deemed an appropriate response choice to measure ability to perform functional activities, but not to measure concussion modifiers (e.g. knowledge of concussion does not precipitate symptoms after a given time period). Response choices are presented on a continuum including "big problem", "small problem", "small help" and "big help". Boxes are placed at each of the 4 points on the scale for the respondent to check in lieu of numerical values. The resultant

clean look of the questionnaire was endorsed during cognitive interviews as enabling respondents to complete the questionnaire by reducing the visual burden associated with repeated rows of numbers.

Scale 3: Global Functional Recovery Scale.

Pre-injury comparison and expectation for recovery is measured using a single assessment numerical evaluation (SANE). Descriptive and numeric anchors are placed at the ends, with 0 representing “No function” and 100% representing “Full function”. Respondents are asked to select the numeric value on the scale that best reflects the extent of their recovery. The SANE was chosen for its low burden on respondents and clinicians, ease of administration and scoring, and ability to be administered verbally. Thigpen et al. (2018) found that the SANE demonstrated good test-retest reliability ($ICC_{2,1}$=0.84, SEM=3.8) and was well correlated with other measures of functioning across different treatment groups ($ICC_{2,1}$=0.72; SEM=5.2 to $ICC_{2,1}$=0.85; SEM=3.4) (27).

Recall time frame.

We adopted a one-week reporting period to minimize the risk of recall bias and respondent burden, while balancing sufficient time for the person to provide a reliable estimate of the impact of persistent symptoms on functioning. A shorter recall period of 24-hours commonly seen in concussion symptom questionnaires was considered too short to capture items that may not occur on a daily basis (28,29). Similarly, we considered the 30-day recall period of the World Health Organization Disability Assessment Schedule too vulnerable to memory problems with recollection and too long to measure progressive changes in functioning over time (30).

Scoring.

Each scale is scored separately. No total CORE-Q score is generated as each scale is based on different underlying constructs and differences in rating scales.

Scale 1: Post-Concussion Functional Scale.

Each response time category is assigned a point value, where an "unable" response to an item is assigned 0 points; "1-30 minutes", 1 point; "31-60 minutes", 2 points; "61-90 minutes", 3 points; "91-120 minutes", 4 points, and "more than 2 hours", 5 points. Any "have not tried" response is recorded as a missing value. An overall mean score and domain-specific mean scores are calculated. The mean is used instead of a summed scale to deal with missing values associated with an "have not tried" response.

Domain-specific mean scores are calculated by adding the point values for all items and dividing the score by the number of *completed* item responses within each domain, producing scores out of 5. For example, in the "Mental activities" domain, the summed score would normally be divided by 6. If one "Mental activities" item is missing or scored as "have not tried", the summed score would be divided by 5. The overall mean score is calculated by adding all domain-specific mean scores together and dividing by the number of domains (normally 5). This value is then transformed to a score out of 100 by multiplying by 20. This is done to make the score easier to compare with other measures scored on a 0-100 score. Higher scores indicate better functional recovery. Differences between domain scores highlight areas of greater concern.

Responses may also be interpreted clinically within each domain as the actual time before symptom onset or worsening in minutes. The highest response value for each item is recorded. For example, a response of "1-30 minutes" would be recorded

as “30 minutes”. Future electronic versions of the scale will include a slider bar for more precise measurement. Repeat measures over time may be graphed to demonstrate objective changes in recovery that are easily interpretable to the person with concussion and allow concrete recommendations for planning and pacing.

Scale 2: Concussion Modifiers Scale.

An overall mean score and domain-specific scores are calculated as described for the PCFS. Higher scores represent higher levels of support for recovery. Again, responses may be clinically interpreted to identify person-oriented issues that may be addressed through education, intervention, accommodations, or modifications to support recovery and improve outcomes.

Scale 3: Global Functional Recovery Scale.

Scores on the GFRS numeric recovery rating scale range from 0-100. The number that the respondent circles to indicate their pre-injury comparison and expectation for recovery is recorded as a simple score. A higher score represents higher functional recovery. There is no mean score for the GFRS.

5.5 Discussion

Defining and measuring limitations in functioning post-concussion has been challenging due to the lack of outcome measure that accurately reflects those issues that are most relevant to adults with PPCS. To address this need for a concussion-specific measure of functional status, we developed the CORE-Q using international recommendations for the development of patient-reported outcome measures (19,20,31). It is designed to be used for monitoring outcomes in clinical practice and in clinical intervention trials.

While the primary purpose of the conceptual model was to guide the development of the item sets for the CORE-Q, it also has clinical relevance. Some concepts included in the model, for example physical activity tolerance, physical health, and mental health, are commonly assessed with outcome measures such as the Buffalo Concussion Treadmill Test , Dizziness Handicap Inventory, and Patient Health Questionnaire-9 (32–34). While results of these tests may provide the clinician with direction to treatment, a person's overall functioning may be limited in other ways as illustrated by the conceptual model. For example, a person's physical activity tolerance may be the most important problem to treat from the clinician's perspective, since it reduces overall physical capacity. However, it is easy to imagine how attitude of friends and family may also have a large impact on the person's functioning if they were to invalidate her symptoms, contributing to symptoms of depression. We encourage clinicians, thus, to consider the person as a whole, as well as in the context of their environment. As such, the conceptual model we have presented moves our understanding away from a narrow focus on PPCS, and towards a broader biopsychosocial understanding of the overall impact of concussion on functioning. This will allow us to consider how modifications, accommodations, interventions, and education targeted at concussion modifiers that may influence outcomes (Table 5.7).

Table 5.7. Example of modifications, accommodations, interventions, and educations directed towards barriers to recovery identified by the CMS can influence functioning reported on the PCFS.

Barrier identified on the CMS	Modification/ accommodation/ intervention/education	Functional improvement as measured on the PCFS
Q.32. Your current knowledge of concussion	Educate concussed individual regarding self-management techniques such as planning and pacing.	Improved physical activity tolerance by alternating physical and mental tasks to stay below symptom threshold.
Q.33. Your mental health	Provide prognosis and expected recovery; normalize symptoms; medication; cognitive behavioural therapy	Increased resilience to participate in functional activities.
Q.38. Your ability to work or study at previous level or quality	Recommendations for return to work modifications (e.g. flexible work hours, reduced screen time, quiet work area, independent work)	Minimize symptom triggers associated with screen time or large group meetings.
Q.44. Access to healthcare	Recommend clinicians with expertise in concussion; telehealth.	Global impact on function through individualized treatment; improved access to care and decreased symptoms associated with traveling long distances for care if using telehealth.
Q.45. Level of support you're getting at home	Educate family members as to a person's needs and encourage areas they can help at home (e.g. delegate domestic duties to others)	Reduce symptom triggers associated with meal preparation, housework, or childcare duties).

Abbreviations: CMS, Concussion Modifiers Scale; PCFS, Post-Concussion Functional Scale

Coding the CORE-Q to the ICF allows the questionnaire to be compared to the ICF Core Sets for Traumatic Brain Injury, as well as other outcome measures developed from or linked to the ICF. This will help clinicians, researchers, and persons with concussion to select the most appropriate functional status measure for their needs by providing greater insight into the content coverage of different instruments (35). Instruments can, thus, be compared with respect to both the breadth and depth of concepts covered (35).

Future large-scale testing is planned to assess the psychometric properties of the CORE-Q with adults following concussion. Test-retest reliability will be assessed over a

1-week period, using a minimum kappa statistic of ≥0.7 as an acceptable measure of reliability. Construct validation will be performed against other generic measures of functioning such as the WHODAS-2 (30). Spearman's rank correlation will be used to assess the strength of association between scores. Future studies are planned to assess responsiveness to change and to determine the minimal clinically important difference of each scale in a post-concussion population.

Clinical implications.

Once validated, we expect the PCFS could be used clinically on initial assessment to screen for level of functioning in major life areas and as a repeat measure to monitor recovery over time. The novel assessment approach of measuring time before onset or worsening of symptoms provides clinically relevant information to determine readiness to return to various work, educational, or home-based activities, set clinical goals, and facilitate individualized planning and pacing strategies.

The goal of the CMS is to facilitate improved assessment of the environmental, personal, and social consequences of concussion. We envision that the CMS would be administered on initial assessment as part of a comprehensive battery of tests to provide clinically important information about factors that may modify recovery. This information would provide a useful guide as to how barriers could best be modified or accommodated through education or intervention to improve outcomes.

Finally, the GFRS is designed to provide a global overview of the pre-injury comparisons and expectations for recovery from the person's perspective. The first question provides a clinical snapshot of recovery that will likely prove most useful as a quick assessment of recovery trajectories in a busy clinical practice, and as a secondary

end point in clinical trials where functional status isn't the main focus. Additionally, responses to recovery expectations give an indication whether the person's resilience needs to be probed further. Finally, persons are given the opportunity to identify their 3 biggest issues, thereby opening the door to improved person-clinician collaboration and goal setting, which forms the cornerstone of person-centered care.

Overall, while clinicians and persons with concussion both agreed that the questionnaire was lengthy when completed in its entirety, the overwhelming consensus was that there was clinically valuable information to be gained from completing all sections that justified the length of the questionnaire. Concussion participants unanimously reported that the CORE-Q tapped into issues of high relevance to them that wasn't addressed in other questionnaires.

Limitations.

Phase I development of conceptual model.

Our conceptual model presents a graphical representation of functional recovery as the result of interactions between functional capacity in major life activities, and various social and environmental factors. Interactions and relationships between these concepts may exist which did not come out in our data and are, thus, not depicted here. These differences would likely be unique to each person due to the complex nature of interactions. While associations and causal links between concepts may be explored in future studies, the model is only intended to guide the user into considering the person within the context of their environment, and not quantify the relationships.

Phase II item generation.

Due to study timelines and available resources, only one researcher (JV) developed the initial pool of items, categorized them into bins, analyzed results of the cognitive interviews, and made the revision decisions. Thus, we cannot reject the possibility of confirmation bias in the generation and refinement of questionnaire items. Consensus on content coverage and scale design by both persons with concussion and clinicians during multiple rounds of cognitive interviews, however, minimizes this bias.

Phase III item refinement.

Although persons with concussion in this study were purposively selected to represent a variety of different personal and injury characteristics, our sample population tended to have a university level education. This may, however, not be a serious limitation, as problem items encountered by more highly educated persons would fairly certainly have been problematic most users, and subject to revision and evaluation during subsequent cognitive interviews (36). Additionally, due to time and resource constraints, we recruited this subsample of participants from our qualitative study for our cognitive interviews. Introducing new participants who were naïve to the CORE-Q may have better informed the utility of the measure. This sample was predominantly female, therefore the questions may be more reflective of women's concerns. Finally, the PCFS and CMS were developed around the themes of functioning, barriers and facilitators, and capacity identified in our previous qualitative work. Although these constructs align with the components of Activities and Participation, and Contextual Factors within the ICF, not having done a confirmatory factor analysis limits the interpretation or delineation of the constructs underlying each scale.

A strength of this study is the robust collection of qualitative data to elicit concepts that are unique and relevant to persons with concussion and clinicians; investigators with expertise in concussion and qualitative methodologies; and the use of rigorous methods for outcome measure development. Data saturation during the concept elicitation phase and cognitive interviews phase provides evidence of strong content validation.

5.6 Conclusion

The CORE-Q is a new standardized measure of functional status for persons with concussion, that considers functioning from a biopsychosocial perspective. It is intended to be used to evaluate functional capacity and factors that modify recovery in clinical practice and intervention trials. The novel time-based approach to measuring functioning introduced here is expected to facilitate clinical decisions regarding readiness to return to work, school, or home-based activities, facilitate individualized planning and pacing strategies, and measure recovery over time. Knowledge of concussion modifiers will allow clinicians to address barriers to functioning through modifications, accommodations, interventions, and education. Further studies are necessary to provide evidence of the measure's psychometric properties.

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Disclosure of interest.

The authors report no commercial conflict of interest. JV has a clinical practice in orthopaedic and sports physiotherapy involving persons with concussion. SM has a clinical practice in physical medicine and rehabilitation, and was the project team leader

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CONCUSSION RECOVERY QUESTIONNAIRE (CORE-Q)

These questions ask about things that might be hard for you to do since your concussion.

Do you need help filling out this questionnaire? **Yes** **No**

POST-CONCUSSION FUNCTIONAL SCREEN

Over the *past week*, on average, *how long* can you do the following activities before your symptoms *start or worsen*? This means in the way you did before injury, without any strategies to help you.

Some examples of symptoms include headache, physical or mental fatigue, dizziness, nausea, irritability, anger, clumsiness or fogginess. You may also have other symptoms not listed here.

For each question, check *one* box only.

	Number of minutes before symptoms start or worsen						
Sensory Tolerance	**unable**	**1-30 min**	**31-60 min**	**61-90 min**	**91-120 min**	**More than 2 hours**	**Have not tried**
1. Look at a screen (e.g. TV, computer games, video)	☐	☐	☐	☐	☐	☐	☐
2. Use the Internet (e.g. text, email, surf Internet, scrolling)	☐	☐	☐	☐	☐	☐	☐
3. Tolerate lights (e.g. sun, fluorescent, headlights)	☐	☐	☐	☐	☐	☐	☐
4. Tolerate noises (e.g. traffic, pitches, music)	☐	☐	☐	☐	☐	☐	☐

Physical Activity Tolerance	**unable**	**1-30 min**	**31-60 min**	**61-90 min**	**91-120 min**	**More than 2 hours**	**Have not tried**
5. Easy physical activity (e.g. climb stairs, walk, carry groceries)	☐	☐	☐	☐	☐	☐	☐
6. Medium physical activity (e.g. dance, vacuum, rake leaves)	☐	☐	☐	☐	☐	☐	☐
7. Hard physical activity (e.g. run, bike, swim, go to gym)	☐	☐	☐	☐	☐	☐	☐

Mental Activities	**unable**	**1-30 min**	**31-60 min**	**61-90 min**	**91-120 min**	**More than 2 hours**	**Have not tried**
8. Concentrate (e.g. focus on tasks; learn new things)	☐	☐	☐	☐	☐	☐	☐
9. Read (e.g. letters, books, newspapers)	☐	☐	☐	☐	☐	☐	☐
10. Write down ideas (e.g. letters, filling in forms)	☐	☐	☐	☐	☐	☐	☐
11. Do more than one thing at a time (e.g. listen to radio and do a chore)	☐	☐	☐	☐	☐	☐	☐
12. Have a conversation with one person (e.g. talk with a friend, order a meal)	☐	☐	☐	☐	☐	☐	☐
13. Follow group conversation (e.g. many people speaking)	☐	☐	☐	☐	☐	☐	☐

Please continue to the next page…

Independence	Number of minutes before symptoms start or worsen: unable	1-30 min	31-60 min	61-90 min	91-120 min	More than 2 hours	n/a
14. Care for yourself (e.g. bathe, dress, groom)	☐	☐	☐	☐	☐	☐	☐
15. Care for others (e.g. feed, dress, bathe)	☐	☐	☐	☐	☐	☐	☐
16. Care for pets (e.g. walk dog, feed, groom)	☐	☐	☐	☐	☐	☐	☐
17. Prepare meals (e.g. cook, chop vegetables)	☐	☐	☐	☐	☐	☐	☐
18. Do housework (e.g. dishes, clean, laundry)	☐	☐	☐	☐	☐	☐	☐
19. Drive (e.g. car)	☐	☐	☐	☐	☐	☐	☐
20. Ride public transit (e.g. bus, subway, train)	☐	☐	☐	☐	☐	☐	☐
21. Go shopping (e.g. grocery store or mall)	☐	☐	☐	☐	☐	☐	☐
22. Do your usual work (e.g. paid or unpaid work, school)	☐	☐	☐	☐	☐	☐	☐
23. Other difficulties _____	☐	☐	☐	☐	☐	☐	☐

24. *How many* of *all* the activities above can you do in a typical day before symptoms start or worsen?

_____

25. If you did too much in a day and your symptoms got worse, *how long* would it typically take for symptoms to go back to usual (e.g. minutes, hours, day)?

_____

Social Participation	Number of minutes before symptoms start or worsen: unable	1-30 min	31-60 min	61-90 min	91-120 min	More than 2 hours	n/a
26. Eat in a restaurant (e.g. lunch or dinner)	☐	☐	☐	☐	☐	☐	☐
27. Go to the movies (e.g. sound, picture)	☐	☐	☐	☐	☐	☐	☐
28. Go to a small social activity (e.g. family dinner, coffee with friends)	☐	☐	☐	☐	☐	☐	☐
29. Go to a large social activity (e.g. club, party, religious activity)	☐	☐	☐	☐	☐	☐	☐
30. Be in a crowded place (e.g. sporting event, concert, theatre)	☐	☐	☐	☐	☐	☐	☐

Please continue to the next page…

CONCUSSION MODIFIERS SCALE (CMS)

How much do the following things affect your functional recovery?

Big problem	Small problem	Small help	Big help	n/a
☐	☐	☐	☐	☐
☹			☺	
This has a serious impact on my day-to-day life	This causes some problems, but they are manageable	This makes my life a little easier	This allows me to do my day-to-day activities	This doesn't apply to me

Please *circle* your response to each question.

How does your physical health and knowledge affect your recovery?

31. Your physical health (e.g. other injuries, pre-existing conditions, illnesses, diseases)

Big problem	Small problem	Small help	Big help	n/a
☐	☐	☐	☐	☐
☹			☺	

32. How much you know about concussion (e.g. prognosis, types of treatment, where to get help)

Big problem	Small problem	Small help	Big help	n/a
☐	☐	☐	☐	☐
☹			☺	

How does your emotional health affect your recovery?

33. Your mental health (e.g. feeling down, depression, anxiety, self-harm)

Big problem	Small problem	Small help	Big help	n/a
☐	☐	☐	☐	☐
☹			☺	

34. Being okay with your new sense of self since your concussion (e.g. social role; how you've changed)

Big problem	Small problem	Small help	Big help	n/a
☐	☐	☐	☐	☐
☹			☺	

35. Being able to cope with day-to-day frustrations (e.g. losing keys, stepping in a puddle)

Big problem	Small problem	Small help	Big help	n/a
☐	☐	☐	☐	☐
☹			☺	

36. Being able to cope with a stressful event (e.g. travel, job loss, financial stress, moving, trauma)

Big problem	Small problem	Small help	Big help	n/a
☐	☐	☐	☐	☐
☹			☺	

If you are struggling with the above, the following resource may be helpful:
Ontario Brain Injury Association www.obia.ca 1-800-263-5404

Please continue to the next page…

How does your cognitive function affect your recovery?

37. Being able to run the household (e.g. schedule chores, organize house, plan activities)

Big problem	Small problem	Small help	Big help	n/a
☐	☐	☐	☐	☐
☹			☺	

38. Being able to work or study at previous workload or quality (e.g. skill level, problem-solve, make decisions)

Big problem	Small problem	Small help	Big help	n/a
☐	☐	☐	☐	☐
☹			☺	

39. Being able to manage money and personal finances (e.g. banking, pay bills, track expenses)

Big problem	Small problem	Small help	Big help	n/a
☐	☐	☐	☐	☐
☹			☺	

How does your social health affect your recovery?

40. Relationships with family and friends (e.g. strain on family, connection with friends, isolation, social life)

Big problem	Small problem	Small help	Big help	n/a
☐	☐	☐	☐	☐
☹			☺	

41. Attitude of family and friends (e.g. understand your injury; judge you; believe in you; accept you)

Big problem	Small problem	Small help	Big help	n/a
☐	☐	☐	☐	☐
☹			☺	

42. Using social media (e.g. Facebook, Twitter, Instagram, Snapchat)

Big problem	Small problem	Small help	Big help	n/a
☐	☐	☐	☐	☐
☹			☺	

How does your environment affect your recovery?

43. Having enough money to meet your needs (e.g. afford food, housing, childcare)

Big problem	Small problem	Small help	Big help	n/a
☐	☐	☐	☐	☐
☹			☺	

44. Access to healthcare (e.g. knowledgeable clinicians, treatment costs, waitlists, distance)

Big problem	Small problem	Small help	Big help	n/a
☐	☐	☐	☐	☐
☹			☺	

Please continue to the next page…

45. How much support you get at home (e.g. live alone, accommodating your needs; helping out; independence)

Big problem	Small problem	Small help	Big help	n/a
☐	☐	☐	☐	☐
☹			☺	

46. How much support you get from friends, colleagues, support groups (e.g. helping out; emotional support)

Big problem	Small problem	Small help	Big help	n/a
☐	☐	☐	☐	☐
☹			☺	

47. How much support you get at work or school (e.g. accommodating your needs; flexibility; return to work help)

Big problem	Small problem	Small help	Big help	n/a
☐	☐	☐	☐	☐
☹			☺	

48. Feeling safe (e.g. physical or emotional abuse)

Big problem	Small problem	Small help	Big help	n/a
☐	☐	☐	☐	☐
☹			☺	

49. Being outdoors (e.g. in nature, walking, weather)

Big problem	Small problem	Small help	Big help	n/a
☐	☐	☐	☐	☐
☹			☺	

50. Dealing with insurance company (e.g. filing claim, being denied, emotional impact)

Big problem	Small problem	Small help	Big help	n/a
☐	☐	☐	☐	☐
☹			☺	

GLOBAL FUNCTIONAL RECOVERY SCALE

Please *circle* your response.

51. Overall, how much do you *feel like* you've recovered from your concussion?

No function 0 10 20 30 40 50 60 70 80 90 Full function 100%

52. How much do you *expect* to recover?

No function 0 10 20 30 40 50 60 70 80 90 Full function 100%

53. What are the 3 biggest issues for you?

1. _____
2. _____
3. _____

This completes the questionnaire. Thank you.

Chapter 6: Content comparison of a new concussion-specific measure of functional status, the CORE-Q, with existing outcome measures used in concussion research

The work in this chapter has been submitted for publication in *Clinical Rehabilitation*.

Ethics approval was not required for this study.

6.1 Introduction

Although most persons recover within the first few weeks following concussion, 10—15% will go on to develop persistent post-concussion symptoms (PPCS) (1,2). PPCS can have a significant impact across the broad domains of physical, emotional, social, and cognitive functioning (3). The cause of PPCS is incompletely understood, and thought to be influenced by a wide variety of psychosocial factors (4). Outcomes in concussion research often use generic measures of health status (e.g. Short-Form Health Survey-36), quality of life (e.g. Quality of Life after Brain Injury), symptoms (e.g. Rivermead Post-Concussion Symptoms Questionnaire), or emotional well-being (e.g. Patient Health Questionnaire-9) (5–8) rather than the construct of functioning. The primary goal of rehabilitation should be to maximize functioning through remediation of functional impairments, overcoming activity limitations, addressing participation restrictions, or removing environmental and personal barriers to functioning. One of the challenges clinicians and researchers face in evaluating the efficacy of rehabilitation is the large number of available outcome measures to choose from. Yet despite the growing body of literature on concussion, no research has been undertaken to determine the suitability of existing instruments in measuring functioning post-concussion, perhaps due to the difference in concepts, scales, and items in different instruments (9). In order to make valid assumptions about recovery, assurance is needed that an outcome measure is measuring what it intends to measure. The International Classification of Functioning, Disability and Health (ICF) has been proposed as a means of comparing content within health status instruments (10).

Description of ICF.

Developed by the World Health Organization (WHO), the International Classification of Functioning, Disability and Health (ICF) is a standardized framework that uses alphanumeric codes to describe health and health-related factors (11). The ICF is a complex, hierarchical taxonomy in a nested structure comprised of two parts, *Functioning and Disability*, and *Contextual Factors*. *Functioning and Disability* contains 3 components: body functions (b), that define physiological and psychological functions; *Body Structures* (s), that describe anatomical parts of the body; and *Activities and Participation* (d) that comprises the full range of life areas. *Contextual Factors* are external factors that influence *Functioning and Disability*, and include the components of *Environmental Factors* (e) and *Personal Factors*. *Environmental Factors* (e) describe the physical, social and attitudinal environment in which people live and conduct their lives. *Personal Factors* include details that are not part of the health condition, such as age, gender and coping style. Personal factors have not yet been classified into detailed categories. The ICF is recognized as having value in guiding the comparison and selection of health status measures in TBI (12).

Standardized rules have been established to link health status outcome measures to the ICF for means of comparing content (9). These linking rules have been used to describe problems in functioning in persons across all severities of TBI based on the ICF (12–16). Several studies have been published comparing content of various outcome measures to the ICF (17). Participation outcome measures used in TBI have previously been compared to the ICF Core Sets for TBI (Comprehensive and Brief) (18).

This study adds to the literature by comparing existing measures of functioning and contextual factors used in clinical trials of concussion to a new concussion-specific measure of functional status, the Concussion Recovery Questionnaire (CORE-Q) in order to identify any gaps in existing outcome measures that would establish the need for the new measure.

Development of the CORE-Q.

Content for the CORE-Q was derived from focus-group interviews with persons with concussion and semi-structured interviews with clinician with expertise in concussion (manuscript in preparation for publication). Relevant issues identified in the interviews were transformed into a conceptual model of functioning. These concepts were incorporated as questionnaire items or examples, using person-centred language and phrases wherever possible, to maintain the content validity of the measure. A detailed description of the concepts elicited from the qualitative study is being prepared separately.

The CORE-Q was designed as a multi-dimensional self-report outcome measure to assess level of function and concussion modifiers in adults with PPCS. The questionnaire is comprised of 53 questions across 3 scales, the Post-Concussion Functional Scale (PCFS), the Concussion Modifier Scale (CMS), and the Global Functional Recovery Scale (GFRS). The PCFS assesses functional capacity in terms of how long a person can perform various activities before the onset of symptoms in blocks of 30-minute increments. Clinically, it may be used to screen for level of functional independence in order to monitor recovery on a repeated basis, set clinical goals, and facilitate planning and pacing strategies. In the CMS, persons with

concussion rate the impact of environmental and personal factors on their recovery on a 4-point scale from ‘big problem’ to ‘big help’. Responses are evaluated qualitatively to identify user-oriented issues that could be modified or accommodated through education or intervention to improve outcomes. Finally, the GFRS provides a global overview of recovery and expectations for recovery from the person’s perspective. It provides a clinical snapshot of recovery.

Aim of the study.

To compare the content of existing outcome measures used in clinical trials of concussion with concepts contained in a new concussion-specific outcome measure, the CORE-Q.

Specific objectives:

1. Identify outcome measures used in clinical trials of concussion.
2. Classify the content of these measures using the ICF as a conceptual framework.
3. Compare the extent to which these measures cover the content of the CORE-Q.
4. Appraise the reliability, validity, and responsiveness of outcome measures containing a minimum of 70% of the concepts contained in the CORE-Q.

6.2 Methods

We conducted a systematic literature search to identify all clinical trials conducted on adults with concussion. Selected studies were reviewed, and relevant outcome measures were identified and classified with respect to their underlying construct. Outcome measures that were retained were examined for content by extracting meaningful concepts and linking them to the ICF using established linking rules (9,10).

Content coverage was established by comparing the ICF categories contained within existing measures to the CORE-Q.

Identification of outcome measures.

Our systematic review was performed and reported in accordance with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines (19). In accordance with the guidelines, our systematic review was registered with the International Prospective Register of Systematic Reviews (PROSPERO) on 27 September 2017 and was last updated on 2 November 2018 (registration number CRD42017075588). We searched four electronic databases between January 1, 2008 and August 24, 2018, including Medline (OVID), Embase (OVID), PsycINFO (OVID), ClinicalTrials.gov (https://clinicaltrials.gov). The timeframe was chosen to coincide with the widely adopted guidelines on concussion management introduced at the 3rd International Conference on Concussion in Sport in 2008. Search terms included “Brain Injuries”, “Brain Concussion”, and “Post-Concussion Syndrome” AND clinical trial (Table 1). Keywords were matched to database-specific subject headings. We limited the searched to full-length, peer-reviewed journals in English describing English-language health status instruments. Only clinical trials of concussion with adults aged 18-65 years conducted one month or more post-injury were considered. We excluded studies that exclusively measured outcomes within the first month post-injury; studies that examined the experience or characteristics of caregivers or families of people with traumatic brain injury; neuroradiological measurements; and neurophysiological measurements.

Table 6.1. Search strategy for Medline (OVID)

1. Brain Concussion/
2. Post-Concussion Syndrome/
3. traumatic brain injury*.mp.
4. mild head injury*.mp.
5. concussion*.mp.
6. tbi.mp.
7. mtbi.mp.
8. Post-concussion syndrome*.mp.
9. Postconcussion syndrome*.mp.
10. Post-concussion symptom*.mp
11. Postconcussion symptom*.mp
12. Brain Injuries, Traumatic/
13. 1 or 2 or 3 or 4 or 5 or 6 or 7 or 8 or 9 or 10 or 11 or 12
14. limit 13 to (humans and yr="2008-Current" and clinical trial, all)

All outcome measures contained within the included studies were extracted and examined for content. A key conceptual decision was made to select outcome measures based on the construct the instrument was intending to capture, as some items contained within questionnaires do not reflect the underlying construct(20). Where ambiguity existed, the item content and instructions for administration of the questionnaire were examined to assist in the classification. Outcome measures were selected if they assessed the components of *Activities and Participation*, *Environmental Factors*, or *Personal Factors*. If an outcome measure assessed multiple components, they were retained, described as 'multi-dimensional', and the relevant concepts linked. Since the domains of *Body Function* and *Body Structure* were not represented within the questionnaire, outcome measures intending to evaluate these constructs exclusively were removed from further examination. This represents a departure from previous linking studies (9,10,21) that compared the content of individual questionnaire items.

We felt the decision to classify instruments based on construct better aligned with the purpose of this study to compare the content of existing outcome measures with the CORE-Q in order to establish the need for a new questionnaire. The full list of included questionnaires was then cross-referenced against the National Institute of Neurological Disorders and Stroke list of recommended Sport-Related Concussion Common Data Elements to ensure relevant questionnaires were not missed. Additionally, the extracted questionnaires were then checked against the core set of outcome measures recommended for use in traumatic brain injury (TBI) research by the interagency TBI Outcome Workgroup (22). In cases where two instruments were identified with one being an adapted version (e.g. MOS Short Form-36 Health Survey and Veterans Rand 36 Item Health Survey), the most updated version was retained and classified to represent current considerations. Additionally, when both short-form versions and the original scales were represented (e.g. Patient Health Questionnaire-2, Patient Health Questionnaire-4, and Patient Health Questionnaire-9), the short-form versions were considered duplicates, and only the longer version was considered for classification to ensure complete coverage of concepts. For reasons of practicality, one researcher (JV) assessed the eligibility of studies and identified the outcome measures.

Linking of content contained within the outcome measures.

Content was examined by first identifying meaningful concepts and then linking those concepts to the ICF codes previously assigned to each item of the new questionnaire. Items were linked to 2nd-level categories of the ICF both for the stem of the question and for examples used to describe the concept. Any terms related to recall period (e.g. over the past week) and qualifiers such as ‘how often’, ‘difficulty’, or ‘importance’ were not

considered meaningful concepts, and therefore not linked to the ICF (Table 2). For reasons of feasibility, linking was performed by one researcher (JV) according to established linking rules (9,10).

Table 6.2. Example of linking questions to the ICF category and code

Question	Meaningful Concept	ICF Category
*In the past 30 days, how much difficulty did you have in:** Starting and maintaining a conversation? (WHODAS 2) (23)	Conversation	D350 Conversation

WHODAS 2, World Health Organization Disability Assessment Schedule II
*Note: text in italics is the qualifier for the question and was not classified as a meaningful concept.

Content comparison between existing outcome measures and the CORE-Q.

To determine the proportion of CORE-Q concepts contained within existing outcome measures, we calculated the number and percentage of 2nd-level ICF categories that mapped onto each scale of the CORE-Q. The extent of overlap between measures was compared to establish whether concepts contained within existing measures adequately represented the CORE-Q. The higher the number of concepts that mapped onto the CORE-Q, the higher number of questions that evaluated similar content. Evidence that the CORE-Q contained concepts not evaluated by any other measure was considered necessary to justify the introduction of a new self-report measure of functional status into the plethora of existing measures.

Assessment of psychometric properties.

Our intent was to assess the reliability, validity, and responsiveness of existing outcome measures in a concussion population for those measures that contained at least 70% of

concepts contained within the CORE-Q as a complete measure, and at a scale level, consistent with the methodology of Gorecki et al. (2014) (24). However, we lowered our cutoff for content comparison to 70% to be more inclusive. According to our findings, none of the included outcome measures met our *a priori* threshold for content validity, therefore, we did not appraise the psychometric properties of any of the measures.

6.3 Results

Our search yielded 3557 references for screening. After removal of duplicates (n=360) and articles not meeting eligibility criteria (n=2993), 204 studies were assessed for full-text eligibility. Of these, a total of 169 studies were included (Figure 6.1).

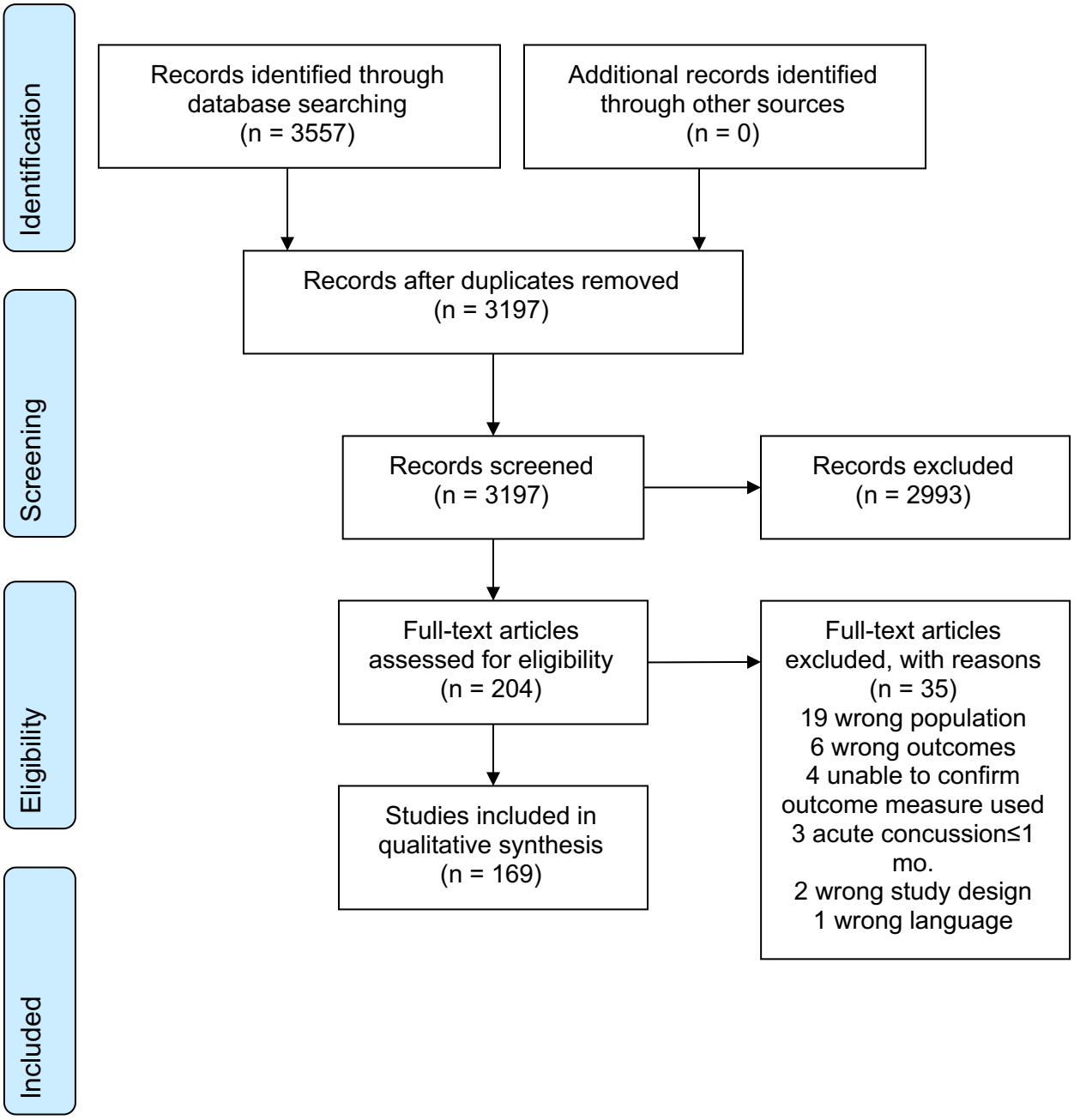

Figure 6.1. Study identification PRISMA flow diagram. PRISMA, Preferred Reporting Items for Systematic Reviews and Meta-Analysis.

Included outcome measures.

These 169 studies contained 196 unique outcome measures. No additional questionnaires were identified through examination of the National Institute of Neurological Diseases and Stroke Common Data Elements or the TBI Outcome Workgroup recommendations. We removed outcome measures (n= 120/196) that addressed constructs not covered by the CORE-Q (e.g. quality of life), were not self-report measures (e.g. clinician-rated), computer adaptive tests (e.g. non-fixed length questionnaires from large item banks), were used in the wrong population (e.g. pediatric), or that we were unable to locate. Eighteen outcome measures were excluded because they were adapted versions of longer outcome measures that met our inclusion criteria. A final set of 58 outcome measures used in 169 trials was retained for content comparison. The 58 measures were fairly evenly distributed between multidimensional measures of Functioning and Disability (n= 19/58; 33%), Activities and Participation (n=17/58; 29%), and Personal Factors (n=16/58; 28%). A limited number of Environmental (n=4/58; 7%) and Other (n=2/58; 3%) measures were included (Figure 6.2).

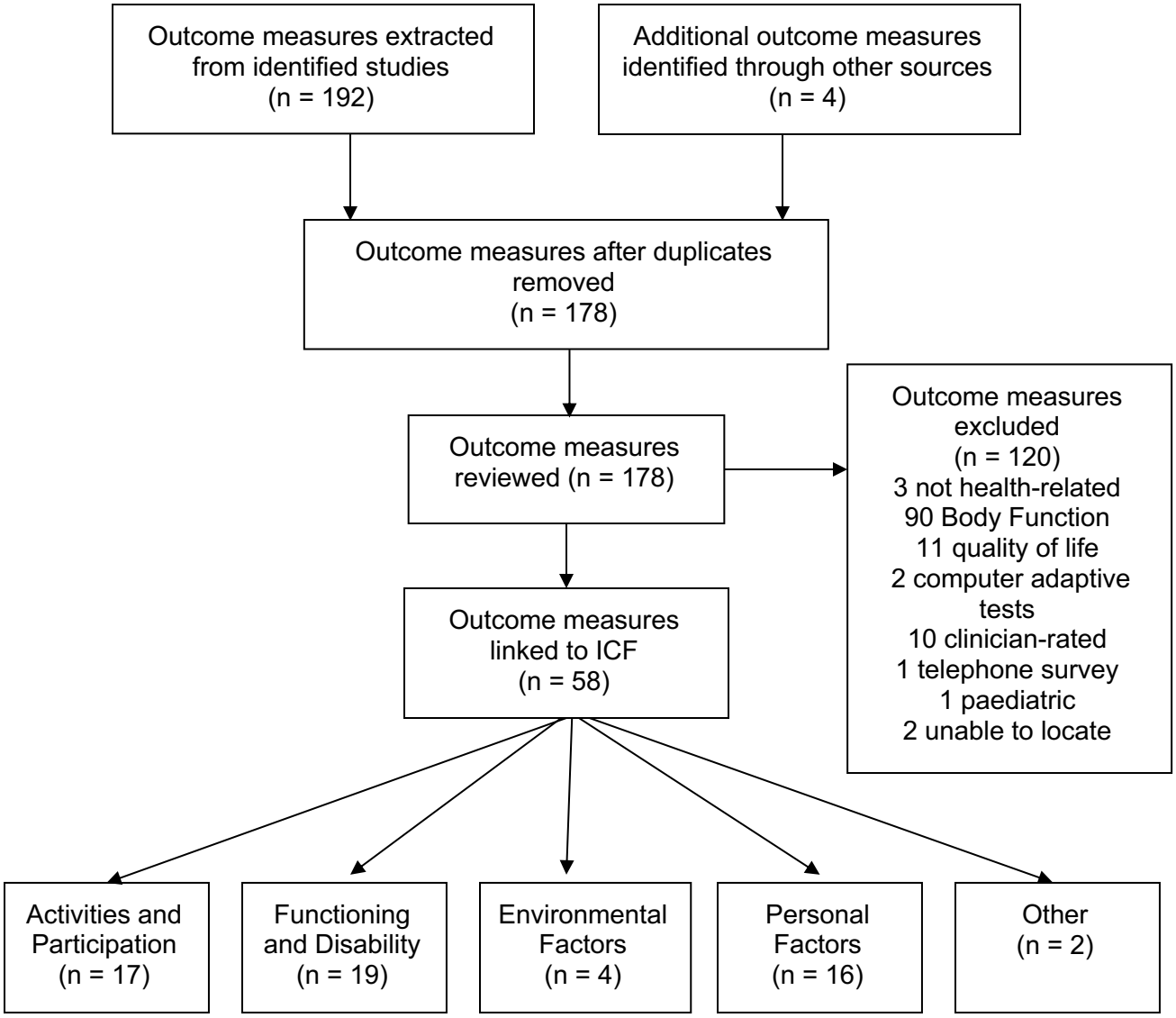

Figure 6.2. Selection of outcome measures

When considering the use of the measures in the 169 trials, both the Craig Handicap Assessment and Reporting Technique-Short Form (CHART-SF) and the Community Integration Questionnaire were the most often used measures of Activities and Participation (n=7/169; 4%). The most commonly used measure of Functioning and Disability was the Post-Traumatic Stress Disorder Checklist-5, which was used in 58/169 (34%) of the studies. Of the rarely used measures of Environmental Factors, the Interpersonal Support Evaluation List-Short Form and UCLA Loneliness Scale were both used most frequently in 2/169 (1%) studies each. The Connor Davidson Resilience Scale-10 was the most frequently used Personal Factors measure (n=6/169;4%), and the Patient Global Impression of Change was the most often used Other measure (n=2/169; 1%). Of the 58 measures included, over half were used in only one study (n= 31/58; 53%) (Tables 6.3-6.5).

Table 6.3. Use of Activity and Participation measures (n=19) in the 169 included studies

Outcome measure		Rank order	Frequency of use across all included studies, N=169 (%)
CHART-SF	Craig Handicap Assessment and Reporting Technique-Short Form	1	7 (4)
CIQ	Community Integration Questionnaire	1	7 (4)
MIDAS	Migraine Disability Assessment Scale	2	6 (4)
ABCs	Activities-Specific Balance Confidence Scale	3	5 (3)
PART-O	Participation Assessment with Recombined Tools-Objective	4	4 (2)
DCCASP	Daily Cognitive-Communication and Sleep Profile	5	3 (2)
SPRS	Sydney Psychological Reintegration	5	3 (2)
WHODAS-2	Scale	6	2 (1)
	World Health Organization Disability		
RRTWS	Schedule-2	6	2 (1)
LTCQ	Readiness for Return to Work Scale	6	2 (1)
FAD	La Trobe Communication	6	2 (1)
CRIS	Questionnaire	6	2 (1)
	Family Assessment Device		
BRIQ	Community Reintegration for Service Members	7	1 (1)
LAM	Behavioural Responses to Illness Questionnaire-short form	7	1 (1)
OGQ	LAM Employment Absence and	7	1 (1)
TBI-WIS	Productivity Scale	7	1 (1)
VVAS	Occupational Gaps Questionnaire	7	1 (1)
	TBI Work Instability Scale		
	Visual Vertigo Analog Scale		

Note. Blank spaces mean no entry in this field.
Percentages do not add up to 100, as several studies used more than one outcome measure. Percentages are rounded up to the nearest whole percent.

Table 6.4. Use of Functioning and Disability measures (n=19) in the 169 included studies

Outcome measure		Rank order	Frequency of use across all included studies, N=169 (%)
PCL-5	Post-Traumatic Stress Disorder Checklist-5	1	58 (34)
SF-36	Short-Form Health Survey-36	2	22 (13)
SDS	Sheehan Disability Scale	3	4 (2)
FAQ	Functional Activities Questionnaire	4	2 (1)
GHQ	General Health Questionnaire	4	2 (1)
NRI	Neurobehavioural Rating Scale	4	2 (1)
TFI	Tinnitus Functional Index	4	2 (1)
COPSOQ	Copenhagen Psychosocial	5	1 (1)
EBIQ	Questionnaire	5	1 (1)
FSE	European Brain Injury Questionnaire	5	1 (1)
MOS-CFS	Functional Status Examination	5	1 (1)
NDI	Medical Outcomes Study-Cognitive Functioning Scale	5	1 (1)
NFI-D	Neck Disability Index	5	1 (1)
PSFS	Neurobehavioural Functioning Inventory-Depression	5	1 (1)
PTSS-10	Patient Specific Functional Scale	5	1 (1)
RHIFUQ	Post-Traumatic Stress Syndrome-10	5	1 (1)
SIQR	Rivermead Head Injury Follow-Up Questionnaire	5	1 (1)
THI	Revised Symptom Impact	5	1 (1)
WI-8	Questionnaire	5	1 (1)
	Tinnitus Handicap Inventory		
	Whiteley-8 Index		

Note. Blank spaces mean no entry in this field.
Percentages do not add up to 100, as several studies used more than one outcome measure.

Table 6.5. Use of Environmental Factors (n=4), Personal Factors (n=16), and Other measures (n=2) in the 169 included studies

Outcome measure		Rank order	Frequency of use across all included studies, N= 169 (%)
Environmental Factors			
ISEL-SF	Interpersonal Support Evaluation List-SF	1	2 (1)
UCLA LS	UCLA Loneliness Scale	1	2 (1)
PAAS	Personal Advocacy Activity Scale	2	1 (1)
SSEHS	Social Support for Exercise Habits Scale	2	1 (1)
Personal Factors			
CD-RISC	Connor Davidson Resilience Scale-10	1	6 (4)
IPQ-R	Illness Perception Questionnaire Revised	2	5 (3)
GSE	General Self Efficacy Scale	2	5 (3)
UCL	Utrecht Coping List	3	4 (2)
CES	Combat Exposure Scale	4	3 (2)
SE-SMS	Self-Efficacy for Symptom Management Scale	4	3 (2)
BIPQ	Brief Illness Perception Questionnaire	5	1 (1)
DRRI-2	Deployed Risk and Resilience Inventory	5	1 (1)
LEC	Life Events Checklist	5	1 (1)
MHLCS	Multidimensional Health Locus of Control Scale	5	1 (1)
PSDQ	Physical Self-Description Questionnaire	5	1 (1)
RSA	Resilience Scale for Adults	5	1 (1)
SAS	Self-Advocacy Scale	5	1 (1)
SCS	Self-Compassion Scale	5	1 (1)
SEQ	Self-Efficacy Questionnaire	5	1 (1)
TBI-SEQ	TBI Self-Efficacy Questionnaire	5	1 (1)
Other			
PGIC	Patient Global Impression of Change	1	2 (1)
IIP-64	Inventory of Interpersonal Problems-64	2	1 (1)

Note. Blank spaces mean no entry in this field.
Percentages do not add up to 100, as several studies used more than one outcome measure.
TBI, traumatic brain injury

Content comparison between existing outcome measures and the CORE-Q.

Concussion Recovery Questionnaire.

A total of 57 of the 58 concepts contained within the CORE-Q were identified across all the included outcome measures, although there was a wide variation in which concepts were represented within each individual measure. No one ICF category was contained in all of the identified outcomes measures. The measure with the broadest overall content coverage was the CRIS-Extent of Participation Scale (CRIS-EPS), which was linked to 23 (40%) different ICF categories within the CORE-Q. On a scale level, the CRIS-EPS covered 15 (48%) of all items on the PCFS, 9 (32%) of all items on the CMS, and none of the items on the GFRS (0%). Seven measures (Neurobehavioural Functioning Inventory-Depression, Post-Traumatic Stress Disorder Checklist-5, Patient Specific Functional Scale, Post-Traumatic Stress Syndrome-10, Combat Exposure Scale, Utrecht Coping List, and Patient Global Impression of Change) provided the least coverage of the CORE-Q with only one ICF category each (2%). The number of items and proportion of ICF categories contained across each scale is summarized in Tables 6.6 through 6.8.

Table 6.6. Number of items and percentage of ICF categories contained within measures of Activities and Participation (n= 17) that can be linked to the CORE-Q.

	ABCs	BRIQ	CHART-SF	CIQ	CRIS-EPS	DCCAS-P	FAD	LAM	LTCQ	MIDAS	OGQ	PART-O	RRTWS	SPRS	TBI-WIS	VVAS	WHO-DAS 2
Number of items	16	20	32	15	50	209	53	4	30	7	28	24	22	12	23	9	36
ICF categories used for linkage																	
CORE-Q (n)	5	8	22	12	23	10	10	2	2	8	17	15	3	10	2	6	22
(%, N=58)	9	14	38	21	40	17	17	3	3	14	29	26	5	17	3	10	38
Per Scale																	
PCFS (n)	5	1	17	8	15	8	3	1	2	8	14	13	1	8	1	6	16
(%, N=31)	16	3	55	26	48	26	10	3	6	26	45	42	3	26	3	19	52
CMS (n)		7	6	7	9	2	7	1			4	5	1	5	1		9
(%, N=28)		25	21	25	32	7	25	4			14	18	4	18	4		32
GFRS (n)													1				
(%, N=3)													33				

Blank spaces mean no entry in this field.
N = total number of ICF categories within the CORE-Q and each of the respective subscales.
n = number of concepts within each outcome measure that can be linked to one of the ICF categories within the CORE-Q and each of the individual subscales.
Percentages are calculated as the number of concepts within each outcome measure that can be linked to one of the ICF categories contained within the CORE-Q, and each of the individual subscales.
Total number of ICF categories used for linkage in CORE-Q does not equal the sum of categories within each CORE-Q subscale, since 4 categories are represented in both the PCFS and CMS.
ABCs, Activities Specific Balance Confidence Scale; *BRIQ*, Behavioural Responses to Illness Questionnaire; *CHART*, Craig Handicap Assessment and Reporting Technique-Short Form; *CIQ*, Community Integration Questionnaire; *CMS*, Concussion Modifiers Scale; *CORE-Q*, Concussion Recovery Questionnaire; *CRIS-EPS*, Community Reintegration for Service Members-Extent of Participation Scale; *DCCASP*, Daily Cognitive-Communication and Sleep Profile; *FAD*, Family Assessment Device; *GFRS*, Global Functional Recovery Scale; *ICF*, International Classification of Functioning, Disability and Health; *LAM*, LAM Employment Absence and Productivity Scale; *LTCQ*, La Trobe Communication Questionnaire; *MIDAS*, Migraine Disability Assessment Scale; *OGQ*, Occupational Gaps Questionnaire; *PART-O*, Participation Assessment with Recombined Tools-Objective; *PCFS*, Post-Concussion Functional Scale; *RRTWS*, Readiness for Return to Work Scale; *SPRS*, Sydney Psychological Reintegration Scale; *TBI-WIS*, TBI Work Instability Scale; *VVAS*, Visual Vertigo Analog Scale; *WHODAS 2*, World Health Organization Disability Scale.

Table 6.7. Number of items and percentage of ICF categories contained within measures of Functioning and Disability (n= 19) that can be linked to the CORE-Q.

	COPSOQ	EBIQ	FAQ	FSE	GHQ	MOS-CFS	NDI	NFI-D	NRS	PCL-5	PSFS	PTSS-10	RHIFUQ	SDS	SF-36	SIQR	TFI	THI	WI-8
Number of items	44	67	10	39	12	6	10	13	29	20	7	10	14	3	36	21	25	25	14
ICF categories used for linkage																			
CORE-Q (n)	7	14	5	15	4	4	7	1	2	1	1	1	10	4	10	10	10	14	2
(%, N=58)	12	24	9	26	7	7	12	2	3	2	2	2	17	7	17	17	17	24	3
Per CORE-Q Scale																			
PCFS (n)	2	6	4	12	1	2	7	1	1	1	1		7	3	8	9	6	8	1
(%, N=31)	6	19	13	39	3	6	23	3	3	3	3		23	10	26	29	19	26	3
CMS (n)	6	8	1	4	3	2	1		1			1	4	3	3	1	6	7	1
(%, N=28)	21	29	4	14	11	7	4		4			4	14	11	11	4	21	25	4
GFRS (n)																			
(% , N=3)																			

Blank spaces mean no entry in this field.
N = total number of ICF categories within the CORE-Q and each of the respective subscales.
n = number of concepts within each outcome measure that can be linked to one of the ICF categories within the CORE-Q and each of the individual subscales.
Percentages are calculated as the number of concepts within each outcome measure that can be linked to one of the ICF categories contained within the CORE-Q, and each of the individual subscales.
Total number of ICF categories used for linkage in CORE-Q does not equal the sum of categories within each CORE-Q subscale, since 4 categories are represented in both the PCFS and CMS.
CSM, Concussion Modifiers Scale; *COPSOQ*, Copenhagen Psychosocial Questionnaire; *CORE-Q*, Concussion Recovery Questionnaire; *EBIQ*, European Brain Injury Questionnaire; *FAQ*, Functional Activities Questionnaire; *FSE*, Functional Status Examination; *GFRS*, Global Functional Recovery Scale; *GHQ*, General Health Questionnaire; *ICF*, International Classification of Functioning, Disability and Health; *MOS-CFS*, Medical Outcomes Study Cognitive Functioning Scale; *NDI*, Neck Disability Index; *NFI-D*, Neurobehavioural Functioning Inventory-Depression; *NRS*, Neurobehavioural Rating Scale; *PCFS*, Post-Concussion Functional Scale; *PCL-5*, Post-Traumatic Stress Disorder Checklist-5; *PSFS*, Patient Specific Functional Scale; PSS, Post-Traumatic Symptom Scale; *PTSS-10*, Post-Traumatic Stress Syndrome-10; *RHIFUQ*, Rivermead Head Injury Follow-Up Questionnaire; *SDS*, Sheehan Disability Scale; *SF-36*, Short-Form Health Survey-36; *SIQR*, Revised Symptom Impact Questionnaire; *TFI*, Tinnitus Functional Index; *THI*, Tinnitus Handicap Inventory; WI-8, Whiteley-8 Index

Table 6.8. Number of items and percentage of ICF categories contained within measures of Environmental Factors (n=4), Personal Factors (n= 16) and Other measures (n=2) that can be linked to the CORE-Q.

	Environmental Factors				Personal Factors																Other	
	ISEL-SF	PAAS	SSEHS	UCLA -LS	BIPQ	CD-RISC	CES	DRRI-2	GSE	IPQ-R	LEC	MHLCS	PSDQ	RSA	SAS	SCS	SEQ	SE-SMS	TBI-SEQ	UCL	IIP-64	PGIC
Number of items	12	12	13	20	9	10	7	30	10	31	17	23	47	33	8	26	13	13	6	26	26	2
ICF categories used for linkage																						
CORE-Q (n)	7	4	4	7	5	3	1	2	2	6	8	8	3	10	2		3	11	10	1	3	1
(%, N=58)	12	7	7	12	9	5	2	3	3	10	14	14	5	17	3		5	19	17	2	5	2
Per CORE-Q Scale																						
PCFS (n)	4	1	1	1		1					4		1	1			2	6	3			
(%, N=31)	13	3	3	3		3					13		3	3			6	19	10			
CMS (n)	4	3	3	6	4	2	1	2	2	5	4	8	2	9	2		2	5	7	1	3	
(%, N=28)	14	11	11	21	14	7	4	7	7	18	14	29	7	32	7		7	18	25	4	11	
GFRS (n)					1					1												1
(%, N=3)					33					33												33

Blank spaces mean no entry in this field.
N = total number of ICF categories within the CORE-Q and each of the respective subscales.
n = number of concepts within each outcome measure that can be linked to one of the ICF categories within the CORE-Q and each of the individual subscales.
Percentages are calculated as the number of concepts within each outcome measure that can be linked to one of the ICF categories contained within the CORE-Q, and each of the individual subscales.
Total number of ICF categories used for linkage in CORE-Q does not equal the sum of categories within each CORE-Q subscale, since 4 categories are represented in both the PCFS and CMS.
BIPQ, Brief Illness Perception Questionnaire; *CD-RISC*, Connor Davidson Resilience Scale-10; *CES*, Combat Exposure Scale; *CMS*, Concussion Modifiers Scale; *CORE-Q*, Concussion Recovery Questionnaire; *DRRI-2*, Deployed Risk and Resilience Inventory (Combat Experiences and Postbattle Experiences Scales); *GFRS*, Global Functional Recovery Scale; *GSE*, General Self Efficacy Scale; *ICF*, International Classification of

Functioning, Disability and Health; *IIP-64*, Inventory of Interpersonal Problems-64; *IPQ-R*, Illness Perception Questionnaire Revised; *ISEL-SF*, Interpersonal Support Evaluation List-Short Form; *LEC*, Life Events Checklist; *MHLCS*, Multidimensional Health Locus of Control Scale; *PAAS*, Personal Advocacy Activity Scale; *PCFS,* Post-Concussion Functional Scale; *PGIC*, Patient Global Impression of Change; *PSDQ*, Physical Self-Description Questionnaire; *RSA*, Resilience Scale for Adults; *SAS*, Self-Advocacy Scale; *SCS*, Self-Compassion Scale; *SEQ*, Self-Efficacy Questionnaire; *SE-SMS*, Self-Efficacy for Symptom Management Scale; *SSEHS,* Social Support for Exercise Habits Scale; *TBI-SEQ*, Traumatic Brain Injury Self-Efficacy Questionnaire; *UCL*, Utrecht Coping List; *UCLA-LS*, UCLA Loneliness Scale

Post-Concussion Functional Scale.

The CHART-SF covered the broadest range of categories within the PCFS with 55% (n=17). The ICF category most frequently linked to the PCFS was *d920 Recreation and leisure*, which was contained in almost half (n=26, 45%) of the outcome measures. Two (3%) ICF categories from the PCFS were represented separately in only one of the included measures. The category *d220 Multi-tasking* was only contained within the CRIS-EPS, and *d115 Listening* was only contained within the CHART-SF. One (2%) ICF category from the PCFS (i.e. *nc, capacity*) was not included in any of the other outcome measures.

Concussion Modifiers Scale.

The CRIS-EPS, World Health Organization Disability Schedule-2, and Resilience Scale for Adults shared the highest coverage of categories contained within the CMS with 32% (n=9) each. Within the CMS, *d850 Remunerative employment* was most frequently assessed in 22 (38%) of the measures. One (2%) ICF category from the CMS was found in only one outcome measure, namely *e125 Products and technology for communication* was only contained within the Occupations Gaps Questionnaire. One (2%) ICF category from the CMS (i.e. *Social security services, systems and policies*) was not included in any of the other outcome measures.

Global Recovery Scale.

Only 3 measures contained a category within the GFRS, with one apiece (33%). The item *nc, expectation of recovery* was the ICF category from the GFRS included in the most measures (n=3, 5%). One item (2%) from the GFRS was contained within only one of the included measures, the Patient Global Impression of Change. Tables 6.9-

6.11 summarize the frequency of different ICF categories from each measure that were linked to each of the scales within the CORE-Q.

Table 6.9. Frequency of ICF categories contained within measures of Activities and Participation (n= 17) that are linked to the CORE-Q.

ICF Code	2nd-level ICF Category	CORE-Q	ABCs	BRIQ	CHART-SF	CIQ	CRIS-EPS	DCCASP	FAD	LAM	LTCQ	MIDAS	OGQ	PART-O	RRTWS	SPRS	TBI-WIS	VVAS	WHODAS2
Post-Concussion Functional Scale																			
d110	Watching	2			1		1	1											
d115	Listening	1			1														
d155	Acquiring new skills	1								1	1							2	1
d160	Focusing attention	3					1	1											1
d166	Reading	2					3	1					2						
d170	Writing	2			1								1						
d220	Multi-tasking	1					2												
d350	Conversation	2			1		1	2	4		6					1			1
d360	Using communication devices	2			1			1					1	1				1	
d4	Mobility	1			2														1
d430	Lifting and carrying objects	1	1																
d450	Walking	1	7				1											1	1
d455	Moving around	1	1				1												1
d470	Using transportation	1			3		1						1	1		1			
d475	Driving	1					2						1	1		1		1	
d5	Self-care	1														1			3
d620	Acquisition of goods and services	1			1	2						1	1	1					3
d630	Preparing meals	1			1	1							1	1					3
d640	Doing housework	1	1		2	1			1			1	2	1					3
d650	Caring for household objects	1			1		1					1	2	1					3
d660	Assisting others	1			2							1	1	1					
d830	Higher education	1			1	1						2		2		2			2
d850	Remunerative employment	1			1	1	2					2	1	1	22	3	9		4
d855	Nonremunerative employment	1			1	1							1	1		1			1
d9	Community, social and civic life	3					1							4					
d920	Recreation and leisure	3	2	1	2	2	2		1			1		4		2		1	2
e125	Products and technology for communication	1			1		1	1				1	1						

Table 6.9. continued

ICF Code	2nd-level ICF Category	CORE-Q	ABCs	BRIQ	CHART-SF	CIQ	CRIS-EPS	DCCASP	FAD	LAM	LTCQ	MIDAS	OGQ	PART-O	RRTWS	SPRS	TBI-WIS	VVAS	WHODAS2
e240	Light	1																1	
e250	Sound	1						1											
nc	Capacity	2																	
nc	Other difficulties	1						1											3
Total frequency of categories		43	12	1	23	9	20	9	6	1	7	10	16	20	22	12	9	7	33
Proportion of PCFS categories (%)		100	28	2	53	21	47	21	14	2	16	23	37	47	51	28	21	16	77
Concussion Modifiers Scale																			
d175	Solving problems	1							2										1
d177	Making decisions	1			1				2										
d230	Carrying out daily routine	1		1		1		1											
d240	Handling stress	2					2												
d750	Informal social relationships	1		1	1	1	3							1					2
d760	Family relationships	1		1	3	1	2		1							1			1
d770	Intimate relationships	1		1	2	1	3		1					2		2			1
d830	Higher education	1			1	1						2		2		2			2
d850	Remunerative employment	1			1	1	2					2	1	1	22	3	9		4
d855	Nonremunerative employment	1			1	1							1	1		1			1
d865	Complex economic transactions	1				1	2						1	1					
e125	Products and technology for communication	1			1		1	1				1	1						
e165	Assets	1					1		1										1
e2	Natural environment and human-made changes to environment	1																	
e310	Support from immediate family	1																	
e315	Support from extended family	1																	
e320	Support from friends	1																	
e325	Support from peers/community	1																	
e330	Support from people in authority	1																	
e410	Attitudes of immediate family	1		1					1										

Table 6.9. continued

ICF Code	2nd-level ICF Category	CORE-Q	ABCs	BRIQ	CHART-SF	CIQ	CRIS-EPS	DCCASP	FAD	LAM	LTCQ	MIDAS	OGQ	PART-O	RRTWS	SPRS	TBI-WIS	VVAS	WHODAS2
e415	Attitudes of extended family	1		1					1										
e420	Attitudes of friends	1		1															
e570	Social security services, systems and policies	1																	
e580	Health services, systems and policies	1					2												
pf	Knowledge of concussion	2																	
nd	Physical health	1													1				1
nd	Mental health	1					1	1		1									
nc	Feeling safe	1																	
Total frequency of categories		30	0	7	11	8	18	3	9	1	0	5	4	8	23	9	9	0	14
Proportion of CMS categories (%)		100	0	23	33	27	60	10	30	3	0	17	13	27	77	30	30	0	47
Global Functional Recovery Scale																			
nc	Perception of recovery	1																	
nc	Expectation of recovery	1																	
nc	List problems	1																	
Total frequency of categories		3	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Proportion of GFRS categories(%)		100	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

Blank spaces mean no entry in this field.
nc, not covered*; nd,* not definable*; ICF,* International Classification of Functioning, Disability and Health; *pf,* personal factor
ABCs, Activities Specific Balance Confidence Scale; *BRIQ*, Behavioural Responses to Illness Questionnaire; *CHART*, Craig Handicap Assessment and Reporting Technique-Short Form; *CIQ*, Community Integration Questionnaire; *CMS*; Concussion Modifiers Scale; *CORE-Q*, Concussion Recovery Questionnaire; *CRIS-EPS*, Community Reintegration for Service Members-Extent of Participation Scale; *DCCASP*, Daily Cognitive-Communication and Sleep Profile; *FAD*, Family Assessment Device General Functioning Scale; *GFRS*, Global Functional Recovery Scale; *LAM*, LAM Employment Absence and Productivity Scale; *LTCQ*, La Trobe Communication Questionnaire; *MIDAS*, Migraine Disability Assessment Scale; *OGQ*, Occupational Gaps Questionnaire; *PART-O*, Participation Assessment with Recombined Tools-Objective; *PCFS*, Post-Concussion Functional Scale; *RRTWS*, Readiness for Return to Work Scale; *SPRS*, Sydney Psychological Reintegration Scale; *TBI-WIS*, TBI Work Instability Scale; *VVAS*, Visual Vertigo Analog Scale; *WHODAS-2*, World Health Organization Disability Scale.

Table 6.10. Frequency of ICF categories contained within measures of Functioning and Disability (n= 19) that are linked to the CORE-Q.

ICF Code	2nd-level ICF Category	COPSOQ	EBIQ	FAQ	FSE	GHQ	MOS-CFS	NDI	NFI-D	NRS	PCL-5	PSFS	PTSS-10	RHIFUQ	SDS	SF-36	SIQR	TFI	THI	WI-8
Post-Concussion Functional Scale																				
d110	Watching																			
d115	Listening																			
d155	Acquiring new skills	1					2													
d160	Focusing attention		1	1		1	1	1		1	1							2	1	
d166	Reading							1											1	
d170	Writing																			
d220	Multi-tasking																			
d350	Conversation		2											2				1		
d360	Using communication devices																			
d4	Mobility																			
d430	Lifting and carrying objects							1								2	1			
d450	Walking				1											3	1			
d455	Moving around				3											3	1			
d470	Using transportation				1															
d475	Driving				1			1												
d5	Self-care		1		1			1								1	1			
d620	Acquisition of goods and services			1	1												1		1	
d630	Preparing meals			2										1			1		1	
d640	Doing housework		1		1									1		1	2		1	
d650	Caring for household objects				1									1		1			1	
d660	Assisting others				1													1		
d830	Higher education														1			1		
d850	Remunerative employment	36			7			1						2	1	6		1	1	
d855	Nonremunerative employment																	1		
d9	Community, social and civic life				1															
d920	Recreation and leisure		2	1	2			1	1					2	1	3		1	1	
e125	Products and technology for communication																			1
e240	Light																1			

Table 6.10. continued

ICF Code	2nd-level ICF Category	COPSOQ	EBIQ	FAQ	FSE	GHQ	MOS-CFS	NDI	NFI-D	NRS	PCL-5	PSFS	PTSS-10	RHIFUQ	SDS	SF-36	SIQR	TFI	THI	WI-8
e250	Sound																1			
nc	Capacity																			
nc	Other difficulties		1									7		4						
Total frequency of categories		37	8	5	21	1	3	7	1	1	1	7	0	13	3	20	10	8	8	1
Percentage of PCFS categories (%)		86	19	12	49	2	7	16	2	2	2	16	0	30	7	47	23	19	19	2
Concussion Modifiers Scale																				
d175	Solving problems	1					1													
d177	Making decisions	1	1			1	1													
d230	Carrying out daily routine	1	1			1														
d240	Handling stress													1					1	
d750	Informal social relationships		1											1				1	1	
d760	Family relationships													1				1	1	
d770	Intimate relationships				1													1	1	
d830	Higher education														1			1		
d850	Remunerative employment	36			7			1						2	1	6		1	1	
d855	Nonremunerative employment																	1		
d865	Complex economic transactions		1	2																
e125	Products and technology for communication																			1
e165	Assets																			
e2	Natural environment and human-made changes to environment																			
e310	Support from immediate family																			
e315	Support from extended family																			
e320	Support from friends																			
e325	Support from peers/community	2																		
e330	Support from people in authority	2																		
e410	Attitudes of immediate family		1																	
e415	Attitudes of extended family		1																	
e420	Attitudes of friends		1																	

Table 6.10. continued

ICF Code	2nd-level ICF Category	COPSOQ	EBIQ	FAQ	FSE	GHQ	MOS-CFS	NDI	NFI-D	NRS	PCL-5	PSFS	PTSS-10	RHIFUQ	SDS	SF-36	SIQR	TFI	THI	WI-8
e570	Social security services, systems and policies																			
e580	Health services, systems and policies																			
pf	Knowledge of concussion																			
nd	Physical health				5											4			1	4
nd	Mental health		1		1	1			1	3			2			4	2	2	2	
nc	Feeling safe																			
Total frequency of categories		43																		
Percentage of CMS categories (%)																				
Global Functional Recovery Scale																				
nc	Perception of recovery																			
nc	Expectation of recovery																			
nc	List problems																			
Total frequecy of categories																				
Percentage of GFRS categories (%)																				

Blank spaces mean no entry in this field.
nc, not covered*; nd,* not definable*; ICF,* International Classification of Functioning, Disability and Health; *pf,* personal factor
CMS, Concussion Modifiers Scale; *COPSOQ*, Copenhagen Psychosocial Questionnaire; *CORE-Q*, Concussion Recovery Questionnaire; *EBIQ*, European Brain Injury Questionnaire; *FAQ*, Functional Activities Questionnaire; *FSE*, Functional Status Examination; *GFRS*, Global Functional Recovery Scale; *GHQ*, General Health Questionnaire; *MOS-CFS*, Medical Outcomes Study Cognitive Functioning Scale; *NDI*, Neck Disability Index; *NFI-D*, Neurobehavioural Functioning Inventory-Depression; *NRS*, Neurobehavioural Rating Scale; *PCFS*, Post-Concussion Functional Scale; *PCL-5*, Post-Traumatic Stress Disorder Checklist-5; *PSFS*, Patient Specific Functional Scale; PSS, Post-Traumatic Symptom Scale; *PTSS-10*, Post-Traumatic Stress Syndrome-10; *RHIFUQ*, Rivermead Head Injury Follow-Up Questionnaire; *SDS*, Sheehan Disability Scale; *SF-36*, Short-Form Health Survey-36; *SIQR*, Revised Symptom Impact Questionnaire; *TFI*, Tinnitus Functional Index; *THI*, Tinnitus Handicap Inventory; WI-8, Whiteley-8 Index

Table 6.11. Frequency of ICF categories contained within measures of Environment Factors (n= 4), Personal Factors (n= 16) and Other measures (n=2) that are linked to the CORE-Q.

ICF Code	2nd-level ICF Category	Environmental Factors				Personal Factors																Other	
		ISEL-SF	PAAS	SSEHS	UCLA LS	BIPQ	CD-RISC	CES	DRRI-2	GSE	IPQ-R	LEC	MHLCS	PSDQ	RSA	SAS	SCS	SEQ	SE-SMS	TBI-SEQ	UCL	IIP-64	PGIC
Post-Concussion Functional Scale																							
d110	Watching																						
d115	Listening																						
d155	Acquiring new skills																						
d160	Focusing attention						1												1				
d166	Reading				1																		
d170	Writing			1																			
d220	Multi-tasking																						
d350	Conversation														1								
d360	Using communication devices																						
d4	Mobility																						
d430	Lifting and carrying objects																						
d450	Walking																		1				
d455	Moving around																						
d470	Using transportation											1							1				
d475	Driving											1											
d5	Self-care																						
d620	Acquisition of goods and services																		1				
d630	Preparing meals																						
d640	Doing housework		1																1				
d650	Caring for household objects		1																1				
d660	Assisting others																						
d830	Higher education																	2		1			
d850	Remunerative employment											1						1		1			
d855	Nonremunerative employment																						
d9	Community, social, civic life																						

Table 6.11. continued

ICF Code	2nd-level ICF Category	Environmental Factors				Personal Factors																Other	
		ISEL-SF	PAAS	SSEHS	UCLA LS	BIPQ	CD-RISC	CES	DRRI-2	GSE	IPQ-R	LEC	MHLCS	PSDQ	RSA	SAS	SCS	SEQ	SE-SMS	TBI-SEQ	UCL	IIP-64	PGIC
d920	Recreation and leisure		3		1							1		9						1			
e125	Products and technology for communication				3																		
e240	Light																						
e250	Sound																						
nc	Capacity																						
nc	Other difficulties																						
Total frequency of categories																							
Percentage of PCFS categories (%)																							
Concussion Modifiers Scale																							
d175	Solving problems		2		1						3					2	1		1		1	3	1
d177	Making decisions																						
d230	Carrying out daily routine																						
d240	Handling stress				1			1		2	1	1	1				1				1		
d750	Informal social relationships						2									3					1		
d760	Family relationships		1				1							1		4					1		
d770	Intimate relationships		1				1							1		4					1		
d830	Higher education																		2		1		
d850	Remunerative employment											1							1		1		
d855	Nonremunerative employment																						
d865	Complex economic transactions																			1	1		
e125	Products and technology for communication																						
e165	Assets										1												
e2	Natural environment and human-made changes to environment										1	3											

Table 6.11. continued

ICF Code	2nd-level ICF Category	Environmental Factors				Personal Factors																	Other	
		ISEL-SF	PAAS	SSEHS	UCLA LS	BIPQ	CD-RISC	CES	DRRI-2	GSE	IPQ-R	LEC	MHLCS	PSDQ	RSA	SAS	SCS	SEQ	SE-SMS	TBI-SEQ	UCL	IIP-64	PGIC
e310	Support from immediate family				4								1		3				2				
e315	Support from extended family				4								1		3				2				
e320	Support from friends				4								1		1				2				
e325	Support from peers/community																		1				
e330	Support from people in authority																						
e410	Attitudes of immediate family					1									1								
e415	Attitudes of extended family					1									1								
e420	Attitudes of friends					1																	
e570	Social security services, systems and policies																						
e580	Health services, systems and policies		1				1				2		1	1						1		1	
pf	Knowledge of concussion			1			1																
nd	Physical health		1				1	1			1 8	1	9	4									
nd	Mental health						1			1							3					2	
nc	Feeling safe								1			6											
Total frequency of categories																							
Percentage of CMS categories (%)																							
Global Functional Recovery Scale																							
nc	Perception of recovery																						2
nc	Expectation of recovery						1				3												
nc	List problems																						
Total frequency of categories																							
Percentage of GFRS categories (%)																							

Blank spaces mean no entry in this field.

nc, not covered*; nd,* not definable*; ICF,* International Classification of Functioning, Disability and Health; *pf,* personal factor

BIPQ, Brief Illness Perception Questionnaire; *CD-RISC*, Connor Davidson Resilience Scale-10; *CES*, Combat Exposure Scale; *CMS*, Concussion Modifiers Scale; *CORE-Q*, Concussion Recovery Questionnaire; *DRRI-2*, Deployed Risk and Resilience Inventory; *GFRS*, Global Functional

Recovery Scale; *GSE*, General Self Efficacy Scale; *IIP-64*, Inventory of Interpersonal Problems-64; *IPQ-R*, Illness Perception Questionnaire Revised; *ISEL-SF*, Interpersonal Support Evaluation List-Short Form; *LEC*, Life Events Checklist; *MHLCS*, Multidimensional Health Locus of Control Scale; *PAAS*, Personal Advocacy Activity Scale; *PCFS*, Post-Concussion Functional Scale; *PGIC*, Patient Global Impression of Change; *PSDQ*, Physical Self-Description Questionnaire; *RSA*, Resilience Scale for Adults; *SAS*, Self-Advocacy Scale; *SCS*, Self-Compassion Scale; *SEQ*, Self-Efficacy Questionnaire; *SE-SMS*, Self-Efficacy for Symptom Management Scale; *SSEHS,* Social Support for Exercise Habits Scale; *TBI-SEQ*, Traumatic Brain Injury Self-Efficacy Questionnaire; *UCL*, Utrecht Coping List; *UCLA LS*, UCLA Loneliness Scale

6.4 Discussion

This study compared content contained within existing outcome measures used in clinical trials of concussion with the CORE-Q. Linking items from the outcome measures to the ICF using established guidelines enabled us to use a standardized language with which report our findings. Similar studies have demonstrated the feasibility of the ICF in comparing content of health-related outcome measures in TBI and stroke (9,25,26). Comparing the content of outcome measures allows clinicians and researchers to gain new insights into the instruments in order to select the most appropriate measure to meet their needs (9,21,27).

Most of the items in the outcome measures were linked to the PCFS, which aligns most closely with the ICF categories within the component Activities and Participation. This is likely attributable to the interest in measuring areas of functioning that may benefit from rehabilitation (21,28). Many outcome measures covered key concepts of focusing attention, housework, employment status, and leisure activities, but differed in their approach to measurement (e.g. frequency, level of agreement, extent of change, or level of difficulty). Return to work is a common goal of rehabilitation and has been emphasized as an important measure of function (5,29). Previous research has found being able to return to work and engage in leisure activities as being positively correlated with quality of life and an important marker of function (30). These concepts contained within the PCFS were only modestly covered by other outcome measures. While this provides evidence of its construct validity, it also suggests that existing measures are not adequately measuring some concepts relevant to persons with concussion.

The CMS specifically assesses how much environmental factors such as technology, social support, relationships, attitudes of others, access to health services, and economic independence influence recovery. Interestingly, environmental factors contained within the CMS were poorly represented in the outcome measures. Those measures that did assess environmental factors focused primarily on social relationships. Few focused on the ability to carry out complex economic transactions such as banking, attitudes of others, support systems, or health services. It is well recognized that activities and participation are influenced by psychosocial and environmental factors (31,32), yet these factors appear underrepresented in existing outcome measures. Asking about social support is clinically important since it has been found to have a significant relationship with post-concussion symptoms (33). Furthermore, social support, attitudes of family, and social relations have been shown to be amongst the most important factors in reducing disability by enabling persons maintain their ability to participate in functional activities (9,34,35). Early recognition of the need for support may help the clinician refer the person on to local or online support groups and facilitate conversations with family members as to how they can support the person through recovery.

The GFRS provides a global overview of recovery and expectations for recovery from the perspective of the person with concussion. Two questions probe both perceived level of current recovery and expected recovery from the perspective of the person with concussion using a single assessment numeric evaluation. Expectation of recovery has been theorized to account for a general response bias in symptom reporting in what has been termed the “good old days bias” (36). Persons who expect

significant symptoms following a concussion may fail to remember pre-injury symptoms and selectively attribute symptoms to their injury. This would result in a lower perceived level of recovery. Similarly, increased public awareness of the long-term consequences of concussion may lead to a person to expect a prolonged recovery due to a heightened sense of concern. This is clinically significant, as education regarding typical concussion symptoms, prognosis, and expected recovery time has been shown to reduce the risk of persistent post-concussion symptoms (37). Understanding a person's expectation for recovery may shed some light on variations in self-reported symptoms, and the need for educational interventions. This is an area vastly unexamined in existing outcome measures.

The large number of different outcome measures being used in clinical trials demonstrates a lack of consensus regarding what should be measured post-concussion. Alternatively, researchers may be interested in measuring diverse concepts following concussion. Furthermore, our comparison of content between outcome measures used in clinical trials and the CORE-Q highlights the large variation in concepts being measured. Careful consideration should be given to evaluating concepts that are relevant to persons with concussion when selecting an outcome measure.

While scoring systems were not explicitly examined in this study, it should be noted that the concept of measuring level of functioning in the PCFS based on time before the onset of symptoms is a radical departure from the most common system of measurement, a Likert scale describing frequency or level of difficulty. This is an important consideration in concussion assessment, as persons can often perform a

given activity, but are limited by symptom onset, rather than difficulty of the task. Therefore, classic measurements may underestimate the extent of limitations experienced by persons after concussion.

While longer item outcome measures allow measurement of different aspects contributing to functioning, the single assessment numerical evaluation used in the GFRS has been promoted as a means of evaluating subjective function with minimal user burden (38). The single assessment numeric evaluation has been shown to demonstrate moderate to strong correlations compared with other measures of functional status, and sensitivity to change in level of functioning (38,39). The GFRS therefore, lends itself to being the preferred means of capturing a snapshot of recovery by clinicians in a busy clinical practice.

Previous research has compared select domain-specific outcome measures to the ICF or evaluated their psychometric properties without consideration of content relevance for persons with concussion (9,17,18,21). This study adds to the literature by comparing the content of outcome measures used in clinical trials of concussion with a new questionnaire developed from rigorous qualitative methods that assess those concepts most relevant from the person with concussion and clinician perspective. This has important clinical relevance, as correct conclusions regarding outcomes of the person with concussion can only be made if the measurement tool has good content relevance, regardless of its psychometric properties.

Before the CORE-Q can be adopted into clinical practice, psychometric evaluation is required to assess for dimensionality using exploratory factor analysis. Once the number factors have been determined for each scale, the CORE-Q will need

to be assessed for reliability to determine the internal consistency of each subscale and the overall reproducibility of the tool using a test-retest repeat measure design. Further validation of the CORE-Q is required, with moderate correlations expected with measures of similar constructs such a the WHODAS-2, SF-36, and CHART-SF. Finally, known-groups validation studies are required to ensure the CORE-Q can adequate discriminate between adults with PPCS and those without.

Limitations.

For reasons of feasibility, only one researcher (JV), the developer of the CORE-Q, screened the studies, identified the included outcome measures, and coded the items on each outcome measure to the ICF. Potentially relevant studies and their included outcome measures may have been missed in this process. Other researchers may also have coded items differently, affecting our results and how we interpreted the outcome measures. However, the included tables present the coding results in complete transparency to minimize any potential or perceived bias towards the CORE-Q. We only identified outcome measures used in clinical trials of concussion research. It is possible that relevant questionnaires exist that are used clinically were not included in our search. However, given that the outcome measures identified in this study match up with those recommended by different groups for use in clinical trials of TBI minimizes this possibility (22,40–42). Personal Factors have not yet been coded to the ICF leading to possible discrepancies in interpretation of items. Coding items to the ICF allowed for a standardized means of comparing outcome measures, however, it's possible that we interpreted the intended meaning of some items differently. However, given that the highest proportion of content coverage was only 55% (CHART-SF), it seems unlikely

that minor differences in coding would have resulted in an outcome measure being identified as containing a significant proportion of items from the CORE-Q.

Clinical Messages.

- The CORE-Q assesses concepts of functioning and contextual factors not adequately covered by existing outcome measures.
- The PCFS measures functioning as time before onset of symptoms.
- The CMS assesses environmental and contextual factors that influence recovery.
- The GFRS provides a global overview of the recovery from the perspective of the person with concussion.

6.5 Conclusion

The CORE-Q represents a new self-report measure of functional status for persons with concussion that has been developed using rigorous qualitative methodology (43–50). This systematic review identified and compared 58 outcome measures used in clinical trials on concussion between 1 January 2008 and 24 August 2018 to the CORE-Q using the ICF as a standard language. Our results showed that there was large variability in content between included outcome measures. None of the outcome measures contained a significant proportion of the concepts contained in the CORE-Q, suggesting that existing outcome measures may not be adequately assessing content relevant to persons with concussion. The newly developed CORE-Q represents a unique instrument that measures concepts untapped by existing outcome measures used in concussion clinical trials, notably the concepts of multitasking, capacity, social support, attitudes of others, and expectation of recovery. This suggests that the CORE-Q fills an important gap as a comprehensive standardized measure of functional status in

persons with concussion. Further studies are warranted to assess the psychometric properties of the CORE-Q in this population.

Author Contributions.

J.V., H.S., S.M., and I.G. contributed to the conception and design of the study. J.V. developed the CORE-Q, reviewed the literature, performed the content analysis, and drafted the manuscript. H.S., S.M., and I.G. supervised the work and revised the manuscript critically. All authors read and approved the final manuscript.

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Conflict of Interest Statement.

The authors declare no commercial conflict of interest. JV has a clinical practice in orthopaedic and sports physiotherapy involving persons with concussion. SM has a clinical practice in physical medicine and rehabilitation, and was the project team leader on national concussion guidelines. IDG is a recipient of a CIHR Foundation Grant (FDN# 143237).

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Chapter 7: Integrative discussion and conclusion

7.1 Overview

Increased media attention resulting from high profile athletes being sidelined with persistent postconcussion symptoms (PPCS) has raised public awareness about concussion in sport, although general knowledge of concussion remains low, and PPCS poorly understood (Merz, Van Patten, & Lace, 2017). Despite recent progress in advanced neurodiagnostic imaging techniques, it remains difficult to monitor recovery following concussion. Currently, no objective biomarker of concussion exists that is diagnostically or prognostically accurate. Diagnosis of PPCS still relies heavily on self-reported symptom endorsement that is influenced by a complex interaction of neurophysiological and psychosocial factors (Ontario Neurotrauma Foundation, 2018).

Up to one-third of adults continue to report symptoms beyond the first month disabling enough to limit their ability to return to their previous level of employment, education, physical or social activities (Losoi et al., 2016; Ontario Neurotrauma Foundation, 2018). Given that concussions cannot be eliminated entirely, and that no biomarker or objective diagnostic or prognostic measure of concussion and recovery currently exists, understanding the impact of concussion on person is of utmost importance.

Statement of Positionality.

My interest in this research was built on extensive personal and professional experience in the field of concussion and PPCS. My beliefs have been largely shaped by personal experiences with PPCS and the challenges encountered by adults trying to find their way back to whatever semblance of normal they experienced before their concussion. Having worked as orthopaedic and sport physiotherapist with recreational through to

Olympic athletes for over 20 years gave me further insight into the extensive toll that persistent symptoms have on all aspects of a person's life. Although I endeavoured to understand the needs of my patients in order to best address their overall needs, my approach to concussion management was initially shaped by clinical experience and later guided by the emergence of expert consensus guidelines. However, there continued to remain a seeming disconnect between my patients' experience and the growing body of research. That gap is what prompted the research that resulted in this dissertation.

Summary of Findings.

In this dissertation, I aimed to understand what concepts were relevant to our definition of functioning in persons with concussion (Chapters 3 and 4). Then, I synthesized this information to create a conceptual model of functioning post-concussion (Chapter 5). Guided by the relationships between variables within the conceptual model as a template, I created a concussion-specific functional status measure, the Concussion Recovery Questionnaire (CORE-Q) (Chapter 5). Finally, I compared the content within existing patient-reported outcome measures (PROMs) used in clinical trials of concussion and the CORE-Q to determine if the new measure was sufficiently unique to justify further examination into its use (Chapter 6). I conducted this research to address a gap in clinical tools within the National Institute of Neurological Disorders and Stroke (NINDS) Common Data Elements (CDE) Sport-Related Concussion. Here, I summarize the findings from each study and discuss the implications and relevance of this research within the broader context of clinical practice and policy.

In Chapter 2, I present the proposed steps for the development of a concussion-specific outcome measure from conceptual development through to initial psychometric validation using best practice methodology. At the outset, I had intended to develop a PROM that assessed health-related quality of life (HRQOL) in persons with concussion. In response to explicit feedback elicited early on during focus groups and semi-structured interviews, persons with concussion and clinicians with expertise in concussion consistently expressed that a measure of functional status following concussion would provide a more useful assessment of recovery. Those qualitative findings are discussed in further detail in Chapter 4. The protocol described in Chapter 2 formed the methodological template for this dissertation, and is comprised of three overarching objectives: (1) conceptualization of functioning post-concussion; (2) questionnaire development; (3) initial psychometric testing. This dissertation addresses the first two of these objectives, culminating in the CORE-Q. Before the CORE-Q is incorporated into clinical practice, further psychometric testing is necessary to assess the questionnaire for dimensionality, internal consistency, reproducibility, and construct validity.

Objective 1: Conceptualization of functioning post-concussion

The purpose of the first section of the dissertation (Chapters 3 and 4) was to understand which concepts best define the construct of functioning post-concussion by examining the content of existing PROMs in the literature, and interviewing persons with lived experience of concussion, as well as clinicians with expertise in concussion management, before a concussion-specific measure of functional status could be developed. The systematic review presented in Chapter 3 highlights the wide range of

concepts relevant to prolonged recovery following concussion. These concepts covered multiple domains within individual activities, societal participation, and environmental and personal factors. The breadth of concepts identified in this review reflects the complexity of concussion, the lack of consistency regarding what should be measured, and the focus on different concepts depending on different study objectives. We deemed it essential to validate which of these concepts was most relevant to the construct of functioning rather than generating a list of questionnaire items solely based on concepts derived from a systematic review. Therefore, we used the concepts identified in this systematic review to inform the interview guides for our qualitative research in Chapter 4.

In Chapter 4, I asked persons with concussion and clinicians with expertise in concussion management to identify what concepts were most relevant to recovery following concussion, and how they should best be measured. Three main themes emerged from the qualitative findings: (1) functioning; (2) barriers and facilitators; and (3) capacity. Respondents were unanimous that the impact of concussion would best be captured by a measure of functional status rather than by HRQOL, as we initially intended to measure. Both groups felt that measuring functional status would provide more useful information to guide clinical decision-making compared with questions of satisfaction typically associated with measures of HRQOL. Clinicians echoed the sentiments of persons with concussion regarding the pervasive impact of environmental and personal factors on functioning on a continuum from barrier to facilitator. Importantly, capacity emerged from participant narratives as being central to the measurement of functional status, defined as the length of time one could perform a

task before the onset of symptoms, the length of time it took to recovery from those symptoms, and needing to choose which activities to limit in order to minimize symptoms.

Objective 2: Questionnaire development

In Chapter 5, I synthesized the concepts derived from the qualitative findings to develop a conceptual model of functioning post-concussion. The conceptual model provides a graphical representation of the relationship between the three identified themes of functioning, barriers and facilitators (concussion modifiers), and capacity. Using the concepts derived from the qualitative study, I then generated an initial list of questionnaire items that represented the three themes. I then pretested the questionnaire through multiple rounds of cognitive interviews with persons with concussion and clinicians with concussion expertise to seek feedback on the content and design of the questionnaire. I did this in order to refine, revise and delete inappropriate questions.

The final questionnaire is presented as the CORE-Q, which is comprised of 53 items over three complimentary subscales, namely the Post-Concussion Functional Scale (PCFS), the Concussion Modifiers Scale (CMS), and the Global Functional Recovery Scale (GFRS). Each subscale corresponds to one of the three themes above. Feedback from both persons with concussion and clinicians consistently emphasized that the length of the questionnaire was justified given the clinically valuable information assessed with each subscale. Persons with concussion were also pleased that the CORE-Q tapped into important concepts that hadn't been assessed in questionnaires they had previously completed. Before proceeding further with

psychometric testing of the CORE-Q, we deemed it necessary to compare the content of the CORE-Q with the content of other relevant PROMs to justify the need for a new concussion-specific PROM, before adding to the plethora of generic and domain-specific measures already in existence.

In Chapter 6, I examined published literature and registered research protocols to extract all PROMs used in clinical trials of concussion. By using the ICF to code the concepts in those PROs to the constructs of functioning, barriers and facilitators, and capacity covered by the CORE-Q, I was able to critically evaluate the content of each PROM and the proportion of similar concepts shared with the CORE-Q. The findings suggest that none of the PROMs currently used in studies of concussion tap sufficiently into many of the concepts assessed by the CORE-Q, notably multitasking, capacity, social support, attitudes of others, and expectation of recovery. Before the CORE-Q can be considered as a measure of functional status to supplement the battery of tools recommended by the NINDS CDE Sport-Related Concussion to be adopted into clinical practice or used in intervention trials, reliability and validity of the measure needs to be tested in a concussion population.

Discussion and Implications.

The International Classification of Functioning, Disability and Health (ICF) uses a biopsychosocial model to describe functioning at the level of body (e.g. physiological and psychological impairments, including symptoms, and anatomical structures), the individual (e.g. limitations in activities, such as walking), and society (e.g. restrictions participating in life situations, such as employment) (World Health Organization, 2001). According to the framework of the ICF, environmental and personal factors interact with

all levels of functioning, acting as both barriers and facilitators (World Health Organization, 2001). In this dissertation, I used the framework of the ICF to understand which concepts best define the construct of functioning post-concussion at the level of the individual and society, and contextual factors that influence functioning (Chapters 3 and 4), and again in Chapter 6 as a standard taxonomy to compare content between the CORE-Q and existing PROMs. The ICF has been used to compare content of measures of participation (Chung, Yun, & Khan, 2014; Noonan et al., 2009), HRQOL (Cieza & Stucki, 2005), in health conditions such as stroke (Geyh, Cieza, Kollerits, Grimby, & Stucki, 2007), and in TBI research (Laxe et al., 2012) using recommended linking guidelines (Cieza et al., 2002, 2016, 2005). The ICF has also previously been used to develop generic measures of health and disability (e.g. World Health Organization Disability Schedule-2) (Garin O Almansa J, Nieto M, Chatterji S, Vilagut G, Alonso J, Cieza A, Svetskova O, Burger H, Racca V, Francescutti ,C. et al., 2010) and activities and participations (e.g. ICF Measure of Participation and ACTivities - Screener) (Post et al., 2008). In developing the CORE-Q, I intentionally focused on measuring functioning at the level of the individual and society, and the influence of environmental and personal factors on functioning. The reason for the omission of concepts at the level of the body (function and structures) was three-fold: Primarily, so as not to create a redundant scale, as several concussion-specific measures of symptoms exist have been validated in a PCSS population, such as the Rivermead Postconcussion Symptoms Questionnaire (King, Crawford, Wenden, Moss, & Wade, 1995), British Columbia Postconcussion Symptom Inventory (Iverson, 2006), and the Postconcussion Symptom Scale (Lovell et al., 2006). Second, feedback from relevant

stakeholders was firm and emphatic that problems with functioning were not well captured with symptoms, rather the *impact* of symptoms on functioning was a better metric of recovery. Third, the lack of a concussion-specific measure of functioning in the NINDS CDE Sport-Related Concussion represents a gap in the literature as to how to measure recovery at the level of the individual and society.

Focusing on functioning at the level of the individual and society, has the potential to compliment current Canadian guidelines published by the Ontario Neurotrauma Foundation (ONF) that recommend a symptom-based approach to managing PPCS (Ontario Neurotrauma Foundation, 2018). Current recommendations are not surprising, as symptom resolution is the most commonly reported metric of recovery following concussion (Willer et al., 2018). Symptom-based management allows a clinician to target their treatment approach using evidence-based strategies validated for similar symptoms in other conditions. The implication of measuring functional status is discussed at a clinical level below.

Defining recovery is even more challenging given the lack of objective biomarkers or neurodiagnostic imaging techniques. Furthermore, as concussion symptoms are non-specific and commonly present in other conditions such as depression, anxiety, and post-traumatic stress disorder (Ontario Neurotrauma Foundation, 2018), it is unclear whether PPCS represents persistent injury to the brain (Harmon et al., 2019) or the complex interaction of neurobiological and psychosocial factors (Ontario Neurotrauma Foundation, 2018). Iverson et al. (2019) reinforce the latter, proposing a network analysis approach that shifts our conceptualization of PPCS away from an underlying latent disorder towards a biopsychosocial understanding of the

disorder (Iverson, 2019). Under this framework, the use of a predominantly symptom-based approach limits our conceptualization of recovery post-concussion at the level of the body, without consideration of the person's life experiences or external environment.

A main finding of Chapter 4 was that both persons with concussion and clinicians de-emphasized the importance of symptoms as a measure of recovery in favour of level of functioning. This disconnect between current clinical recommendations and measures of perceived importance to relevant stakeholders indicates discordance regarding how recovery should be measured. For example, persons with concussion stressed that the *consequence* of post-traumatic headache on life activities and social participation was much more meaningful when measured as how long they could complete a task before the headache got worse, compared with the severity of the headache. Since persons with concussion often limited their individual activities and participation in society as a means of managing symptoms, they felt a low score on a symptom scale was less likely reflective of recovery, and more likely represented a reduction in their engagement in life activities. Chapter 5 details how this perspective was intentionally built into the content and response format of the CORE-Q and offers suggestions as to how the questionnaire should be used.

Implication of measuring functional status at a clinical level.

The time-based approach to measuring functional capacity, in terms of length of time one can perform a task before onset of symptoms on the CORE-Q subscale, provides a means of quantifying functioning that can be used to prescribe planning and pacing of activities and measure recovery. For example, question #1 on the PSFS asks *how long* a person can look at a screen before symptoms start or worsen. That

knowledge would enable an individualized prescription of how many minutes the person with concussion could perform that task without fear of worsening symptoms, by staying below the provocative threshold. Combined with measuring *how many* of these activities the persons with concussion can perform in a typical day and the amount of rest required (questions #24 and #25), the results would allow the healthcare team in consultation with the person with concussion to plan out a daily schedule that allows them to function below their symptom threshold. Changes to time before onset of symptoms would then be one metric of recovery, and would provide an objective means of prescribing activities as the person's capacity grows. This would allow the person with concussion to start to re-engage in life activities in a productive and healthy way, and provide clinically relevant information to determine readiness to return to various work, educational, or home-based activities. While interest in planning and pacing to control symptoms post-concussion is gaining traction, as evidenced by its inclusion within the most recent Canadian concussion guidelines (Ontario Neurotrauma Foundation, 2018), no objective means of quantifying the prescription was provided. Recommendations to adopt planning and pacing into clinical practice without providing a means of implementing the strategy leaves room for clinical interpretation, potentially limiting significant uptake amongst clinicians; hence the need for a standardized measure such as the CORE-Q. As Chapter 6 illustrates, the omission of a planning and pacing tool within the Canadian concussion guidelines likely reflects the absence of any such objective measure. Likewise, although it is well accepted that environmental and personal factors influence health outcomes in general (World Health Organization, 2001), and concussion in particular (Kenzie et al., 2017), current guidelines do not

provide any recommendations as to how to measure the impact of these factors on recovery post-concussion. Since environmental and personal factors have been identified as being highly relevant to person-centred recovery (Chapter 4), consideration should be given as to how to incorporate their impact into clinical care and guidelines. The CORE-Q subscale, the CMS, developed as part of this dissertation (Chapter 5), might be a valuable tool to investigate the environmental considerations as an endpoint in a clinical trial, or in clinical practice to identify barriers to recovery that could be mediated through modifications, accommodations, education, or interventions. For example, question #44 asks the respondent how much their ability to access healthcare affects their recovery. Long waitlists, the ability to afford treatment, and knowledgeable healthcare providers have all been identified as being significant barriers to recovery following concussion (Chapter 4). Use of the CMS in clinical practice has the potential to improve person-clinician communication to identify these barriers and reduce them through referrals to specialized concussion clinics, clinics with shorter wait times, publicly funded programs, and self-management strategies. As discussed in the next section, a conceptual shift is needed before the impact of environmental barriers on functional capacity is adopted at a policy level.

Implication of measuring functional status at a policy level.

When concussion guidelines emphasize symptom-based management without consideration for the consequences of those symptoms on limitations in activities and participation restrictions, guideline developers are missing the opportunity to educate clinicians to measure the *impact* of those symptoms in a meaningful way. As with the NINDS CDE Sport-Related Concussion recommendations (“National Institute of

Neurological Disorders and Stroke Sport-Related Concussion (SRC) Common Data Elements (CDE)," n.d.), the absence of a concussion-specific functional status PROM from the Canadian Guideline for Concussion/Mild Traumatic Brain Injury & Persistent Symptoms (Ontario Neurotrauma Foundation, 2018) likely represents both the lack of an existing measure at the time of writing of this dissertation, and a bias towards measuring symptoms instead of function. As reported in Chapter 4, persons with concussion and clinicians with concussion expertise emphasized the importance of functioning over symptoms. Current Canadian Standards for Post-Concussion Care recommend the multidisciplinary management of persons with concussion, stating that concussion clinics should have at a minimum, a physician, and two or more different regulated healthcare providers (Ontario Neurotrauma Foundation, 2017). Approaching concussion management from a physician-directed, symptom-based perspective perpetuates an outdated medical-model of healthcare, whereby the disability is considered to be the result of the concussion (World Health Organization, 2001), and best managed by the healthcare system. Guidelines that emphasized a multidisciplinary model of care within a biopsychosocial approach to managing PPCS might lead to a more personalized rehabilitation that addresses the interconnection between symptoms, the person, and the environment.

7.2 Future research directions

First, and foremost, a standardized definition of recovery following concussion must be established against which to measure outcomes. Currently, resolution of symptoms at rest and with activity remains the cornerstone for establishing recovery, often in conjunction with biomarkers of physiological recovery (McCrea et al., 2017),

evidence of changes on neurodiagnostic imaging (McCrea et al., 2017), measures of cognition (Williams, Puetz, Giza, & Broglio, 2015), and clinical measures such as balance (Howell, Osternig, & Chou, 2015; Lynall et al., 2017), exercise tolerance (Leddy, Baker, Haider, Hinds, & Willer, 2017; Leddy, Haider, Hinds, Darling, & Willer, 2018), and vestibular impairments (Burkhart, Ellis, & Smurawa, 2019; Master et al., 2017). The importance of each metric in terms of prognostic value, long term implications, and stakeholder relevance must all be considered in defining recovery.

Immediate next steps in the future include examining the CORE-Q for dimensionality, internal consistency, and reproducibility. Based on best practice recommendations of 10 respondents per questionnaire item (Boateng, Neilands, Frongillo, Melgar-Quiñonez, & Young, 2018), a sample size of approximately 530 representative from the target population (persons with concussion) would be required to perform a factor analysis. Factors with the largest eigenvalues should be retained within the scale. Those items that load weekly on factors should be removed to reduce the number of items on the CORE-Q and lessen respondent burden. Items that load weekly on any one factor may be retained if they assess a clinically important variable. Each subscale on the CORE-Q should subsequently be examined for internal consistency using Cronbach's α. Items with an α of 0.7 or greater would indicate they are inter-correlated with other items on the scale and should be considered acceptable for inclusion.

Next, the CORE-Q should be assessed for test-retest reliability using an intraclass correlation coefficient (ICC) with a 95% confidence interval. Based on clinical experience and the chronicity of PPCS, two-week repeat testing would be appropriate to

balance the risk of recall bias with changes in physiological recovery. Sample size should be calculated at 5 to 10 respondents per questionnaire item. An ICC of at least 0.7 would be considered the minimum acceptable level of reliability.

Finally, the CORE-Q should be examined for construct validity against the commonly used generic health status measure Short-Form 36 and the participation measure Craig Handicap Assessment and Reporting Technique-Short Form. It would be reasonable to hypothesize that the CORE-Q would demonstrate moderate correlations with the generic measures using Spearman's rank correlation, suggesting that they evaluate the same construct without undue redundancy. Further construct validity might explore differences between persons with concussion and healthy peers. Evidence that persons with concussion scored significantly lower on the CORE-Q (e.g. $p \leq 0.05$) would provide support that the questionnaire can detect differences in functional status between persons with concussion and healthy comparators.

Before adopting a new functional status measure into clinical practice and inclusion into clinical guidelines, there needs to be strong evidence that measuring functioning as a complement to current measures is feasible, a valid measure of recovery, instrumental in making treatment decisions, and effective at measuring change. There also needs to be buy-in from the person and the clinician in order to change clinical practice patterns. Given the gaps in the literature, more rigorous research is needed to inform clinical practice and guideline development to monitor recovery post-concussion.

Future research should also examine the reliability of scores when measured via various modes. Initial feedback from respondents suggests that differences exist in the

preference of how the CORE-Q questionnaire would be delivered that is unique to a concussion population. Persons with concussion largely preferred a paper-based format due to vision problems when using screens. In contrast, clinicians preferred a web-based mode of delivery for ease of administration, scoring, and record keeping. Future web-based versions may need to incorporate the option to print or be sent to the respondent in advance using a unique link with the option to save and complete over multiple sessions.

Further gaps in knowledge include differences in level of functioning between a post-concussion population compared with healthy peers; a comprehensive understanding of the role of environmental and personal factors on recovery trajectories; and the extent to which functioning can be improved through education, interventions, accommodations and modifications. Future research needs to explore each of these issues in turn.

7.3 Conclusion

This dissertation contributes to the literature by broadening our understanding of the experiences of person with concussion and clinicians regarding recovery, what influences recovery following a concussion, and how recovery post-concussion should be measured. Findings from each study informed subsequent steps and culminated in the development of a concussion-specific measure of functional status, the CORE-Q, which seeks to fill the gap in CDE recommendations and national concussion guidelines regarding measuring functional status postconcussion.

An important finding that emerged from the research is that persons with concussion consider functional capacity, as measured in time, to be a key metric by

which to monitor recovery. This has the potential to compliment current clinical practice and guidelines that recommend managing concussion at a symptom level. Hence, the CORE-Q provides the means of measuring the *impact* of symptom resolution, rather than inferring improved function based on symptom status.

Furthermore, environmental and personal factors exert a significant influence on recovery that should be evaluated by the clinician in a standardized manner that aligns with a biopsychosocial perspective of health. Identifying barriers on a scale from problem to help provides a useful guide for mediating function through modifications, accommodations, education, and interventions. Additionally, given the wide variations in how each person experiences PPCS, there is value added to providing them an opportunity to specify any additional issues that aren't elicited within the context of the traditional assessment. This has the potential to improve person-clinician communication and goal setting, a cornerstone of person-centred care. The importance of these findings is evidenced by persons with concussion who felt the CORE-Q tapped into relevant issues previously unexplored throughout their journey to recovery. The CORE-Q has obvious importance to clinicians who can use the tool to set clinical goals, prescribe individualized planning and pacing strategies, and determine readiness to return to work, educational, or home-based activities. In the future, guideline developers should consider a more comprehensive understanding of recovery that encompasses a biopsychosocial perspective that includes the impact of environmental and personal factors on functioning. Finally, national working groups have an opportunity to make recommendations to a broad range of clinicians and researchers

regarding CDEs that would improve study design, allow for study comparisons, and improve clinical treatment.

In this dissertation, I found that those issues most relevant to persons with concussion and considered important to measure by clinicians were not reflected in the content of existing PROMs used in clinical trials of concussion. Going forward, rigorous research is needed to assess the reliability and validity of the CORE-Q before it can be incorporated into clinical practice, updated guidelines, CDE recommendations, or clinical effectiveness trials.

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Appendix A: Ethical Approval

Ottawa Hospital Research Institute
Institut de recherche de l'Hôpital d'Ottawa

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UNIVERSITY OF OTTAWA HEART INSTITUTE
INSTITUT DE CARDIOLOGIE DE L'UNIVERSITÉ D'OTTAWA

Ottawa Health Science Network Research Ethics Board/ Conseil d'éthique de la recherche du Réseau de science de la santé d'Ottawa

Civic Box 411 725 Parkdale Avenue, Ottawa, Ontario K1Y 4E9 613-798-5555 ext. 14902 Fax : 613-761-4311
http://www.ohri.ca/ohsn-reb

October 31, 2017

Dr. Shawn Marshall
The Ottawa Hospital Rehabilitation Centre
Ottawa Hospital - General Campus
505 Smyth Road
Ottawa, ON
K1H 8M2

Dear Dr. Marshall:

Re: Protocol # 20170720-01H **Health-Related Quality of Life in Adults after Concussion**

Protocol approval valid until - October 30, 2018

I'm pleased to inform you that this protocol underwent delegated review by the Ottawa Health Science Network Research Ethics Board (OHSN-REB) and is approved. No changes, amendments or addenda may be made to the protocol or the consent forms without the OHSN-REB's review and approval.

PLEASE NOTE: THE APPROVAL OF THIS PROTOCOL IS CONDITIONAL UPON A FULLY-SIGNED STUDY CONTRACT/AGREEMENT BETWEEN THE OTTAWA HOSPITAL RESEARCH INSTITUTE, THE PRINCIPAL INVESTIGATOR AND THE SPONSOR (OR AS OTHERWISE REQUIRED). YOU CANNOT START THE STUDY, OR BEGIN TO RECRUIT RESEARCH PARTICIPANTS INTO THE STUDY UNTIL THE STUDY CONTRACT/AGREEMENT HAS BEEN SIGNED BY ALL PARTIES, AND HAS BEEN RECEIVED BY THE OTTAWA HOSPITAL RESEARCH INSTITUTE'S CONTRACTS OFFICE. FOR FURTHER DETAILS, PLEASE CONTACT CONTRACTS ADMINISTRATION AT CONTRACTS@OHRI.CA OR AT 613-798-5555 EXT. 19843.

Please also note: this approval is conditional upon approval from the Health Sciences and Science Research Ethics Board, University of Ottawa.

Your request for a French exemption was reviewed and is approved. Therefore, you will only recruit English-speaking participants for this study.

Approval is for the following documents:

- Study Protocol, version 1.1, dated May 31, 2017
- English Email Script for clinician recruitment, version 2.0, dated October 12, 2017
- English Telephone Script for patient recruitment screening, version 2.0, dated October 12, 2017
- English Participant Recruitment Letter, version 2.0, dated October 12, 2017
- English Recruitment Flyer, no version date, uploaded August 31, 2017
- English Interview Reminder, version 2.0, dated October 12, 2017
- English Informed Consent Form – Clinician, version 1.1, dated March 31, 2017
- English Informed Consent Form – Patients, version 1.1, dated March 31, 2017

- English Quality of Life after Brain Injury Questionnaire, no version date, uploaded April 12, 2017
- English Focus Group Background Information Sheet, version 1.2, dated May 31, 2017
- English HRQoL Focus Group Discussion Guide - Patients, version 1.1, dated May 31, 2017
- English Semi-structured Discussion Guide – Clinicians, version 1.0, dated March 31, 2017
- English Semi-structured Discussion Guide – Patients, version 1.0, dated March 31, 2017
- English World Health Organization Quality of Life Questionnaire - BREF, copyright 2004

The following are acknowledged:

- CRRD Impact Form, signature dated August 08, 2017
- Thesis Committee permission letter, dated October 26, 2016

If the study is to continue beyond the expiry date noted above, an Annual Renewal Report should be submitted to the OHSN-REB approximately one month prior to the current expiry date. If the study has been completed by this date, a Termination Report should be submitted.

OHSN-REB complies with the membership requirements and operates in compliance with the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans; the International Conference on Harmonization - Good Clinical Practice: Consolidated Guideline; and the provisions of the Personal Health Information Protection Act 2004

Chairperson
Ottawa Health Science Network Research Ethics Board

/hl

Université d'Ottawa University of Ottawa
Bureau d'éthique et d'intégrité de la recherche Office of Research Ethics and Integrity

LETTRE D'APPROBATION ADMINISTRATIVE | LETTER OF ADMINISTRATIVE APPROVAL

Numéro de dossier / Ethics File Number	A11-17-03
Titre du projet / Project Title	Health-Related Quality of Life in Adults after Concussion
Type de projet / Project Type	Doctoral thesis
CÉR primaire / Primary REB	OHSN-REB
Statut du projet / Project Status	Administrative Approval
Date d'approbation (jj/mm/aaaa) / **Approval Date** (dd/mm/yyyy)	08/11/2017
Date d'expiration (jj/mm/aaaa) / **Expiry Date** (dd/mm/yyyy)	30/10/2018

Équipe de recherche / Research Team

Chercheur / Researcher	*Affiliation*	*Role*
Shawn MARSHALL	The Ottawa Hospital Rehabilitation Centre	Principal Investigator
Heidi SVEISTRUP	Faculty of Health Sciences / Rehabilitation Sciences	Supervisor
Jacquie VAN IERSSEL	Faculty of Health Sciences / Rehabilitation Sciences	Student-investigator

Conditions spéciales ou commentaires / Special conditions or comments:

L'Université d'Ottawa a signé une Entente, conforme aux exigences de la plus récente version de l'EPTC et tout autre règlement ou législation applicable, permettant au CÉR ci-haut nommé d'être désigné comme CÉR primaire pour les projets de recherche où

1) les activités principales de recherche sont menées sous l'autorité ou sous les auspices de l'établissement lié au CÉR primaire et
2) Une partie du projet est également réalisé sous l'autorité ou sous les auspices de l'Université d'Ottawa.

Cette lettre confirme que l'Université d'Ottawa a autorisé que le CÉR primaire soit le CÉR officiel pour l'évaluation et la supervision de ce projet de recherche. Ceci n'est pas une approbation éthique.

Afin de nous aider à garder votre dossier à jour, veuillez soumettre une copie de toutes demandes de modification, renouvellement d'approbation éthique etc. soumis à et approuvé par le CÉR primaire dès qu'elles sont disponibles.

Cette approbation administrative est valide pour la durée indiquée ci-haut et est sujette aux conditions énumérées dans la section intitulée « Conditions spéciales ou commentaires ».

The University of Ottawa has signed an Agreement, compliant with current TCPS guidelines and any other applicable guidelines or legislation regarding multisite review, allowing the REB named above to serve as Board of Record (BoR) for research projects where

1) the main research activities are conducted within the auspices or jurisdiction of the BoR's institution and
2) parts of the project are also conducted under the jurisdiction or auspices of the University of Ottawa.

This letter confirms that the University of Ottawa has authorized the REB named above to serve as Board of Record for the review and oversight of this research project. This is not an REB approval.

In order to help us keep your file up to date, please submit a copy of all amendment requests, project renewals or any other changes submitted to and approved by the BoR, as they become available.

Administrative approval is valid for the period indicated above and is subject to the conditions listed in the section entitled "Special conditions or comments".

Directrice/Director

Ottawa Hospital Research Institute
Institut de recherche de l'Hôpital d'Ottawa

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Civic Box 411 725 Parkdale Avenue, Ottawa, Ontario K1Y 4E9 613-798-5555 ext. 14902 Fax : 613-761-4311
http://www.ohri.ca/ohsn-reb

May 09, 2018

Dr. Shawn Marshall
The Ottawa Hospital Rehabilitation Centre
Ottawa Hospital - General Campus
505 Smyth Road
Ottawa, ON
K1H 8M2

Dear Dr. Marshall:

Re: Protocol # 20170720-01H Health-Related Quality of Life in Adults after Concussion

I am pleased to inform you that your Amendment request was reviewed by the Ottawa Health Science Network Research Ethics Board (OHSN-REB) and is approved as of May 02, 2018

Approval is for the following:
- Protocol Amendment Report dated April 16, 2018
- Revised English-only Participant Informed Consent Form Patient version 1.2 dated April 14, 2018
- Revised English-only Participant Informed Consent Form Clinician version 2.0 dated April 14, 2018
- Revised English-only Participant Recruitment Letter version 2.2 dated April 14, 2018
- Revised English-only Email Script for Clinician Recruitment version 2.1 dated April 14, 2018
- English -only CONQOL version 1.0 dated April 14, 2018

The projected date of study completion has been extended to December 31, 2018

Ethical approval remains in effect until October 30, 2018

The OHSN-REB complies with the membership requirements and operates in compliance with the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans; the International Conference on Harmonization - Good Clinical Practice: Consolidated Guideline; and the provisions of the Personal Health Information Protection Act 2004.

Yours sincerely,

Chairperson
Ottawa Health Science Network Research Ethics Board

RS/gb

Ottawa Hospital Research Institute
Institut de recherche de l'Hôpital d'Ottawa

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Civic Box 411 725 Parkdale Avenue, Ottawa, Ontario K1Y 4E9 613-798-5555 ext. 14902 Fax : 613-761-4311
http://www.ohri.ca/ohsn-reb

October 22, 2018

Dr. Shawn Marshall
The Ottawa Hospital Rehabilitation Centre
Ottawa Hospital - General Campus
505 Smyth Road
Ottawa, ON
K1H 8M2

Dear Dr. Marshall:

RE: Protocol# - 20170720-01H **Health-Related Quality of Life in Adults after Concussion**

Renewal Expiry Date - October 22, 2019

I am pleased to inform you that your Annual Renewal Request was reviewed by the Ottawa Health Science Network Research Ethics Board (OHSN-REB) and is approved. No changes, amendments or addenda may be made in the protocol or the consent forms without the OHSN-REB's review and approval.

This renewal is approved as of: October 22, 2018

Renewal is valid for a period of one year. If the study is to continue beyond the expiry date noted above, a Renewal Form should be submitted to the REB, in hardcopy. All Annual Renewal Reports, regardless of review type (i.e., full board or delegated), must now be submitted according to the full board meeting submission deadlines AND at least 30 days prior to the expiry date of the study to prevent a lapse in approval. If the study is completed by this date, a Termination Report should be submitted.

The consent forms currently approved for use by the REB are:
- English-only Participant Informed Consent Form Patient version 1.2 dated April 14, 2018
- English-only Participant Informed Consent Form Clinician version 2.0 dated April 14, 2018

The OHSN-REB operates in compliance with, and is constituted in accordance with, the requirements of the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS 2); International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use; Integrated Addendum to ICH E6 (R1): Guideline for Good Clinical Practice E6 (R2) Part C, Division 5 of the Food and Drug Regulations Part 4 of the Natural Health Products Regulations Part 3 of the Medical Devices Regulations and the provisions of the Ontario Personal Health Information Protection Act (PHIPA 2004) and its applicable regulations. OHSN-REB is qualified through the CTO REB Qualification Program and is registered with the U.S. Department of Health and Human Services (DHHS) Office for Human Research Protection (OHRP).

Yours sincerely,

Chairperson
Ottawa Health Science Network Research Ethics Board

RS/gb

HAVE YOU HAD A CONCUSSION?

Co-investigators:

Dr. Heidi Sveistrup, PhD
School of Rehabilitation Sciences
University of Ottawa

Jacquie van Ierssel, PT, PhD candidate
School of Human Kinetics
University of Ottawa

TO ASK QUESTIONS OR TO SIGN UP, CONTACT:

Jacquie van Ierssel at:
_____or
(613) 562-5800 ext. 7099

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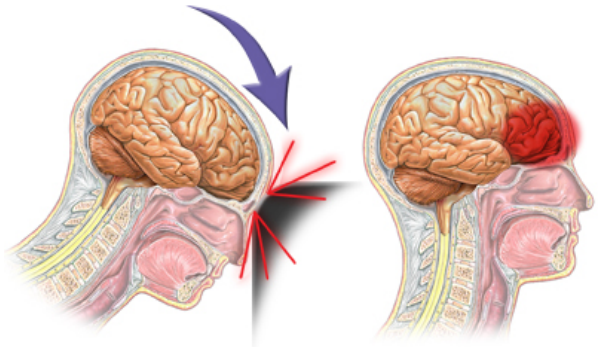

What is this research study about?
We would like to understand the effect of concussion symptoms on your life. This study is part of a project to create an assessment questionnaire for adults to provide better care and education, and assess recovery after a concussion.

Who can participate?
Men and women between the ages of 18-65 years who have had a concussion and still have symptoms for more than one month, and speak English.

What's involved?
A small group discussion to talk about the effect of concussion symptoms on you life. This may take up to 2 hours. You may also take part in a follow-up discussion to review the new questionnaire developed from these discussions and give any suggestions for improvement. This may take up to 1 hour. You may take part in either discussion or both. All your information will be kept confidential. You will not be able to be identified from any information you contribute in the focus group. You will receive a parking voucher or bus fare for the day of the study.

What are the benefits/risks of participating?
Taking part in this study may help to provide better care to adults who have a concussion in the future.

Fatigue and an increase in concussion symptoms may occur during the study. Participation is voluntary and you may stop taking part in the study at any time.

This research study has been approved by the Ottawa Health Science Network Research Ethics Board.

Protocol #20170720-01H
Version 4.0 (August 24, 2018)

Ottawa Hospital Research Institute
Institut de recherche de l'Hôpital d'Ottawa

uOttawa

UNIVERSITY OF OTTAWA HEART INSTITUTE
INSTITUT DE CARDIOLOGIE DE L'UNIVERSITÉ D'OTTAWA

EMAIL SCRIPT FOR CLINICIAN RECRUITMENT

Email Subject Line: University of Ottawa Study – Health-Related Quality of Life in Adults after Concussion

Attachment: Participant Informed Consent Form - Clinician

Hello,
My name is Jacquie van Ierssel, and I am a PhD candidate working under the supervision of Dr. Shawn Marshall, Medical Director of the Traumatic Brain Injury Rehabilitation program at The Ottawa Hospital Rehabilitation Centre, and Dr. Heidi Sveistrup in the School of Rehabilitation Sciences at the University of Ottawa. I am contacting you because you helped develop the Ontario Neurotrauma Foundation Guidelines for Concussion/mTBI & Persistent Symptoms. As part of that project, you agreed to be contacted to assist with other post-concussion projects. You are now being asked to take part in a research study that is seeking to understand how concussion symptoms affect a patient's quality of life. As a clinician with experience working with concussion patients, we are interested in your unique view.

Taking part in this study is voluntary and involves a one-on-one discussion to talk how concussion symptoms affect a patient's quality of life. You will also be asked to look at questionnaires and talk about questions that you feel may be relevant or missing. The discussion will last about 30 minutes. It will take place by either telephone or at a site that works for you, at your request. You may also be asked to take part in a follow-up discussion to review the questionnaire developed from patient and clinician discussions and give any suggestions for improvement. This will take about 30 minutes. You may take part in either discussion or both. You may skip any questions that make you uncomfortable or that you do not wish to answer. I have attached a copy of the Participant Informed Consent Form that gives you full details about the study.

You will receive a parking voucher or bus fare for the day of the study.

The Ottawa Health Science Network Research Ethics Board (OHSN-REB) has reviewed the plans for this research study. The Board considers the ethical aspects of all research studies involving human participants at the Ottawa Hospital. If you have any questions about your rights as a study participant, you may contact the Chairperson at 613-798-5555, extension 16719.

If you are interested in participating or would like more information on this study, please contact me at _____or at 613-562-5800 ext. 7099. I will then contact you to set up a convenient time for an interview.

Thank you in advance for your time and consideration. If I have not heard from you in one week, I will send you a one-time follow up reminder.

Jacquie van Ierssel PT
PhD(candidate) Human Kinetics
Faculty of Health Sciences
University of Ottawa
Tel.: 613-562-5800 ext 7099

FOCUS GROUP DISCUSSION GUIDE - PATIENTS
Health-Related Quality of Life in Adults after Concussion
Researcher: Jacquie van Ierssel

CONFIDENTIALITY

Before we begin our discussion of health-related quality of life, I would like to spend a few moments talking about confidentiality.

- Everything shared by you will be treated confidentially by the research team, and the information you share will be kept anonymous.
- It is important for you all to respect each other's privacy and anonymity.
- You are not obliged to participate in the focus group, nor are you required to answer any questions you do not wish to answer.

Please take a moment to review and sign the consent form. Let me know if you have any questions.

REVIEW CONSENT FORM AND ANSWER ANY QUESTIONS. COLLECT SIGNED CONSENT FORMS AND ENSURE THAT PARTICIPANTS HAVE A COPY OF THE CONSENT FORM TO TAKE WITH THEM. HAVE PENS AVAILABLE FOR EACH PARTICIPANT.

THE COMPLETION OF THE INTRODUCTORY SECTION OF THE FOCUS GROUP SHOULD TAKE APPROXIMATELY 10-15 MINUTES.

OPENING COMMENTS

1. Introduction

Hello everyone. Thank you all for agreeing to participate in this research project, I really appreciate it. I just wanted to introduce myself and Jenn. My name is Jacquie van Ierssel. I am a PhD candidate at the University of Ottawa in the School of Human Kinetics, and a registered physiotherapist and I work with concussion patients in my clinical practice. This is part of my PhD thesis to develop a health-related quality of life questionnaire to help us understand how concussion symptoms have impacted your life. So I'm hoping to get as much from you as possible in terms of what you would like reflected in the questionnaire, what you would like asked, what you think would help us help you. And we want to get it from the best source, which is you, because you know what you need best. Please feel free to ask questions at any time. I hope this will be a very open discussion. Jenn is also a PhD candidate and a physiotherapist working with individuals with TBI.

2. Ground Rules

- I will ask some broad questions to stimulate discussion and ask you to discuss them amongst yourselves.
- I may also ask you to clarify or discuss certain topics in more detail to get a more thorough understanding of your experience.
- There are no right or wrong answers; we want to hear it all.
- When speaking, please use your coded number so your information will be confidential on the tapes and transcripts. I will give you a gentle reminder if you forget.
- We only have up to 2 hours as a group to talk, so I will keep the discussion moving along, so please don't be offended if I redirect the discussion.
- We will be taking a 5-minute break refreshment midway through our discussion. Please feel free to enjoy the refreshments provided at the table at this time.

3. Tape Recorder

- This focus group discussion will be audio-recorded to increase accuracy and to reduce the chance of misinterpreting what anyone says.
- Only I, my academic supervisors, and the research team will have access to the tapes and transcripts (anonymised) of this focus group.

4. Participant Introductions

Let's go around the room and introduce ourselves. Tell us your first name only and why you decided to participate in the focus group.

DISCUSSION QUESTIONS

See Semi-Structured Discussion Guide - Patients

WRAP-UP

- Before leaving, could everyone please fill in a background information sheet and hand it in to help us generally describe the kind of people who were part of the group and how that might impact the results of the study? Please do not put your name on the sheet.

- Remember to respect each others' privacy and anonymity once you leave, and do not reveal the identities of the other participants nor indicate who made specific comments during the discussion.

FOCUS GROUP BACKGROUND INFORMATION SHEET

Health-Related Quality of Life in Adults after Concussion

This information is collected confidentially to understand the background of the participants and how that might impact the results of the study. All information will be aggregated and presented as a group. Your information will be identified with a unique study number, and will not contain any information that identifies you, such as your name, marital status, or income. The link between your unique study number and your name and contact information will be stored securely and separate from your study records, and will only be available to the researchers.

DO NOT PUT YOUR NAME ON THIS SHEET.

Participant Study No.: _____

Instructions: Please provide us with the following information about yourself.

Birthdate: Month: _____ Year: _____

Self-Identified Gender:

- ☐ Male
- ☐ Female
- ☐ Other. I identify as _____

Race

- ☐ Caucasian
- ☐ Asian
- ☐ African/Caribbean Canadian
- ☐ First Nations
- ☐ Other

Marital Status:

- ☐ Single
- ☐ Married
- ☐ Separated
- ☐ Divorced
- ☐ Common-law

Number of Years of Education Completed

- ☐ Elementary school
- ☐ High school
- ☐ College degree/diploma
- ☐ Bachelor's degree
- ☐ Graduate/professional degree
- ☐ Post-graduate degree

Employment Status ***BEFORE*** Injury

- ☐ Employed full-time
- ☐ Employed part-time
- ☐ Unemployed
- ☐ Homemaker
- ☐ Student
- ☐ Disability
- ☐ Retired

Able to Return to Work

- ☐ Yes
- ☐ No

Able to Return to Work at Same Level

- ☐ Yes
- ☐ No

Able to Return to Work

- ☐ Full-time
- ☐ Part-time

Current Annual household income

- ☐ Less than $24,999
- ☐ $25,000 to $49,000
- ☐ $50,000 to $99,000
- ☐ $100,000 to $149,000
- ☐ $150,000 or more

Date of most recent concussion: _____

Mechanism of Injury

- ☐ Sport-related concussion
- ☐ Motor vehicle accident
- ☐ Accident
- ☐ Fall
- ☐ Assault
- ☐ Other

Number of previous diagnosed concussions

- ☐ 0
- ☐ 1
- ☐ 2
- ☐ 3
- ☐ 4

Number of suspected concussions

- ☐ 0
- ☐ 1
- ☐ 2
- ☐ 3
- ☐ 4

PARTICIPANT INFORMED CONSENT FORM
PATIENT

Title of Study: Health-Related Quality of Life in Adults after Concussion

Local Site Principal Investigator (PI): **Shawn Marshall** MD, MSc, FRCPC
Faculty of Medicine
Division of Physical Medicine and Rehabilitation
The Ottawa Hospital Rehabilitation Centre
Tel.: 613-737-8899 ext. 75306

Co-Investigators: **Jacquie van Ierssel** PT, PhD(candidate)
School of Human Kinetics
Faculty of Health Sciences
University of Ottawa
Tel.: 613-562-5800 ext. 7099

Heidi Sveistrup PhD
School of Rehabilitation Sciences
Faculty of Health Sciences
University of Ottawa
Tel.: 613-562-5800 ext. 7101

Sponsor:

This study is not being funded and is being done by the PhD candidate in partial fulfillment of the PhD in Human Kinetics program at the University of Ottawa.

Taking part in this study is voluntary. Please read this Participant Informed Consent Form carefully before you decide if you would like to take part. Ask the study team as many questions as you like.

Why am I being given this form?

You are being asked to take part in this research study because you are still experiencing persistent post-concussion symptoms. You also may have previously participated in a focus group to help us understand what problems people with persistent post-concussion symptoms struggle with.

Why is this study being done?

This discussion is to follow up on suggestions from previous patients in the study who gave us ideas what to include in a health-related quality of life questionnaire. We would like to know if the questionnaire reflects these ideas, and if you have any suggestions to improve the questions or its format.
We expect up to 20 patients will take part in this study.

How is the study designed?

This is a qualitative study.

What is expected of me?

You will be asked to read over the questionnaire we have developed to see if you understand it, and offer any suggestions for improvement. This may mean adding, removing, or changing some of the content of the questions, how the question is asked, or how it looks on the page. This will about 60 minutes. This one-on-one meeting will take place with the lead researcher in a quiet meeting room at the Ottawa Hospital Rehabilitation Centre, or at a quiet location near you, such as a local library or community centre. You do not have to answer any questions you do not want to. Taking part is completely voluntary.

How long will I be involved in the study?

The whole study will last about 6 months. Your part in the study will only be the 30-minute review of the questionnaire.

What are the potential risks I may experience?

You may feel some fatigue or worse symptoms because of the room, or because you will be asked to think for up to 1 hour. You may not like all of the questions that you are asked. You do not have to answer any questions that make you uncomfortable.

All of your data will be kept confidential by the research team, and you will not be able to be identified from any information you contribute in the focus group. All group members will be asked not to tell anyone who was in the group or any specific comments that were made during the small group discussion. The researchers cannot guarantee that all members of the group will respect each other's privacy and anonymity outside the small group.

Can I expect to benefit from participating in this research study?

You will not get any direct benefit from taking part in this study. This study may help the researchers to better understand how concussion symptoms affect quality of life. This may help to take better care of adults who have a concussion in the future.

Do I have to participate? What alternatives do I have? If I agree now, can I change my mind and withdraw later?

Taking part in this study is voluntary. The alternative to this study is not to take part. You do not need to answer any questions you do not wish to and you may take a break or stop participating at any time, for any reason. If you decide to stop participating, you will still receive your parking voucher or reimbursement for bus fare for the day of the study.

You may choose not to be in this study, or to be in the study now, and then change your mind later without affecting your current or future medical care at The Ottawa Hospital.

If you withdraw your consent, you may ask that your study data, including answers to questions, not be used.

Will I be paid for my participation or will there be any additional costs to me?

You will be given a parking voucher or bus fare for the day of the study.

How is my personal information being protected?

All your data from this study will be given a unique study number, and will not contain any information that identifies you, such as your name, contact numbers, or email. The link between your unique study number and your name and contact information will be stored securely and separate from your study records, and will not leave the locked research office.

Any documents or samples leaving the University of Ottawa will contain only your unique study number. This includes publications or presentations resulting from this study.
Information that identifies you will be released only if it is required by law.
For audit purposes only, your original study records may be reviewed under the supervision of Dr. Shawn Marshall's staff by representatives from the Ottawa Health Science Network Research Ethics Board (OHSN-REB) and The Ottawa Hospital.

Research records will be kept for 10 years, after this time they will be destroyed.

Do the investigators have any conflicts of interest?

There are no conflicts of interest to declare related to this study.

Who do I contact if I have any further questions?

If you have any questions about this study, please contact Jacquie van Ierssel at _____ or at 613-562-5800 ext 7099.

Consent to Participate in Research

- I understand that I am being asked to participate in a research study about health-related quality of life in adults after concussion.
- This study was explained to me by _____.
- I have read, or have had it read to me, each page of this Participant Informed Consent Form.
- All of my questions have been answered to my satisfaction.
- If I decide later that I would like to withdraw my participation and/or consent from the study, I can do so at any time.
- I voluntarily agree to participate in this study.
- I will be given a copy of this signed Participant Informed Consent Form.

I agree to be audio recorded. Yes ☐ No ☐ Initials ___

_____	_____	_____
Participant's Printed Name	Participant's Signature	Date

Investigator or Delegate Statement

I have carefully explained the study to the study participant. To the best of my knowledge, the participant understands the nature, demands, risks and benefits involved in taking part in this study.

_____	_____	_____
Investigator/Delegate's Printed Name	Investigator/Delegate's Signature	Date

PARTICIPANT INFORMED CONSENT FORM
CLINICIAN

Title of Study: Health-Related Quality of Life in Adults after Concussion

Local Site Principal Investigator (PI): **Shawn Marshall** MD, MSc, FRCPC
Faculty of Medicine
Division of Physical Medicine and Rehabilitation
The Ottawa Hospital Rehabilitation Centre
Tel.: 613-737-8899 ext. 75306

Co-Investigators: **Jacquie van Ierssel** PT, PhD(candidate)
School of Human Kinetics
Faculty of Health Sciences
University of Ottawa
Tel.: 613-562-5800 ext. 7099

Heidi Sveistrup PhD
School of Rehabilitation Sciences
Faculty of Health Sciences
University of Ottawa
Tel.: 613-562-5800 ext. 7101

Sponsor:

This study is not being funded and is being done by the PhD candidate as part of the PhD in Human Kinetics program at the University of Ottawa.

Taking part in this study is voluntary. Please read this Participant Informed Consent Form carefully before you decide if you would like to take part. Ask the study team as many questions as you like.

Why am I being given this form?

You are now being asked to take part in a research study because of your expertise in concussion. As a clinician working with concussion patients, you may have unique insight into how they are affected.

Why is this study being done?

To help adults after a concussion, we are would like to understand how their symptoms affect their quality of life. This study is part of a project to create a questionnaire for adults to better treat their needs and assess their recovery after a concussion.

We expect up to 10 clinicians will take part in this study.

How is the study designed?

This is a qualitative study.

What is expected of me?

You will be asked to take part in a one-on-one discussion. You will be asked to talk about how concussion symptoms affect a patient's quality of life. You will also be asked to look at questionnaires and talk about questions that you feel may be relevant or missing. You may skip any questions that make you uncomfortable or that you do not wish to answer. This will last about 30 minutes. You may also be asked to take part in a follow-up discussion to review the questionnaire developed from patient and clinician discussions and give any suggestions for improvement. This will take about 30 minutes. You may take part in either discussion or both. Discussions will take place either by telephone or in-person at a site chosen by you. Discussions will be audio recorded and notes will be taken by the researcher. You may still take part in the study if you do not wish to be audio recorded.

How long will I be involved in the study?

The whole study will last about 6 months. Your part in the study will last only for one discussion, about 30 minutes.

What are the potential risks I may experience?

There are no risks from taking part in this study.

Can I expect to benefit from participating in this research study?

You will not get any direct benefit from taking part in this study. This study may help the researchers to better understand how concussion symptoms affect a patient's quality of life. This may help to take better care of adults who have a concussion in the future.

Do I have to participate? What alternatives do I have? If I agree now, can I change my mind and withdraw later?

Taking part in this study is voluntary. The alternative to this study is not to take part.

You may chose not to be in this study, or to be in the study now, and then change your mind later without affecting you or any patient's future care at The Ottawa Hospital.

If you withdraw your consent, you may ask that your study data, including answers to questions, not be used.

Will I be paid for my participation or will there be any additional costs to me?

You will be given a parking voucher or bus fare for the day of the study.

How is my personal information being protected?

All your data from this study will be given a unique study number, and will not contain any information that identifies you, such as your name, contact numbers, email, or where you work. The link between your unique study number and your name and contact information will be stored securely and separate from your study records, and will not leave the locked research office.

Any documents or samples leaving the University of Ottawa will contain only your unique study number. This includes publications or presentations resulting from this study.
Information that identifies you will be released only if it is required by law.
For audit purposes only, your original study records may be reviewed under the supervision of Dr. Shawn Marshall's staff by representatives from the Ottawa Health Science Network Research Ethics Board (OHSN-REB) and The Ottawa Hospital.

Research records will be kept for 10 years, after this time they will be destroyed.

Do the investigators have any conflicts of interest?

There are no conflicts of interest to declare related to this study.

Who do I contact if I have any further questions?

If you have any questions about this study, please contact Jacquie van Ierssel at _____ or at 613-562-5800 ext 7099.

The Ottawa Health Science Network Research Ethics Board (OHSN-REB) has reviewed the plans for this research study. The Board considers the ethical aspects of all research studies involving human participants at The Ottawa Hospital Rehabilitation Centre. If you have any questions about your rights as a study participant, you may contact the Chairperson at 613-798-5555, extension 16719.

Health-Related Quality of Life in Adults after Concussion

Consent to Participate in Research

- I understand that I am being asked to participate in a research study about health-related quality of life in adults after concussion.
- This study was explained to me by _____.
- I have read, or have had it read to me, each page of this Participant Informed Consent Form.
- All of my questions have been answered to my satisfaction.
- If I decide later that I would like to withdraw my participation and/or consent from the study, I can do so at any time.
- I voluntarily agree to participate in this study.
- I will be given a copy of this signed Participant Informed Consent Form.

I agree to be audio recorded. Yes ☐ No ☐ Initials ___

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Participant's Printed Name	Participant's Signature	Date

Investigator or Delegate Statement

I have carefully explained the study to the study participant. To the best of my knowledge, the participant understands the nature, demands, risks and benefits involved in taking part in this study.

_____	_____	_____
Investigator/Delegate's Printed Name	Investigator/Delegate's Signature	Date

Appendix B: Study Forms

HAVE YOU HAD A CONCUSSION?

Co-investigators:

Dr. Heidi Sveistrup, PhD
School of Rehabilitation Sciences
University of Ottawa

Jacquie van Ierssel, PT, PhD candidate
School of Human Kinetics
University of Ottawa

TO ASK QUESTIONS OR TO SIGN UP, CONTACT:

Jacquie van Ierssel at:
_____or
(613) 562-5800 ext. 7099

Ottawa Hospital Research Institute
Institut de recherche de l'Hôpital d'Ottawa

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UNIVERSITY OF OTTAWA HEART INSTITUTE
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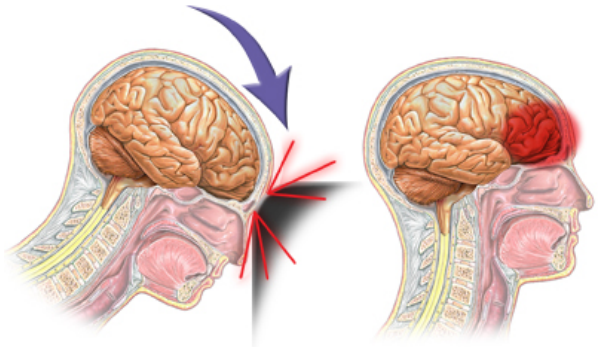

What is this research study about?
We would like to understand the effect of concussion symptoms on your life. This study is part of a project to create an assessment questionnaire for adults to provide better care and education, and assess recovery after a concussion.

Who can participate?
Men and women between the ages of 18-65 years who have had a concussion and still have symptoms for more than one month, and speak English.

What's involved?
A small group discussion to talk about the effect of concussion symptoms on you life. This may take up to 2 hours. You may also take part in a follow-up discussion to review the new questionnaire developed from these discussions and give any suggestions for improvement. This may take up to 1 hour. You may take part in either discussion or both. All your information will be kept confidential. You will not be able to be identified from any information you contribute in the focus group. You will receive a parking voucher or bus fare for the day of the study.

What are the benefits/risks of participating?
Taking part in this study may help to provide better care to adults who have a concussion in the future.

Fatigue and an increase in concussion symptoms may occur during the study. Participation is voluntary and you may stop taking part in the study at any time.

This research study has been approved by the Ottawa Health Science Network Research Ethics Board.

Protocol #20170720-01H
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UNIVERSITY OF OTTAWA HEART INSTITUTE
INSTITUT DE CARDIOLOGIE DE L'UNIVERSITÉ D'OTTAWA

EMAIL SCRIPT FOR CLINICIAN RECRUITMENT

Email Subject Line: University of Ottawa Study – Health-Related Quality of Life in Adults after Concussion

Attachment: Participant Informed Consent Form - Clinician

Hello,
My name is Jacquie van Ierssel, and I am a PhD candidate working under the supervision of Dr. Shawn Marshall, Medical Director of the Traumatic Brain Injury Rehabilitation program at The Ottawa Hospital Rehabilitation Centre, and Dr. Heidi Sveistrup in the School of Rehabilitation Sciences at the University of Ottawa. I am contacting you because you helped develop the Ontario Neurotrauma Foundation Guidelines for Concussion/mTBI & Persistent Symptoms. As part of that project, you agreed to be contacted to assist with other post-concussion projects. You are now being asked to take part in a research study that is seeking to understand how concussion symptoms affect a patient's quality of life. As a clinician with experience working with concussion patients, we are interested in your unique view.

Taking part in this study is voluntary and involves a one-on-one discussion to talk how concussion symptoms affect a patient's quality of life. You will also be asked to look at questionnaires and talk about questions that you feel may be relevant or missing. The discussion will last about 30 minutes. It will take place by either telephone or at a site that works for you, at your request. You may also be asked to take part in a follow-up discussion to review the questionnaire developed from patient and clinician discussions and give any suggestions for improvement. This will take about 30 minutes. You may take part in either discussion or both. You may skip any questions that make you uncomfortable or that you do not wish to answer. I have attached a copy of the Participant Informed Consent Form that gives you full details about the study.

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If you are interested in participating or would like more information on this study, please contact me at _____or at 613-562-5800 ext. 7099. I will then contact you to set up a convenient time for an interview.

Thank you in advance for your time and consideration. If I have not heard from you in one week, I will send you a one-time follow up reminder.

Jacquie van Ierssel PT
PhD(candidate) Human Kinetics
Faculty of Health Sciences
University of Ottawa
Tel.: 613-562-5800 ext 7099

FOCUS GROUP DISCUSSION GUIDE - PATIENTS
Health-Related Quality of Life in Adults after Concussion
Researcher: Jacquie van Ierssel

CONFIDENTIALITY

Before we begin our discussion of health-related quality of life, I would like to spend a few moments talking about confidentiality.

- Everything shared by you will be treated confidentially by the research team, and the information you share will be kept anonymous.
- It is important for you all to respect each other's privacy and anonymity.
- You are not obliged to participate in the focus group, nor are you required to answer any questions you do not wish to answer.

Please take a moment to review and sign the consent form. Let me know if you have any questions.

REVIEW CONSENT FORM AND ANSWER ANY QUESTIONS. COLLECT SIGNED CONSENT FORMS AND ENSURE THAT PARTICIPANTS HAVE A COPY OF THE CONSENT FORM TO TAKE WITH THEM. HAVE PENS AVAILABLE FOR EACH PARTICIPANT.

THE COMPLETION OF THE INTRODUCTORY SECTION OF THE FOCUS GROUP SHOULD TAKE APPROXIMATELY 10-15 MINUTES.

OPENING COMMENTS

1. Introduction

Hello everyone. Thank you all for agreeing to participate in this research project, I really appreciate it. I just wanted to introduce myself and Jenn. My name is Jacquie van Ierssel. I am a PhD candidate at the University of Ottawa in the School of Human Kinetics, and a registered physiotherapist and I work with concussion patients in my clinical practice. This is part of my PhD thesis to develop a health-related quality of life questionnaire to help us understand how concussion symptoms have impacted your life. So I'm hoping to get as much from you as possible in terms of what you would like reflected in the questionnaire, what you would like asked, what you think would help us help you. And we want to get it from the best source, which is you, because you know what you need best. Please feel free to ask questions at any time. I hope this will be a very open discussion. Jenn is also a PhD candidate and a physiotherapist working with individuals with TBI.

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- I will ask some broad questions to stimulate discussion and ask you to discuss them amongst yourselves.
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- We will be taking a 5-minute break refreshment midway through our discussion. Please feel free to enjoy the refreshments provided at the table at this time.

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- Only I, my academic supervisors, and the research team will have access to the tapes and transcripts (anonymised) of this focus group.

4. Participant Introductions

Let's go around the room and introduce ourselves. Tell us your first name only and why you decided to participate in the focus group.

DISCUSSION QUESTIONS

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WRAP-UP

- Before leaving, could everyone please fill in a background information sheet and hand it in to help us generally describe the kind of people who were part of the group and how that might impact the results of the study? Please do not put your name on the sheet.

- Remember to respect each others' privacy and anonymity once you leave, and do not reveal the identities of the other participants nor indicate who made specific comments during the discussion.

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DO NOT PUT YOUR NAME ON THIS SHEET.

Participant Study No.: _____

Instructions: Please provide us with the following information about yourself.

Birthdate: Month: _____ Year: _____

Self-Identified Gender:

- ☐ Male
- ☐ Female
- ☐ Other. I identify as _____

Race

- ☐ Caucasian
- ☐ Asian
- ☐ African/Caribbean Canadian
- ☐ First Nations
- ☐ Other

Marital Status:

- ☐ Single
- ☐ Married
- ☐ Separated
- ☐ Divorced
- ☐ Common-law

Number of Years of Education Completed

- ☐ Elementary school
- ☐ High school
- ☐ College degree/diploma
- ☐ Bachelor's degree
- ☐ Graduate/professional degree
- ☐ Post-graduate degree

Employment Status ***BEFORE*** Injury

- ❑ Employed full-time
- ❑ Employed part-time
- ❑ Unemployed
- ❑ Homemaker
- ❑ Student
- ❑ Disability
- ❑ Retired

Able to Return to Work

- ❑ Yes
- ❑ No

Able to Return to Work at Same Level

- ❑ Yes
- ❑ No

Able to Return to Work

- ❑ Full-time
- ❑ Part-time

Current Annual household income

- ❑ Less than $24,999
- ❑ $25,000 to $49,000
- ❑ $50,000 to $99,000
- ❑ $100,000 to $149,000
- ❑ $150,000 or more

Date of most recent concussion: _____

Mechanism of Injury

- ❑ Sport-related concussion
- ❑ Motor vehicle accident
- ❑ Accident
- ❑ Fall
- ❑ Assault
- ❑ Other

Number of previous diagnosed concussions

- ❑ 0
- ❑ 1
- ❑ 2
- ❑ 3
- ❑ 4

Number of suspected concussions

- ❑ 0
- ❑ 1
- ❑ 2
- ❑ 3
- ❑ 4

PARTICIPANT INFORMED CONSENT FORM
CLINICIAN

Title of Study: Health-Related Quality of Life in Adults after Concussion

Local Site Principal Investigator (PI): **Shawn Marshall** MD, MSc, FRCPC
Faculty of Medicine
Division of Physical Medicine and Rehabilitation
The Ottawa Hospital Rehabilitation Centre
Tel.: 613-737-8899 ext. 75306

Co-Investigators: **Jacquie van Ierssel** PT, PhD(candidate)
School of Human Kinetics
Faculty of Health Sciences
University of Ottawa
Tel.: 613-562-5800 ext. 7099

Heidi Sveistrup PhD
School of Rehabilitation Sciences
Faculty of Health Sciences
University of Ottawa
Tel.: 613-562-5800 ext. 7101

Sponsor:

This study is not being funded and is being done by the PhD candidate as part of the PhD in Human Kinetics program at the University of Ottawa.

Taking part in this study is voluntary. Please read this Participant Informed Consent Form carefully before you decide if you would like to take part. Ask the study team as many questions as you like.

Why am I being given this form?

You are now being asked to take part in a research study because of your expertise in concussion. As a clinician working with concussion patients, you may have unique insight into how they are affected.

Why is this study being done?

This discussion is to follow up on suggestions from previous patients in the study who gave us ideas what to include in a health-related quality of life questionnaire. We would like to know if the questionnaire reflects these ideas, and if you have any suggestions to improve the questions or its format.
We expect up to 20 patients will take part in this study.

How is the study designed?

This is a qualitative study.

What is expected of me?

You will be asked to read over the questionnaire we have developed to see if you understand it, and offer any suggestions for improvement. This may mean adding, removing, or changing some of the content of the questions, how the question is asked, or how it looks on the page. This will about 60 minutes. This one-on-one meeting will take place with the lead researcher in a quiet meeting room at the Ottawa Hospital Rehabilitation Centre, or at a quiet location near you, such as a local library or community centre. You do not have to answer any questions you do not want to. Taking part is completely voluntary.

How long will I be involved in the study?

The whole study will last about 6 months. Your part in the study will only be the 30-minute review of the questionnaire.

What are the potential risks I may experience?

You may feel some fatigue or worse symptoms because of the room, or because you will be asked to think for up to 1 hour. You may not like all of the questions that you are asked. You do not have to answer any questions that make you uncomfortable.

All of your data will be kept confidential by the research team, and you will not be able to be identified from any information you contribute in the focus group. All group members will be asked not to tell anyone who was in the group or any specific comments that were made during the small group discussion. The researchers cannot guarantee that all members of the group will respect each other's privacy and anonymity outside the small group.

Can I expect to benefit from participating in this research study?

You will not get any direct benefit from taking part in this study. This study may help the researchers to better understand how concussion symptoms affect quality of life. This may help to take better care of adults who have a concussion in the future.

Do I have to participate? What alternatives do I have? If I agree now, can I change my mind and withdraw later?

Taking part in this study is voluntary. The alternative to this study is not to take part.

You may chose not to be in this study, or to be in the study now, and then change your mind later without affecting you or any patient's future care at The Ottawa Hospital.

If you withdraw your consent, you may ask that your study data, including answers to questions, not be used.

Will I be paid for my participation or will there be any additional costs to me?

You will be given a parking voucher or bus fare for the day of the study.

How is my personal information being protected?

All your data from this study will be given a unique study number, and will not contain any information that identifies you, such as your name, contact numbers, email, or where you work. The link between your unique study number and your name and contact information will be stored securely and separate from your study records, and will not leave the locked research office.

Any documents or samples leaving the University of Ottawa will contain only your unique study number. This includes publications or presentations resulting from this study.
Information that identifies you will be released only if it is required by law.
For audit purposes only, your original study records may be reviewed under the supervision of Dr. Shawn Marshall's staff by representatives from the Ottawa Health Science Network Research Ethics Board (OHSN-REB) and The Ottawa Hospital.

Research records will be kept for 10 years, after this time they will be destroyed.

Do the investigators have any conflicts of interest?

There are no conflicts of interest to declare related to this study.

Who do I contact if I have any further questions?

If you have any questions about this study, please contact Jacquie van Ierssel at _____ or at 613-562-5800 ext 7099.

The Ottawa Health Science Network Research Ethics Board (OHSN-REB) has reviewed the plans for this research study. The Board considers the ethical aspects of all research studies involving human participants at The Ottawa Hospital Rehabilitation Centre. If you have any questions about your rights as a study participant, you may contact the Chairperson at 613-798-5555, extension 16719.

Consent to Participate in Research

- I understand that I am being asked to participate in a research study about health-related quality of life in adults after concussion.
- This study was explained to me by _____.
- I have read, or have had it read to me, each page of this Participant Informed Consent Form.
- All of my questions have been answered to my satisfaction.
- If I decide later that I would like to withdraw my participation and/or consent from the study, I can do so at any time.
- I voluntarily agree to participate in this study.
- I will be given a copy of this signed Participant Informed Consent Form.

I agree to be audio recorded. Yes ☐ No ☐ Initials ___

_____	_____	_____
Participant's Printed Name	Participant's Signature	Date

Investigator or Delegate Statement

I have carefully explained the study to the study participant. To the best of my knowledge, the participant understands the nature, demands, risks and benefits involved in taking part in this study.

_____	_____	_____
Investigator/Delegate's Printed Name	Investigator/Delegate's Signature	Date

PARTICIPANT INFORMED CONSENT FORM
CLINICIAN

Title of Study: Health-Related Quality of Life in Adults after Concussion

Local Site Principal Investigator (PI): **Shawn Marshall** MD, MSc, FRCPC
Faculty of Medicine
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Tel.: 613-562-5800 ext. 7101

Sponsor:

This study is not being funded and is being done by the PhD candidate as part of the PhD in Human Kinetics program at the University of Ottawa.

Taking part in this study is voluntary. Please read this Participant Informed Consent Form carefully before you decide if you would like to take part. Ask the study team as many questions as you like.

Why am I being given this form?

You are now being asked to take part in a research study because of your expertise in concussion. As a clinician working with concussion patients, you may have unique insight into how they are affected.

Why is this study being done?

To help adults after a concussion, we are would like to understand how their symptoms affect their quality of life. This study is part of a project to create a questionnaire for adults to better treat their needs and assess their recovery after a concussion.

We expect up to 10 clinicians will take part in this study.

How is the study designed?

This is a qualitative study.

What is expected of me?

You will be asked to take part in a one-on-one discussion. You will be asked to talk about how concussion symptoms affect a patient's quality of life. You will also be asked to look at questionnaires and talk about questions that you feel may be relevant or missing. You may skip any questions that make you uncomfortable or that you do not wish to answer. This will last about 30 minutes. You may also be asked to take part in a follow-up discussion to review the questionnaire developed from patient and clinician discussions and give any suggestions for improvement. This will take about 30 minutes. You may take part in either discussion or both. Discussions will take place either by telephone or in-person at a site chosen by you. Discussions will be audio recorded and notes will be taken by the researcher. You may still take part in the study if you do not wish to be audio recorded.

How long will I be involved in the study?

The whole study will last about 6 months. Your part in the study will last only for one discussion, about 30 minutes.

What are the potential risks I may experience?

There are no risks from taking part in this study.

Can I expect to benefit from participating in this research study?

You will not get any direct benefit from taking part in this study. This study may help the researchers to better understand how concussion symptoms affect a patient's quality of life. This may help to take better care of adults who have a concussion in the future.

Do I have to participate? What alternatives do I have? If I agree now, can I change my mind and withdraw later?

Taking part in this study is voluntary. The alternative to this study is not to take part.

You may chose not to be in this study, or to be in the study now, and then change your mind later without affecting you or any patient's future care at The Ottawa Hospital.

If you withdraw your consent, you may ask that your study data, including answers to questions, not be used.

Will I be paid for my participation or will there be any additional costs to me?

You will be given a parking voucher or bus fare for the day of the study.

How is my personal information being protected?

All your data from this study will be given a unique study number, and will not contain any information that identifies you, such as your name, contact numbers, email, or where you work. The link between your unique study number and your name and contact information will be stored securely and separate from your study records, and will not leave the locked research office.

Any documents or samples leaving the University of Ottawa will contain only your unique study number. This includes publications or presentations resulting from this study.
Information that identifies you will be released only if it is required by law.
For audit purposes only, your original study records may be reviewed under the supervision of Dr. Shawn Marshall's staff by representatives from the Ottawa Health Science Network Research Ethics Board (OHSN-REB) and The Ottawa Hospital.

Research records will be kept for 10 years, after this time they will be destroyed.

Do the investigators have any conflicts of interest?

There are no conflicts of interest to declare related to this study.

Who do I contact if I have any further questions?

If you have any questions about this study, please contact Jacquie van Ierssel at _____ or at 613-562-5800 ext 7099.

The Ottawa Health Science Network Research Ethics Board (OHSN-REB) has reviewed the plans for this research study. The Board considers the ethical aspects of all research studies involving human participants at The Ottawa Hospital Rehabilitation Centre. If you have any questions about your rights as a study participant, you may contact the Chairperson at 613-798-5555, extension 16719.

Health-Related Quality of Life in Adults after Concussion

Consent to Participate in Research

- I understand that I am being asked to participate in a research study about health-related quality of life in adults after concussion.
- This study was explained to me by _____.
- I have read, or have had it read to me, each page of this Participant Informed Consent Form.
- All of my questions have been answered to my satisfaction.
- If I decide later that I would like to withdraw my participation and/or consent from the study, I can do so at any time.
- I voluntarily agree to participate in this study.
- I will be given a copy of this signed Participant Informed Consent Form.

I agree to be audio recorded. Yes ☐ No ☐ Initials ___

_____	_____	_____
Participant's Printed Name	Participant's Signature	Date

Investigator or Delegate Statement

I have carefully explained the study to the study participant. To the best of my knowledge, the participant understands the nature, demands, risks and benefits involved in taking part in this study.

_____	_____	_____
Investigator/Delegate's Printed Name	Investigator/Delegate's Signature	Date

Appendix C: Published Manuscripts and Permission

BMJ Open

Protocol for the mixed-methods development of a concussion-specific health-related quality of life outcome measure based on the international classification of functioning, disability and health

Jacqueline van Ierssel,[1] Heidi Sveistrup,[2] Shawn Marshall[3,4]

To cite: van Ierssel J, Sveistrup H, Marshall S. Protocol for the mixed-methods development of a concussion-specific health-related quality of life outcome measure based on the international classification of functioning, disability and health. *BMJ Open* 2018;**8**:e022240. doi:10.1136/bmjopen-2018-022240

► Prepublication history for this paper is available online. To view these files please visit the journal online (http://dx.doi.org/10.1136/bmjopen-2018-022240).

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For numbered affiliations see end of article.

ABSTRACT

Introduction Recovery from concussion has traditionally been evaluated by patient-reported symptoms, objective measures such as loss of consciousness, specific dimensions such as depression or fatigue, cognitive status, employment status, level of physical activity and the more complex construct of disability. Increasingly, patient-reported outcome measures of health-related quality of life (HRQOL) are being emphasised as an important end point in patient care, clinical trial and health policy decisions. Currently, no standardised concussion-specific HRQOL outcome measure exists. The process for developing a concussion-specific HRQOL outcome measure based on the international classification of functioning, disability and health is outlined.

Methods and analysis A multistage, patient-centred approach to developing the outcome measure will integrate evidence from systematic reviews, qualitative research and cognitive interviewing into a self-report questionnaire to guide clinical decision-making. The psychometric properties of the questionnaire will be evaluated to assess the inter-rater reliability and construct validity of the measure in individuals with persistent post-concussion symptoms. To date, the systematic review and the clinical expert interviews within the preparatory phase have been completed and work is progressing on the subsequent phases. It is anticipated that the outcome measure will be ready for psychometric testing in September 2018.

Ethics and dissemination Ethical approval was granted by the Ottawa Health Science Network Research Ethics Board (Protocol #20170720-01H) on 31 October 2017 to conduct the patient and clinical expert interviews. Ethical approval for psychometric testing of the outcome measure will be sought by the Ottawa Health Science Network Research Ethics Board in Phase II, after the development of the final HRQOL questionnaire. Results will be disseminated through peer-reviewed journals and professional conferences.

PROSPERO registration Phase I systematic review registration number CRD42017075588 (15 June 2017). Phase II systematic review registration number CRD42017075588 (27 September 2017).

Strengths and limitations of this study

- This study follows the recommendations of the Food and Drug Administration for the development of patient-reported outcome measures.
- The questionnaire will be developed based on a conceptual model to identify the components of health-related quality of life post-concussion and the causal relationships between them.
- Patient contribution to item generation will maximise the content validity of the outcome measure by ensuring that the items on the questionnaire are relevant to patients with persistent post-concussion symptoms.
- Linking items on the questionnaire to the International Classification of Functioning, Disability and Health will enable content comparison of outcome measures and facilitate clinical decision-making by allowing multidisciplinary healthcare professionals to set meaningful patient-directed goals.
- Currently, no concussion-specific HRQOL outcome measure exists; therefore, there is no gold-standard measure against which to evaluate criterion validity of a newly developed questionnaire.

INTRODUCTION

Concussion represents a distinct subset of traumatic brain injury (TBI) at the milder end of severity, which falls outside the expected clinical presentation seen with moderate–severe TBI. The term concussion may be used interchangeably with mild TBI (mTBI) and is defined by The American Congress of Rehabilitation Medicine as a traumatically induced physiological disruption of brain function, as manifested by at least of the following: (1) any period of loss of consciousness; (2) any loss of memory for events immediately before or after the accident; (3) any alteration in mental state at the time of injury

such as feeling dazed, disoriented or confused and (4) focal neurological deficit(s) which may or may not be transient.[1] The severity of the injury may not exceed the following: (1) loss of consciousness of approximately 30 min or less; (2) after 30 min, an initial Glasgow Coma Scale (GCS) of 13–15 and (3) post-traumatic amnesia not greater than 24 hours. Both the International Collaboration of Mild Traumatic Brain Injury Prognosis and the US Department of Defense differentiate mTBI from moderate-severe TBI by the absence of structural abnormalities on either CT or MRI.[2] An expert consensus panel of concussion in sport supports this assertion, stating that the acute clinical symptoms perceived following an mTBI reflect a functional disturbance rather than a structural injury.[3] Structural abnormalities seen in patients with a GCS of 13–15 (complicated mTBI) have been associated with increased disability compared with those without intracranial pathology,[4] supporting the notion that recovery from complicated mTBI is more consistent with that from moderate to severe TBI than uncomplicated mTBI (no evidence of CT abnormalities).[5]

Mild TBI may be further differentiated from moderate-severe TBI based on functional outcome. The extended GCS (GOS-E) is considered the 'gold standard' for functional outcome following TBI. Using a cut-off of 7 on the GOS-E to indicate good recovery, a longitudinal study found that less than one-quarter of mTBI patients continued to experience restrictions in work and social participation and limitations in activities of daily living at 1 year after injury. In contrast, GOS-E scores for 62% of patients with severe TBI and 48% of patients with moderate TBI indicated residual disability at 24 months, with a 'plateauing' of recovery after 12 months[6]. Moderate to severe TBI is, thus, frequently associated with functional dependence both in and outside the home and reduced work and social participation due to cognitive and physical disabilities.

Differences in structural damage, mortality rates, functional outcomes and increased rates of disability suggest that recovery from concussion should be evaluated separately from moderate to severe TBI. This paper will use the term concussion to denote mTBI without the presence of structural abnormalities on standard neurodiagnostic imaging and will focus on those patients with persistent post-concussion symptoms (PPCS), with persistent defined as 3 months or longer postinjury.

Most concussion patients are expected to make a full recovery and return to work and other preinjury activities within days to months. Although best evidence suggests that objective cognitive deficits are not measurable beyond the 3-month period of expected normal recovery post-concussion,[5] 10–15% will go on to develop PPCS, which may persist for months or years.[7] Common symptoms such as headache, fatigue and difficulty concentrating are non-specific to concussion and do not differ significantly from general trauma patients.[4] Since overall mortality and functional dependence following a concussion is rare, it is unclear whether poor outcomes can be attributed to concussion-related brain changes, pre-existing conditions or other factors.

Recovery from concussion has traditionally been evaluated by multimodal measures, such as patient-reported symptoms, objective measures such as loss of consciousness, specific dimensions such as depression or fatigue, cognitive status, employment status, level of physical activity and the more complex construct of disability. However, these measures do not fully capture the *significance* of the impairments or level of participation postinjury as experienced by the individual.

The Interagency Common Data Elements TBI Outcomes Workgroup identified health-related quality of life (HRQOL) as a core construct to be assessed, covering domains relevant to concussion; applied as either part of a comprehensive battery or in addition to other outcome measures.[8] The International Society for Quality of Life Research defines HRQOL as 'the functional effect of a medical condition and/or its consequent therapy on a patient'.[9] HRQOL is often erroneously inferred from other measures of health, such as symptoms, functioning or health status. Symptoms represent a patient's perception of an abnormal physical, emotional or cognitive state.[10] Functioning is defined by the International Classification of Functioning, Disability and Health (ICF) as 'an umbrella term encompassing all body functions, activities and participation'.[11] Whereas the WHO describes health as 'a state of complete physical, mental and social well-being not merely the absence of disease'.[12] When seen from a negative perspective, impairments in body function, activity limitations of the individual and participation restrictions at a societal level are described as disability.[11] While the above measures of health may influence a patient's HRQOL, they do not represent it. What distinguishes HRQOL is the patient's perception of the relative importance of these measures, their own values and their preferences.[13] Although HRQOL is intuitively understood, it must be explicitly distinguished from other related terms, as they represent distinct constructs. Generic HRQOL outcome measures incorporate items across multiple domains to capture a broad spectrum of issues, allowing comparison between populations and various disease states. However, generic measures, such as the WHO quality of life-brief (WHOQOL-BREF) may be insensitive to small, but clinically relevant changes to concepts important to a concussion population, such as persistent problems with cognitive functioning, or social isolation.

Condition-specific HRQOL outcome measures on the other hand, have the advantage of exploring specific health concerns in depth by incorporating items most relevant to a specific patient group and are therefore more sensitive to clinical changes that occur within those individuals.[14] Currently, no standardised concussion-specific HRQOL outcome measure exists.

It has been suggested that the ICF provides an ideal base for the development of new outcome measures in individuals with TBI.[15] Adopted by the WHO in 2001, the

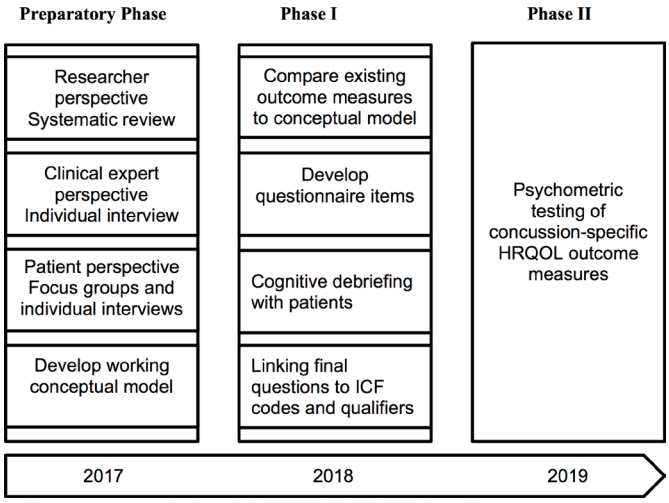

Figure 1 Mixed-method development process of a concussion-specific health-related quality of life (HRQOL) outcome measure based on the International Classification of Functioning for a multistage project started in 2017, with a projected completion date of 2019. The preparatory phase describes the development of a conceptual model of HRQOL; phase I describes the development of a HRQOL questionnaire based on the conceptual model; phase II refers to the assessment of questionnaire's test–retest reliability and construct validity with the WHO quality of life-brief and quality of life after brain injury in a concussion population. Embedded boxes within each phase represent the distinct steps required to complete each phase in successive order.

ICF serves as a universally accepted reference system to classify functioning and disability.[16] Using a biopsychosocial model, the ICF provides a standard language and a conceptual basis to describe health.[17] Both comprehensive and brief ICF core sets for TBI have been developed as a means of describing concepts most relevant to the health of an individual after TBI.[15] Questionnaires are constructed of items that measure an intended concept, such as headache. For example, headache is a common post-concussion concept measured by the item 'Headache' on the symptom evaluation scale of the Sport Concussion Assessment Tool-5[18] and by the broader item 'How often do you suffer (physical) pain?' on the WHOQOL-100.[19] This relationship enables the mapping of concepts to ICF categories.[15] Linking newly developed questionnaire items to ICF categories would enable the comparison of the content of various outcome measures and facilitate communication between multidisciplinary healthcare providers by providing a common language with which to describe function, disability and health.

Persistent post-concussion symptoms significantly impact a broad set of concepts that span across all domains of the ICF. These concepts then influence HRQOL. Measuring HRQOL as a construct determined by these concepts makes conceptual sense in a TBI population, since there is often no relationship between these causal indicators.[20] The purpose of this paper is, thus, to present the steps in the development of a concussion-specific HRQOL outcome measure based on the ICF (figure 1). The construct of HRQOL will be measured as a reflection of multidimensional concepts. In keeping with patient-centred outcomes research, the process is patient driven and consists of multiple phases.

METHODS

Patient and public involvement

Patient involvement will be a keystone in the development of a concussion-specific questionnaire. Within the overarching construct of quality of life, patients will be specifically asked to identify those issues that are greatest importance to them and what issues they would like addressed in a questionnaire based on their lived experience with PPCS. Additionally, their input is being sought in the design of the questionnaire formatting. Clinician input will also be sought to identify issues that may have relevance to patients with PPCS. This will be an iterative process, such that patient preferences and clinician feedback will be reviewed in subsequent discussions to ensure that the views of the patients and clinicians are well represented in the questionnaire. Finally, the working questionnaire will be brought back to a sample of patients to confirm that their priorities and preferences have been adequately captured. On completion of the study, patients and clinicians who have participated in the study will be provided with an electronic copy of the final questionnaire.

The development of a concussion-specific HRQOL outcome measure involves three distinct phases: a preparatory phase, phase I and phase II. The preparatory phase involves the development of a conceptual model, which will form the framework for the concepts to be included in the questionnaire. In phase I, the identified concepts will be transformed into a concussion-specific HRQOL questionnaire. Phase II involves the psychometric testing of the questionnaire in patients with PPCS.

Preparatory phase—development of a conceptual model

Within the preparatory phase, a systematic review has already been performed to develop a *working* conceptual model consisting of broad domains that have been linked to the ICF. Qualitative interviews with clinicians and patient focus groups will identify the specific concepts within each domain that are impacted by concussion in order to further develop and refine the working conceptual model. The *final* conceptual model will be developed through content analysis of the qualitative data.

Researcher perspective: systematic review

A systematic review was undertaken to identify the HRQOL outcome measures used in concussion-specific research since the introduction of the International Classification of Diseases, Tenth Edition code for concussion in 1992. The specific objectives of the review were (1) to identify the concepts contained in the measures using the ICF as a reference,[21 22] (2) to describe the breadth and depth of concepts and (3) to develop a working conceptual model

of HRQOL in individuals with PPCS based on the concepts identified. Eight electronic databases were searched from 1 January 1992 to 12 March 2017, including Medline (OVID), Embase (OVID), PsycINFO (OVID), Cumulative Index to Nursing and Allied Health Literature (CINAHL) (EBSCO), SCOPUS, the Cochrane Database for Systematic Reviews, Prospero and Patient-Reported Outcome and Quality of Life Database (PROQOLID; http://www.qolid.org). Grey literature was searched, reference lists scanned and relevant journals hand-searched. Search terms included database subject headings and keywords for the concepts: 'concussion', 'traumatic brain injury' and 'quality of life' using a Boolean strategy and adapted for each database.

Studies were eligible if they involved primary qualitative or quantitative research exploring the impact of PPCS on HRQOL in adults aged 18–65 years with a diagnosis of concussion. Studies were excluded if they included the results of a moderate–severe TBI sample not differentiated from the concussion sample or patients presented with evidence of structural injury or intracranial bleeding on diagnostic imaging.

Content analysis was performed on individual questions within identified outcome measures by linking concepts to second level ICF categories according to established linkage rules.[21 23] Concepts were then organised into domains at the ICF component level. A working conceptual model of HRQOL post-concussion was proposed based on these results to inform the content of semistructured interviews with clinicians and patient focus groups. This systematic review has been registered with PROSPERO (CRD42017068241).

Clinician perspective: individual interviews

The importance of clinician interviews in the development of an HRQOL outcome measure is twofold. First, clinicians will improve content validity by identifying clinically important domains that should be considered in the conceptual model. Additionally, clinicians in this study will be asked to identify perceived facilitators and barriers to the use of a concussion-specific HRQOL outcome measure in their clinical practice.

Clinicians will be purposively sampled to represent the diverse healthcare provider groups who treat the key domains from which PPCS are comprised. Eligibility includes a minimum of 3 years of clinical experience working with concussion patients and will include at least one representative from each of the following groups: physicians, neuropsychologists, physiotherapists, occupational therapists, neuro-optometrists and speech-language pathologists. These clinicians will be chosen based on their recognition as national experts in the management of post-concussion symptoms, as evidenced by their membership in national concussion guidelines working groups. Written informed consent is required prior to participation.

Concepts perceived by clinicians to have an impact on the HRQOL of patients with PPCS will be identified through semistructured interviews and linked to second level ICF categories. Feedback from clinicians on the use of an HRQOL outcome measure will be incorporated into the design of the questionnaire to facilitate the implementation of the final questionnaire in clinical practice.

Patient perspective: focus groups

A comprehensive list of HRQOL concepts that are relevant to patients with PPCS will be collected using focus groups and linked to second level ICF categories using content analysis.

Patients will be recruited from the Acquired Brain Injury Outpatient Clinic at the Ottawa Hospital Rehabilitation Centre and from community-based medical clinics throughout Ottawa with known concussion management programmes.

Patients will be considered eligible for inclusion if they are English speakers between the ages of 18 and 65 years and have experienced persistent symptoms for at least 3 months following a diagnosed concussion sustained between 2008 and 2018. Patients will be excluded if they have a diagnosis of moderate-severe TBI, if they were receiving treatment for a pre-existing mental health disorder or addiction at the time of injury or if there is evidence of post-traumatic structural injury or intracranial bleeding on diagnostic imaging, if available. Written informed consent is required from all patients prior to participating in the study.

We estimate that a minimum of 30 patients will be sufficient to reach data saturation. The patient perspective will be used to expand on and refine the working conceptual model and identify the most relevant emerging concepts.

Patients will be asked to identify how their concussion has impacted their HRQOL through open-ended questions and review of existing questionnaires, guided by the working conceptual model. Concepts derived from patient focus group discussions will be extracted using content analysis and linked to second level ICF categories. Concepts will then be deductively coded into the domains of the working conceptual model. An inductive approach will also be used to add additional domains as needed to reflect emerging concepts from the data. Data collection and linking will be conducted iteratively during multiple rounds of focus group discussions so that patients in subsequent groups can confirm the relevance and importance of concepts that have emerged from earlier discussions. Two independent researchers will review the domains established through coding to agree on the final conceptual model. Discrepancies will be resolved through discussion with a third researcher.

Intercoder reliability between the researchers will be determined by using the kappa statistic for inter-rater reliability on a select sample of transcripts. A kappa of >0.7 will be considered acceptable for intercoder reliability.

Phase I development of a concussion-specific HRQOL questionnaire

Systematic review

A systematic review will be conducted to determine if existing generic and TBI-specific HRQOL outcome

measures possess sufficient content validity to evaluate outcomes in concussion research. The specific objectives of the review are: (1) to identify existing generic and TBI-specific outcome measures currently being used to evaluate HRQOL in patients post-concussion; (2) to compare the content of existing outcome measures with the concussion-specific conceptual model of HRQOL and (3) to assess whether questions in existing measures reflect domains in the conceptual model (content relevance) and whether all the domains in the conceptual model are represented appropriately (content representativeness) by questions in the identified measures. It is hypothesised that existing HRQOL outcome measures contain both questions that are relevant to concussion patients, such as cognitive abilities, and questions not identified by patients as relevant to their HRQOL post-concussion, such as satisfaction with bodily appearance. More importantly, it is hypothesised that some concussion-specific domains identified by the conceptual model will be under-represented or absent from existing questionnaires, such as social isolation, sense of identity, uncertainty of prognosis or the stigma of an invisible injury.

Eight electronic databases will be searched from 1 January 1992 onwards, including Medline (OVID), Embase (OVID), PsycINFO (OVID), Cumulative Index to Nursing and Allied Health Literature (CINAHL) (EBSCO), SCOPUS, the Cochrane Database for Systematic Reviews, Prospero and Patient-Reported Outcome and Quality of Life Database (PROQOLID; http://www.qolid.org). Grey literature will be searched, reference lists scanned and relevant journals hand-searched. Search terms will include database subject headings and keywords for the concepts: 'concussion', 'traumatic brain injury', and 'quality of life' using a Boolean strategy and adapted for each database.

Studies will be included if they assess self-reported HRQOL in adults aged 18–65 years with persistent symptoms 1 month or more following a diagnosed concussion. Studies using proxy measures, single-item rating scales or involving concussion sustained in conjunction with multiple trauma will be excluded.

Specific questions from existing outcome measures will be linked to second level ICF categories to facilitate content comparison between existing outcome measures and the concussion-specific conceptual model.[16] This will provide a comprehensive understanding of the conceptual basis of what is being measured by each of the outcome measures and identify any potential gaps in assessment tools. Content validity will be assessed with respect to content relevance and representativeness. Within each outcome measure, individual questions will be considered to possess content relevance if they can be linked to second level ICF categories of the concussion-specific conceptual model. Content representativeness will be assessed to determine the extent to which the relevant domains within each outcome measure may be over-represented, under-represented or excluded. If the balance is wrong, the outcome measure will lack content validity. Consistent with the previous studies, existing HRQOL outcome measures will be considered to possess acceptable content validity if 75% or more of the questions demonstrate both content relevance and content representativeness.[24] Psychometric properties, including reliability, and responsiveness in a concussion population will be extracted and analysed from published reports for any existing measures that meet the above criteria. Outcome measures will be considered suitable for use in a concussion population if they demonstrate a minimum threshold of a kappa statistic of 0.7 for intra-rater reliability, and at least a moderate effect size of 0.5 for responsiveness, to indicate the ability to measure clinically important change in patients with PPCS.[25 26] Support for a new concussion-specific HRQOL outcome measure will be established if existing outcome measures do not meet the above criteria.

This systematic review has been registered with PROSPERO (CRD42017075588).

Pilot-questionnaire development

Concepts from the final conceptual model will be transformed from second level ICF codes into a comprehensive list of subjective questions for a pilot concussion-specific HRQOL outcome measure, hereafter referred to as the CONcussion quality of life (CONQOL). The CONQOL will be constructed as a self-administered questionnaire that evaluates the *impact* of each concept on HRQOL, as opposed to how *satisfied* or *bothered* a patient is by the concept identified in the question; for example, 'How much does the stigma of an invisible injury impact your health-related quality of life?'. Framing the questions from the perspective of how much each concept *impacts* HRQOL more directly measures the extent of the problem; whereas HRQOL questions traditionally framed as satisfaction or bother may be confusing for patients to disentangle the magnitude of functional limitations or activity restrictions from their ability to cope with the problem.

Patients will be asked to quantify the magnitude of time or severity of each concept within the past week. This interval was chosen to minimise the risk of recall bias and respondent burden, while balancing sufficient time for the participant to provide a reliable estimate of the impact of PPCS on their HRQOL. Additionally, the persistent nature of PPCS makes natural healing effects unlikely within the specified timeline. The magnitude or severity of each question will be rated on a five-point Likert scale with both descriptive and numerical anchor points for each response (0=No problem 0%–4%; 1=MILD problem 5%–24%; 2=MODERATE problem 25%–49%; 3=SEVERE problem 50%–95% and 4=COMPLETE problem 96%–100%) consistent with the generic qualifiers used to classify ICF codes (see table 1).[11]

Respondents will then be required to rank the top three concerns identified on the questionnaire. Finally, the CONQOL will enable the respondent to identify in an

Table 1 Proposed response scale consistent with the ICF qualifiers

Response options	Descriptor	Scaling
0	No problem	0%–4% of the time
1	Mild problem	5%–24% of the time
2	Moderate problem	25%–49% of the time
3	Severe problem	50%–95% of the time
4	Complete problem	96%–100% of the time

Adapted from ICF, by WHO (2001).
ICF, International Classification of Functioning, Disability and Health.

open-ended qualitative format up to three goals they wish to accomplish with treatment that would have a positive impact on their HRQOL. For each goal, the respondent will be prompted to rate both how important the goal is and to what extent they have achieved it on a 10-point Likert scale (1=not at all; 10=extremely/completely). The addition of patient-reported goals is intended to facilitate clinician–patient communication and identify priorities for interventions. The CONQOL will be scored as an index, with scores generated for each subdomain, and an overall summative score. Each subdomain will be grouped to represent functional domains identified in standardised concussion guidelines, such as cognitive, emotional and vestibular domains, where appropriate. Grouping questions by functional domains will allow clinicians to identify areas that need to be assessed in more detail through further probing of symptoms and standardised outcome measures. This will streamline the clinical assessment based on those domains that have the greatest impact on the patients' HRQOL.

Finally, the CONQOL will include a section that prompts clinicians to provide patients with relevant concussion-specific resources, such as external organisations that provide educational modules, websites, informative handouts and standardised guidelines. Thus, the CONQOL will function to evaluate HRQOL, guide clinical decision-making and provide patient education.

Cognitive interviewing

The CONQOL will then be pretested using face-to-face cognitive interviewing to identify any problems with the questionnaire items, formatting or administration. The purpose is to ensure patient understanding, appropriateness of response options and recall period, level of readability and completeness of the concepts contained in the questions.[27 28] This process is necessary to improve the design of the CONQOL by informing revision decisions and providing evidence of content validity. Cognitive interviews will be performed using the 'think-aloud' technique to describe the patients' thought process as they read each question, followed by 'verbal probing' if necessary to clarify any sources of confusion.[29]

This process will be an iterative approach with multiple rounds of interviewing and item revision. Consistent with published recommendations, a minimum sample size of 15 will be sought to increase the probability of detecting problems with the pilot questionnaire.[29] Initial interviews will explore major conceptual problems and global issues with the CONQOL, with an emphasis on conceptual clarity, content coverage and respondent burden. Subsequent interviews will focus on structural or logical problems with the CONQOL such as unclear wording, grouping of questions, formatting issues and appropriateness of questions. Varying perspectives will be elicited by selecting patients across a broad representation of demographics, mechanism of injury, previous history of concussion, employment characteristics and time since injury. Written informed consent will be obtained.

Questionnaire refinement

Following each round of interviewing, the questionnaire development team will identify problems on an item-by-item basis using the Question Appraisal System-99.[30] Similar to the qualitative research approach to identify issues of importance during the item generation phase, problems with content or construction will be extracted and coded. The questionnaire development team will discuss and resolve identified problems after each round of interviews. Consensus will be required in order to retain, revise, delete or add additional questions or make structural changes to the questionnaire. Careful attention will be paid to ensure that questions pertaining to each domain of the conceptual model are retained.

Phase II psychometric testing

Psychometric testing in phase II will involve a cross-sectional multicentre study to assess the test–retest reliability and construct validity of the CONQOL. Eligibility criteria for patient recruitment will be consistent with those used for during the qualitative phase of item development.

Test–retest reliablity

The CONQOL will be assessed for test–retest reliability at two time points, separated by 2 weeks. Based on clinical experience and the chronicity of PPCS, a 2-week repeat-measures study is an appropriate timeframe to minimise changes in HRQOL due to either recall bias or physiological recovery. Sample size will be calculated to be able to estimate test–retest correlations with a 95% CI (±0.1) and will follow the recommendation of 5–10 subjects per question on a newly developed outcome measure.[31] The minimum requirement for test–retest reliability will be set at a kappa statistic of ≥0.7.

Internal consistency

Outcome measures that assess a single construct, such as anxiety, contain questions that reflect the effect of the construct.[32] Because these *effect indicators* are correlated, the outcome measure is assumed to have a high degree of internal consistency.[32] The theoretical

nature of HRQOL is such that it may be influenced by many different unrelated concepts. These concepts, called *causal indicators*, are responsible for causing changes in HRQOL, rather than HRQOL affecting the concepts.[32] Correlations between causal indicators may be deliberately low in order for questions to represent a broad set of concepts. For example, if patients with PPCS experience a reduction in their post-traumatic headaches because of a new medication, their HRQOL will improve, even though there has been no change in their exercise tolerance, speed of thinking, level of fatigue or return to work status. Because a patient can endorse one concept (eg, improvement in headache) without implying that they would necessarily endorse another (eg, level of fatigue), the concepts would not be expected to necessarily correlate with each other. Therefore, it would be inappropriate to use statistics based on the assumption of homogeneity, such as internal consistency, interitem correlations or factor analysis to assess the construct of HRQOL, as this might lead to false assumptions about reliability or usefulness of the CONQOL.[32] Therefore, concepts will be allocated to subdomains based on their classification according to ICF chapters. This highlights the importance of significant input from patients with PPCS in the development of the questionnaire in order to ensure a high level of content validation.

Content validation

Evidence for the extent to which the CONQOL measures the important concepts of HRQOL in patients with PPCS will be provided through the rigorous development of the questionnaire based on a concussion-specific conceptual model. Cognitive interviewing with patients will then further confirm evidence of content validation by demonstrating that the questions influence HRQOL, no important concepts were missed and the response options, recall period and questionnaire design are appropriate, comprehensive and understandable.[33] This will ensure that each question on the CONQOL relates to one of the domains of the conceptual model (content relevance) and that each domain of the conceptual model is represented with appropriate importance by at least one question (content representativeness).

Construct validation

Construct validation of the CONQOL will be performed against the generic measure WHOQOL-BREF and the TBI-specific measure Quality of Life after Brain Injury (QOLIBRI) to provide support that the CONQOL measures what it intends to measure. It is hypothesised that the CONQOL will demonstrate moderate to high correlations with these existing measures that evaluate the same construct of HRQOL. Spearman's rank correlation will be used to assess the strength of association between similar subdomains on the outcome measures.

Criterion validation

HRQOL is an unobservable construct that cannot be measured directly. It can only be inferred by how well questions on an outcome measure fit the underlying theory. Since there is no 'gold standard' against which a newly developed HRQOL outcome measure can be compared, testing for criterion validation is not applicable.

Significance of study

The strength of the CONQOL to evaluate change in patients with PPCS will be evidenced by the substantial patient input in the development of the outcome measure, thus providing support for a high level of content validation. This concussion-specific HRQOL outcome measure would meet the specific needs of patients with PPCS by prompting clinicians to ask relevant probing questions, identify concerns, perform appropriate standardised tests, set meaningful patient-directed intervention goals, facilitate referrals to specialists and evaluate change.

The proposed design of the CONQOL to provide clinicians with recommendations for a more focused assessment and educational resources that match patient-identified problems would be a novel use of an HRQOL outcome measure to facilitate patient-centred care.

ETHICS AND DISSEMINATION

No personal health information will be collected during this research, and no personal identifying information will be accessed from records or databases. Only names, telephone number and emails of participants will be available to the research team for the purpose of screening for eligibility and scheduling. Written informed consent will be obtained from all participants prior to taking part in the study. Participants will be assigned a respondent number, and data collected will be de-identified. Data will be processed anonymously and presented as aggregate results.

Within the preparatory phase, no ethical approval is required to perform either systematic review or to develop the pilot questionnaire. Ethical approval was granted by the Ottawa Health Science Network Research Ethics Board (Protocol #20170720–01 hour) on 31 October 2017 to conduct the patient and clinical expert interviews. Ethical approval for psychometric testing of the outcome measure will be sought by the Ottawa Health Science Network Research Ethics Board in Phase II, after the development of the final HRQOL questionnaire.

The results of this project will be distributed to professional groups through peer-reviewed publications and presentations. Additionally, the results of the study will be disseminated to clinicians at conferences and strategic meetings.

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REVIEW

Identifying the concepts contained within health-related quality of life outcome measures in concussion research using the International Classification of Functioning, Disability, and Health as a reference: a systematic review

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Abstract

Purpose To identify the concepts contained within health-related quality of life (HRQOL) outcome measures used in concussion-specific research using the International Classification of Functioning, Disability, and Health (ICF) as a reference.

Methods Eight electronic databases were searched from January 1, 1992 to March 12, 2017. Gray literature was searched, reference lists scanned, and relevant journals hand-searched. Agreement for inclusion was reached by consensus by two reviewers. A standardized data extraction tool was used to document study design, population, and key findings. Questionnaire items were linked as concepts to the corresponding second-level category of the ICF. Quality of studies was not assessed, as review was exploratory.

Results Five outcome measures met the inclusion criteria, including the Perceived Quality of Life Scale, EuroQoL-5 dimensions, Quality of Life after Brain Injury, WHOQOL-100, and WHOQOL-BREF. A total of 373 concepts were extracted. 34 questions were linked to *activities and participation* (50.7%), 16 questions (23.9%) referred to *body functions*, and 17 questions (25.4%) were related to the *environment*.

Conclusions The wide range of concepts covered by different outcome measures demonstrates the complexity of recovery post-concussion and a lack of universal agreement in terms of what should be measured in this population. A working conceptual model of HRQOL post-concussion is proposed. *Registration* Prospero #CRD42017068241 (June 15, 2017).

Keywords Brain injuries · Traumatic · Brain concussion · Persistent post-concussion symptoms · Quality of life · International Classification of Functioning, Disability and Health

Abbreviations

EQ-5D	EuroQoL-5 dimensions
HRQOL	Health-related quality of life
ICD	International classification of diseases
ICF	International Classification of Functioning, Disability and Health
PQOL	Perceived Quality of Life Scale
PPCS	Persistent post-concussion symptoms
QOL	Quality of life
QOLIBRI	Quality of life after brain injury
TBI	Traumatic brain injury
VAS	Visual analogue scale
WHOQOL-100	World Health Organization Quality of Life—100
WHOQOL-BREF	World Health Organization Quality of Life—Brief

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Introduction

While most concussions resolve entirely within days to months post-injury [1], a minority of patients will go on to develop persistent post-concussion symptoms (PPCS) such as headache, balance deficits, mood disorders, and difficulty concentrating, which may persist for many months or years. The long-term consequences of physical, emotional, and cognitive dysfunction may be associated with functional limitations, difficulty in returning to school or work, and an increased risk of depression and anxiety [1, 2], adversely influencing a patient's health-related quality of life (HRQOL).

HRQOL is defined as a multidimensional construct that reflects the impact of physical, emotional, and social well-being on an individual's health status [3]. Increasingly, patient-reported HRQOL is being recognized as an important consideration in the evaluation and treatment of patients with chronic health problems, including PPCS. The ability to evaluate those issues that are of greatest importance to a patient based on their priorities is especially relevant to those with PPCS in which symptoms may persist for months, or years, and for which recovery may, ultimately, be incomplete. HRQOL measures may be used to supplement traditional objective clinical or laboratory measures of disease, to form the framework for future research designed to improve patient HRQOL, assess the effectiveness of interventions, distinguish populations, identify priorities of intervention based on patient relevance, set patient goals, and develop treatment plans using a patient centered approach. It is essential then that HRQOL outcome measures in a PPCS population accurately assess the construct they are intended to measure. Although HRQOL measurement is emerging within the field of concussion, existing generic outcome measures currently being employed may be inadequate for evaluating the specific issues of concern to patients suffering from PPCS.

Despite the increasing interest in HRQOL over recent years, many knowledge gaps remain concerning what HRQOL concepts are relevant to adults with PPCS. A larger project has been established to develop a self-report measure of HRQOL in patients with PPCS for use in clinical trials, epidemiological studies, and clinical practice. An essential step in the development of a concussion-specific HRQOL outcome measure is ensuring content validity by identifying those concepts most relevant to the population.

In May 2001, the World Health Organization (WHO) approved the use of the International Classification of Functioning, Disability and Health (ICF) as a standard language and framework for the description of health and health-related states [4]. As such, the ICF can help identify, quantify, and compare concepts contained within different outcome measures to assess their suitability for use in various populations and across various conditions.

The objective of this systematic review was to explore how HRQOL is being measured in concussion-specific research with existing outcome measures. The specific aims were (i) to identify the concepts contained in the outcome measures using the ICF as a reference; (ii) to describe the breadth and depth of concepts between outcome measures; and (iii) to develop a working conceptual model of HRQOL in individuals with PPCS based on the concepts identified.

Methods

This systematic review was performed in accordance with guidelines established by preferred reporting items for systematic reviews and meta-analyses (PRISMA) [5], and involved four steps: step one, selection of studies; step two, identification of outcome measures; step three, linkage of concepts contained in the outcome measures to ICF categories; and step four, schematic representation of concepts as a conceptual model of HRQOL in individuals with PPCS. A detailed protocol was registered on Prospero prior to data collection (CRD42017068241).

Databases and search terms

In step one, the study objective guided the identification and selection of relevant studies. The literature was searched for studies that reported HRQOL in patients post-concussion, including symptoms, function, activities, participation, and the environment as outlined in the ICF [6]. An overview of the study selection process is presented as a PRISMA flow diagram in Fig. 1.

Eight electronic databases were searched from January 1, 1992 to March 12, 2017, including Medline (OVID), Embase (OVID), PsycINFO (OVID), Cumulative Index to Nursing and Allied Health Literature (CINAHL) (EBSCO), SCOPUS, the Cochrane Database for Systematic Reviews, Prospero and Patient-Reported Outcome and Quality of Life Database (PROQOLID; http://www.qolid.org). Given that the diagnostic criteria for concussion continue to evolve, studies were restricted prior to 1992 to reflect the most currently accepted criteria based on the date of introduction of the ICD-10 code for concussion with loss of consciousness less than 30 min [7]. Studies published prior to this date may include subjects with more severe injuries whose recovery is not consistent with PPCS.

Search terms included "concussion," "post-concussion," "traumatic brain injury," "TBI," "mild head injury," "quality of life," and "HRQOL." Keywords were matched to

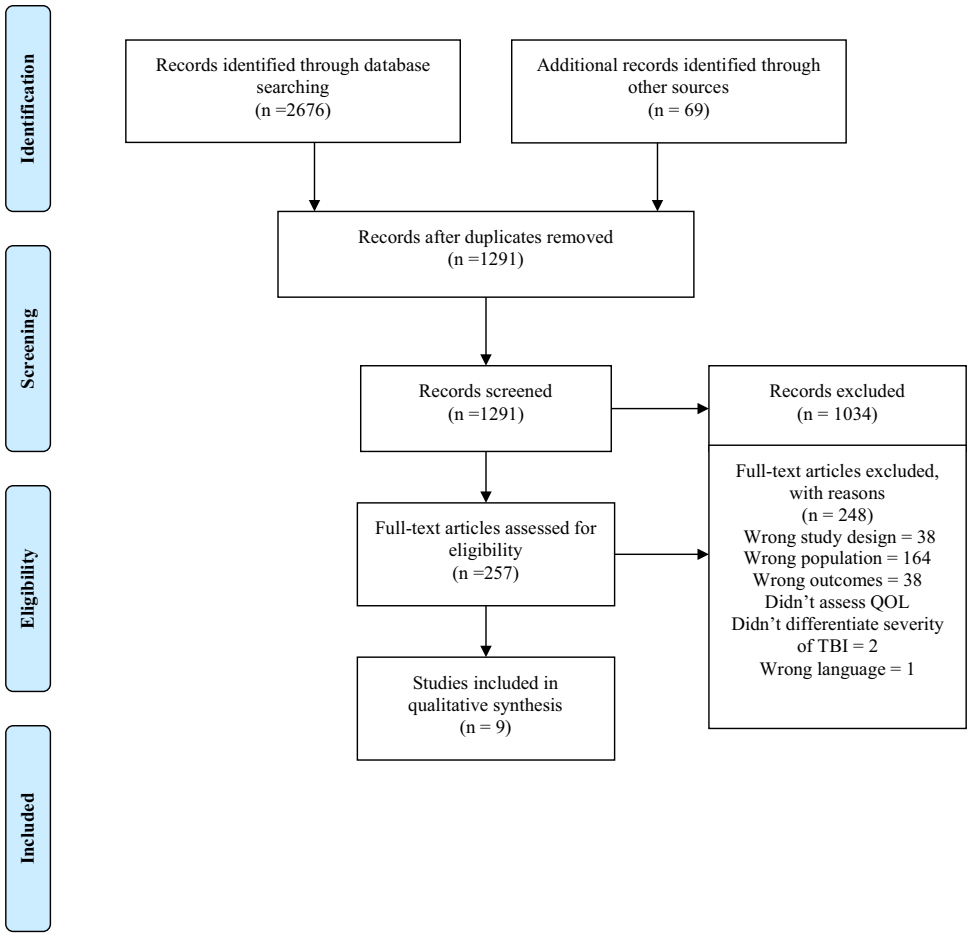

Fig. 1 PRISMA flow diagram as follows: records after duplicates removed (1291), records screened (1291), and records excluded (1282)

database-specific subject headings. Complete search strategies for each database can be found in Online Appendix #1. Additionally, reference lists from included studies were scanned for potentially pertinent studies using a snowballing technique, and relevant journals were hand-searched for appropriate studies, including Brain Injury, Journal of Neurotrauma, Journal of Head Trauma Rehabilitation, and Archives of Physical Medicine and Rehabilitation. A gray literature search was performed for reports, discussion papers, conference proceedings, academic and organizational reports using "Grey Matters, A Practical Search Tool for Evidence-Based Medicine" [8] and Physiotherapy Evidence Database (PEDro), in addition to ProQuest Theses and Dissertations Global. Assistance was sought from an expert medical librarian, experienced in systematic reviews, to develop a comprehensive and inclusive search strategy for all relevant sources.

Eligibility criteria

The citation screening and data extraction tool Covidence (http://www.covidence.org) was used to screen titles and abstracts for eligibility criteria, identify discrepancies between reviewers, and to document a single reason for article exclusion. Studies that were clearly not relevant to the review (e.g., pediatric population) were deemed ineligible and excluded from further review. Full-text articles were retrieved for all abstracts deemed potentially relevant and evaluated against a priori eligibility criteria. Studies that meet the eligibility criteria and were deemed acceptable were included for review (Fig. 1). Studies that failed to meet eligibility criteria were excluded from further consideration. Agreement for inclusion was made through consensus between the two independent reviewers. Unresolved discrepancies were to be resolved through discussion with a third reviewer; however, this was unnecessary as there was complete agreement between the two independent reviewers.

Studies were eligible for inclusion if they involved primary research; explored the impact of PPCS on HRQOL, including symptoms, function, activities, participation, and the environment, as either a primary or secondary end point; either qualitative or quantitative data were reported; subjects were adults aged 18–65 years from any healthcare setting; subjects had received a diagnosis of concussion according to the ICD-10 criteria since 1992, and were published in English or French.

Studies were deemed ineligible if HRQOL outcomes were not reported; the study included a moderate–severe traumatic brain injury (TBI) sample not differentiated from the concussion sample; patients presented with evidence of structural injury or intracranial bleeding on diagnostic imaging if available; if an article was unobtainable or missing data could not be obtained from authors. No limit on methodology was imposed. Additionally, no critical appraisal of methodological quality of included studies was performed since the objective of the study was how HRQOL is being measured in concussion-specific research in order to increase our understanding of the phenomenon without an interpretation of the key findings or theory development. All included studies then passed on to step two of the review.

Data extraction

In step two, HRQOL outcome measures contained within the included studies were identified and labeled as TBI-specific or generic.

In step three, content analysis was performed on the identified outcome measures using the taxonomy of the ICF as the framework for coding and organizing concepts. The ICF is a biopsychosocial model that classifies functioning and disability within its components of *body functions, body structures*, and *activities and participation*, along with contextual factors that incorporate *environmental factors* and *personal factors* (See Fig. 2) [4]. As a universally accepted reference system, the ICF describes functioning, disability, and health as a hierarchical structure using an exhaustive list of alphanumeric codes to categorize components and environmental factors into more detailed levels. The first level of the hierarchy is classified as Chapters (1st level categories). Chapters are composed of second-level categories, which are then further described in more detail in third- and fourth-level categories. Table 1 provides an example how a question on the QOLIBRI, "How bothered are you by pain, including headaches?", would be linked to different levels of the ICF.

Concepts from identified outcome measures were linked to the ICF using established rules for health status measures [9, 10] in a two-step process: (i) identification all meaningful concepts; and (ii) linking each concept to an alphanumeric ICF code. Where questionnaire items contained more than one concept, each concept was extracted separately and

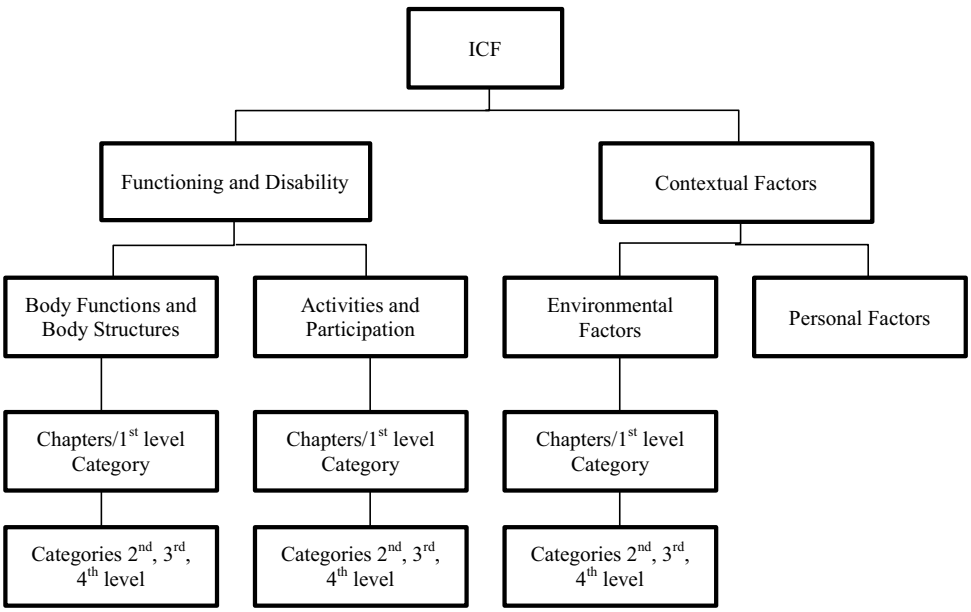

Fig. 2 Structure of the ICF

Table 1 Example of linking the question "How bothered are you by pain, including headaches?" (F.3. QOLIBRI [15]) to the ICF

ICF level	Application in study	Example	Coding
Component	Domain	Body functions	b
Chapter	Subdomain	Sensory functions and pain	b2
Second-level category	Concept	Sensation of pain	b280
Third-level category	Not applied	Pain in body part	b2801
Fourth-level category	Not applied	Pain in head and neck	b28010

ICF International Classification of Functioning, Disability and Health, *QOLIBRI* Quality of Life after Brain Injury

linked accordingly. The hierarchical structure of the ICF was then used to map the concepts at the level of corresponding second-level categories, using pre-prepared data extraction tables derived from the ICF Core Set for TBI. If a concept could be linked to a third- or fourth-level category, it was coded to the corresponding second-level category. Concepts were then further organized into higher-level subdomains at the ICF chapter level, and domains at the ICF component level. Questionnaire concepts that lay within the framework of the ICF, but were not covered by the ICF Core Set for TBI, were linked appropriately and identified. If a meaningful concept identified during the linkage process had insufficient detail to assign the most precise ICF category, the information was documented as 'not definable' (linking rule nine) [9]. Several key concepts not represented by the ICF emerged in the content analysis. These were coded as 'not covered,' according to linking rule ten [9].

In step four, the concepts extracted from the outcome measures were used to create the framework for a working conceptual model of HRQOL in individuals with PPCS, as currently measured with existing tools (Fig. 3). The conceptual model depicts the complex relationship between the construct of HRQOL and the domains of body function, activities, and participation. The contextual factors of personal factors and environment modify these domains, which further influence HRQOL. Subdomains provide a more detailed description of the concepts within each domain and contextual factor.

Results

The literature search retrieved 2676 citations; after removal of duplicates, 1291 articles underwent review of title and abstract. A further 1034 studies did not meet inclusion and exclusion criteria and were excluded. A total of 257 full-text articles were assessed for eligibility, of which 248 were excluded. Nine quantitative studies met review eligibility criteria and were included in the review. No qualitative studies met eligibility criteria for inclusion in the review (Fig. 1). Characteristics of the included studies are summarized in Table 2.

Five outcome measures were identified in the studies that met the inclusion criteria, including the Perceived Quality of Life Scale (PQOL), EuroQoL-5 dimensions (EQ-5D), Quality of Life after Brain Injury (QOLIBRI), WHO-QOL-100, and WHOQOL-BREF. These included one TBI-specific HRQOL tool (QOLIBRI), and four generic HRQOL

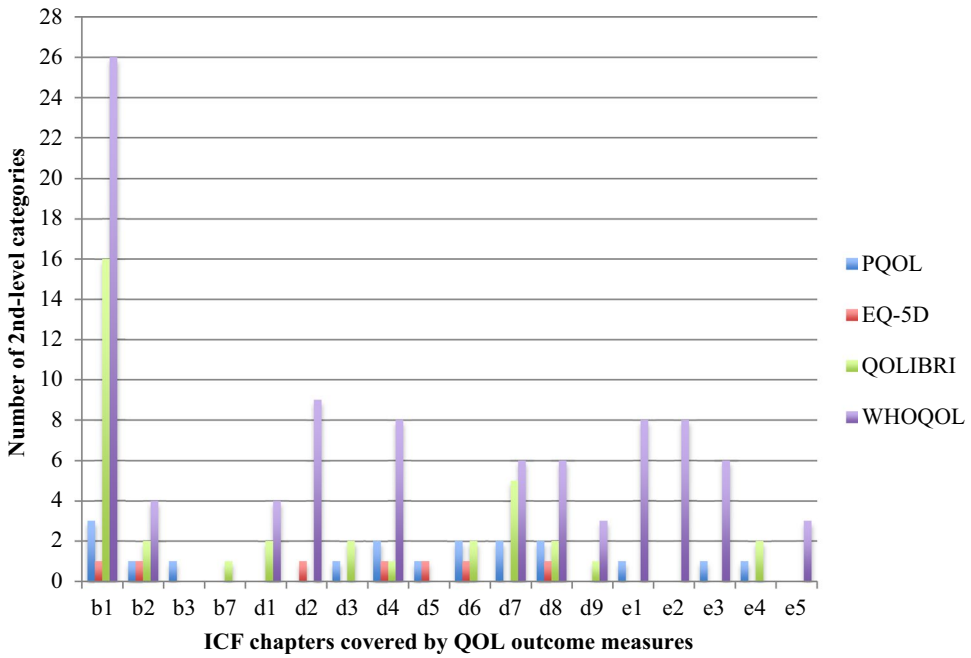

Fig. 3 QOL outcome measures linked to the ICF at the chapter level. Results demonstrate depth and breadth of outcome measures. b1, Mental functions; b2, sensory functions and pain; b3, voice and speech functions; b7, neuromusculoskeletal and movement-related functions; d1, learning and applying knowledge; d2, general tasks and demands; d3, communication; d4, mobility; d5, self-care; d6, domestic life; d7, interpersonal interactions and relations; d8, major life areas; d9, community, social, and civic life; e1, products and technology; e2, natural environment and human-made changes to environment; e3, support and relationships; e4, attitudes e5, services, systems, and policies. *ICF* International Classification of Functioning, Disability and Health, *QOL* Quality of Life, *QOLIBRI* Quality of Life after Brain Injury, *PQOL* Perceived Quality of Life, *EQ-5D* Euro-Qol—5 dimensions, *WHOQOL* World Health Organization Quality of Life

Table 2 Characteristics of included studies assessing HRQOL post-concussion

Author, year	Study design	Age (yrs)	Sample size	Time post-injury (mo.)	HRQOL outcome measure used
Kleffelgaard [11], 2016	PCS	24–45	Concussed: 2 F; 2 M	9–30 mo.	Secondary outcome: QOLIBRI
Scholten [12], 2015	PCS	28–57; $x=45$	Concussed: 298 F; 499 M Other: 70 F; 129 M	6 mo.; 12 mo.	Secondary outcome: PQOL
Azulay [13], 2013	PCS	18–62	Concussed: 11 F; 11 M	7–12 mo. ($n=4$) 13–36 mo. ($n=15$) >36 mo. ($n=1$)	Primary outcome: PQOL
Boussi-Gross [14], 2013	RCT	21–66; $x=44$	Concussed: 32 F; 24 M	12–72 mo.; $x=33$ mo.	Secondary outcomes: EQ-5D, VAS
Fourtassi [15], 2011	CS	34.4 ± 15.5; $x=29.4$	Concussed: 42	12 mo.	Secondary outcome: VAS
King [16], 2011	CS	30–64; $x=44.7$	Concussed: 12 F; 12 M; Control: 29 F; 47 M	24–202; $x=83.7$	Secondary outcome: WHO-QOL-100
Polusny [17], 2011	PCS	31; SD = 8	Concussed: 2 F; 58 M Other: 68 F; 809 M	12 mo.	Secondary outcome: WHOQOL-BREF
Bazarian [18], 2007	PCS	18–31; $x=21.7$	Concussed: 6; Control 6: 4 F; 8 M	1 mo.	Secondary outcome: EQ-5D
Chiu [19], 2006	CS	45.4 ± 20.3	Concussed: 71 F; 128 M	12 mo.; ±8.4 mo.	Primary outcome: WHO-QOL-BREF

Author indicates last name of first author. Year refers to year of publication. Study design coded as follows: *CS* clinical series, *PCS* prospective cohort study, *RCT* randomized controlled trial. Age is coded as follows: years, yrs; x, mean, SD, standard deviation. Sample size coded as follows: *F* female, *M* male; list both if applies. Time post-injury is coded as follows: *mo*. months, *x* mean, *n* number of studies. HRQOL outcome measures: *PQOL* Perceived Quality of Life Scale, *VAS* visual analogue scale

tools. Additionally, one study assessed the deterioration of HRQOL as measured by a visual analogue scale (VAS). Since the VAS assessed deterioration of HRQOL as a global concept, it was unable to be linked to any concepts within the ICF, and was therefore considered 'not covered.'

The PQOL is a 19-item self-report measure that measures a patient's satisfaction with their functioning in three domains (physical, cognitive, and social) [20]. One single global item measures overall happiness as a comparison. Responses are scored on an 11-point Likert scale ranging from extremely dissatisfied (0) to extremely satisfied (10). The mean score of the 19 items is calculated, with a PQOL < 7.5 considered "dissatisfied," and a PQOL > 7.5 considered "satisfied" [20]. The PQOL has been used to measure life satisfaction in a TBI population, with an internal reliability of 0.89 reported [21, 22].

The EQ-5D is a generic measure of HRQOL that provides a simple descriptive profile and single index value [23]. Five domains of mobility, self-care, usual activities, pain/discomfort, and anxiety/depression are measured on a 3-point scale, ranging from no problem, to some problem, to extreme problem/unable to perform. Higher scores are associated with poorer self-reported health.

The QOLIBRI is a TBI-specific measure of HRQOL that consists of 37 items across 6 domains [24, 25]. Four subscales measure satisfaction across the domains of "cognition," "self," "daily life and autonomy," and "social relationships." Two subscales measure how bothered respondent feel by "emotions" and "physical problems." Responses are reported as "not at all," "slightly," "moderate," "quite," or "very," and provide both a profile and a total index score. Psychometric properties are good with an internal consistency of $\alpha=0.81$–0.91 and test–retest reliability of $r=0.68$–0.87.

The WHOQOL-BREF is a short form of the generic WHOQOL-100 that contains 26 questions representing one from each of the 24 facets within the comprehensive WHOQOL-100, in addition to 2 overall quality of life and general health questions. The WHOQOL-100 is recommended for a more comprehensive assessment in epidemiological research, whereas the WHOQOL-BREF is more appropriate in clinical practice, due to its brevity [26]. Since one of the aims was to identify the concepts contained in the outcome measures, data were only extracted from the more comprehensive WHOQOL-100, since it encompassed all the questions in the WHOQOL-BREF, thereby not losing information. The WHOQOL-100 is a self-report outcome measure that measures HRQOL across six domains: physical, psychological, spiritual, environmental, independence, and social [27]. Four additional items pertain to global QOL and general health. All items are scored on a 5-point Likert scale from 1 to 5 using the descriptives "not at all," "a little," "moderately," "mostly," and "completely." The WHOQOL-100 and its short form WHOQOL-BREF have been used in a TBI population to measure HRQOL, and have demonstrated

good internal consistency (0.75–0.89) and test–retest reliability (0.74–0.95) [27].

All concepts from the remaining four outcome measures were then extracted and linked to the ICF where possible. A total of 365 concepts were extracted from the PQOL, EQ-5D, QOLIBRI, and WHOQOL-100. Descriptive statistics were used to assess the frequency of ICF categories contained within each outcome measure (Table 3). 219 (60.0%) of the concepts were linked to the ICF, 12 (3.3%) contained insufficient information to assign the concept to the most precise ICF and were coded as "not definable," 3 (0.8%) concepts were linked to personal factors, and 131 (35.9%) lay outside the framework of the ICF and were coded as "not covered." The vast majority of concepts that were unable to be linked related to questions such as "satisfaction with" or "bothered by" other assignable concepts.

Concepts contained within the identified outcome measures were then compared at the second-level category of the ICF. Of the 219 assignable concepts, 72 were linked to the component *body functions*, 96 concepts were linked to the component *activities and participation*, and 51 concepts to the contextual factor *environmental factors*. No questions in any of the outcome measures referred to the assessment of *body structure* (0%). The 219 concepts contained within the outcome measures were linked to 67 different second-level categories. Concepts that were extracted at a greater specification of detail at the third or fourth level were reported at the second-level category.

The majority of the questions were linked to the domain of *activities and participation* ($n = 34$, 50.7%). Another 16 questions (23.9%) referred to *body functions*, and 17 questions (25.4%) were related to the *environment*. The number of meaningful constructs identified in the four QOL measures and their distribution across the major components of the ICF is outlined in Fig. 2. A comparison of concepts contained within the identified outcome measures is summarized at the second-level category of the ICF in Table 3. The difference in subdomain coverage between the outcome measures at the chapter level is presented in Fig. 4.

HRQOL themes linked to the ICF TBI core set—body functions

Mental functions

Overall impact of mental functions on quality of life (QOL) was the most commonly explored theme by all questionnaires. Global mental function was evaluated primarily by questions asking about patients' level of energy, feeling tired, fatigued, and level of motivation. Satisfaction with amount or quality of sleep and the impact on QOL was frequently asked. Concerns with attention functions were identified by questions regarding the ability to concentrate. Changes in memory function were represented by questions such as how well respondents remember everyday things or rate their memory. A key concept identified by all questionnaires was the consequence of emotional functions on QOL. Questions were heavily weighted in favor of evaluating the impact of negative feelings such as anxiety, depression, loneliness, sadness, boredom, anger, aggressiveness, or despair, over positive feelings such as happiness. Experience of thought functions such as speed of thinking and the ability to understand difficulties in life was only represented in two questionnaires. A single question on higher-level cognitive functions was identified as satisfaction with decision-making.

Sensory functions and pain

Questions relating to sensory functions and pain were included in all identified QOL questionnaires. Of these, the experience of pain and discomfort was frequently assessed. The consequence of these symptoms was identified by numerous evaluative, affective, and functional questions. Evaluative questions were posed in terms of severity and frequency of pain or discomfort, including headaches. Affective questions included emotional feelings about how bothered or worried one is about the pain experience. Functionally, patients were asked to express their difficulty in handling the symptoms, and to what extent suffering prevents them from doing what they need to do. Additionally, patients were asked to report on any change in their quality of life resulting from problems with seeing.

Voice and speech functions

A single question regarding voice and speech functions was reported as the ability to speak clearly and be understood.

Neuromusculoskeletal and movement-related functions

Clumsiness of movement represented the only question investigating neuromusculoskeletal and movement-related functions.

HRQOL themes linked to the ICF TBI core set—body structures

No themes were identified in any of the included questionnaires related to body structures.

HRQOL themes linked to the ICF TBI core set—activities and participation

Learning and applying knowledge

The significance of learning and applying knowledge was represented by four concepts: acquiring skills, reading,

Table 3 Frequency of ICF categories linked to concepts contained in HRQOL outcome measures

			TBI-specific	Generic measure		
ICF code	ICF category	All	QOLIBRI	PQOL	EQ-5D	WHOQOL
Component: body functions						
Chapter 1 Mental functions						
b126	Temperament and personality functions	3				3
b130	Energy and drive functions	6	2			4
b134	Sleep functions	6		2		4
b140	Attention functions	2	1			1
b144	Memory functions	3	1	1		1
b147	Psychomotor functions	1	1			
b152	Emotional functions	23	8	1	2	12
b156	Perceptual functions	1	1			
b160	Thought functions	3	1	1		1
b180*	Experience of self and time functions	8	4			4
Chapter 2 Sensory functions and pain						
b210	Seeing functions	1	1			
b230*	Hearing functions	3	1	1		1
b280	Sensation of pain	9	2		1	6
b289*	Sensation of pain, other specified and unspecified	1			1	
Chapter 3 Voice and speech functions						
b399*	Voice and speech functions, unspecified	1		1		
Chapter 7 Neuromusculoskeletal and movement-related functions						
b760	Control of voluntary movement functions	1	1			
Total body functions concepts		72	24	7	4	37
Component: activities and participation						
Chapter 1 Learning and applying knowledge						
d155	Acquiring skills	3				3
d166	Reading	1	1			
d175	Solving problems	1	1			
d177	Making decisions	2	1			1
Chapter 2 General tasks and demands						
d230	Carrying out daily routine	9			1	8
Chapter 3 Communication						
d330	Speaking	1		1		
d349	Communication, other specified	1	1			
d350	Conversation	3	2	1		
Chapter 4 Mobility						
d450	Walking	2		1	1	
d460*	Moving around in different locations	3	1	2		
d470	Using transportation	1		1		
d475	Driving	1		1		
d489	Moving around using transportation, unspecified	2				2
d499*	Mobility, unspecified	5			1	4
Chapter 5 Self-care						
d510	Washing oneself	2		1	1	
d540	Dressing	1			1	
d599*	Self-care, unspecified	1		1		
Chapter 6 Domestic life						
d620	Acquisition of goods and services	1		1		
d630	Preparing meals	2	1	1		

Table 3 (continued)

			TBI-specific	Generic measure		
ICF code	ICF category	All	QOLIBRI	PQOL	EQ-5D	WHOQOL
d640	Doing housework	1			1	
d649	Household tasks, unspecified	1	1			
d660	Assisting others	4		2		2
Chapter 7 Interpersonal interactions and relationships						
d750	Informal social relationships	4	2	2		
d760	Family relationships	5	2	2		1
d770	Intimate relationships	9	3	2		4
d799*	Interpersonal interactions and relationships, unspecified	2	1			1
Chapter 8 Major life areas						
d839*	Education, other specified and unspecified	2	1		1	
d850	Remunerative employment	7	1	2	1	3
d860	Basic economic transactions	1	1			
d865	Complex economic transactions	1	1			
Chapter 9 Community, social, and civic life						
d910	Community life	4		4		
d920	Recreation and leisure	10	4	4	1	1
d930	Religion and spirituality	1		1		
d999*	Community, social, and civic life, unspecified	2				2
Total activities and participation concepts		96	25	30	9	32
Environmental factors						
Chapter 1 Products and technology						
e110	Products or substances for personal consumption	6		2		4
e155	Design, construction and building products and technology of buildings for private use	1				1
e165	Assets	4		1		3
e199*	Products and technology, unspecified	3				3
Chapter 2 Natural environment and human-made changes to environment						
e225*	Climate	2				2
e235*	Human-caused events	1				1
e250	Sound	2				2
e298*	Natural environment and human-made changes to environment, other specified	2				2
e299*	Natural environment and human-made changes to environment, unspecified	6				6
Chapter 3 Support and relationships						
e310	Immediate family	5		4		1
e315	Extended family	5		4		1
e320	Friends	6		4		2
e355	Health professionals	1				1
e399*	Support and relationships, unspecified	2	1			1
Chapter 4 Attitudes						
e499*	Attitudes, unspecified	2	1	1		
Chapter 5 Services, systems and policies						
e575	General social support services, systems and policies	2				2
e580	Health services, systems and policies	1				1
Total environmental factors concepts		51	2	16	0	33
Total concepts		219	51	53	13	102

Table 3 (continued)

ICF International Classification of Functioning, Disability and Health, *HRQOL* health-related quality of life, *TBI* traumatic brain injury, *QOLIBRI* Quality of Life after Brain Injury, *PQOL* perceived quality of life, *EQ-5D* EuroQOL-5 dimensions, *WHOQOL-100* World Health Organization Quality of Life

*Linked to ICF, not included in the ICF Comprehensive TBI Core Set

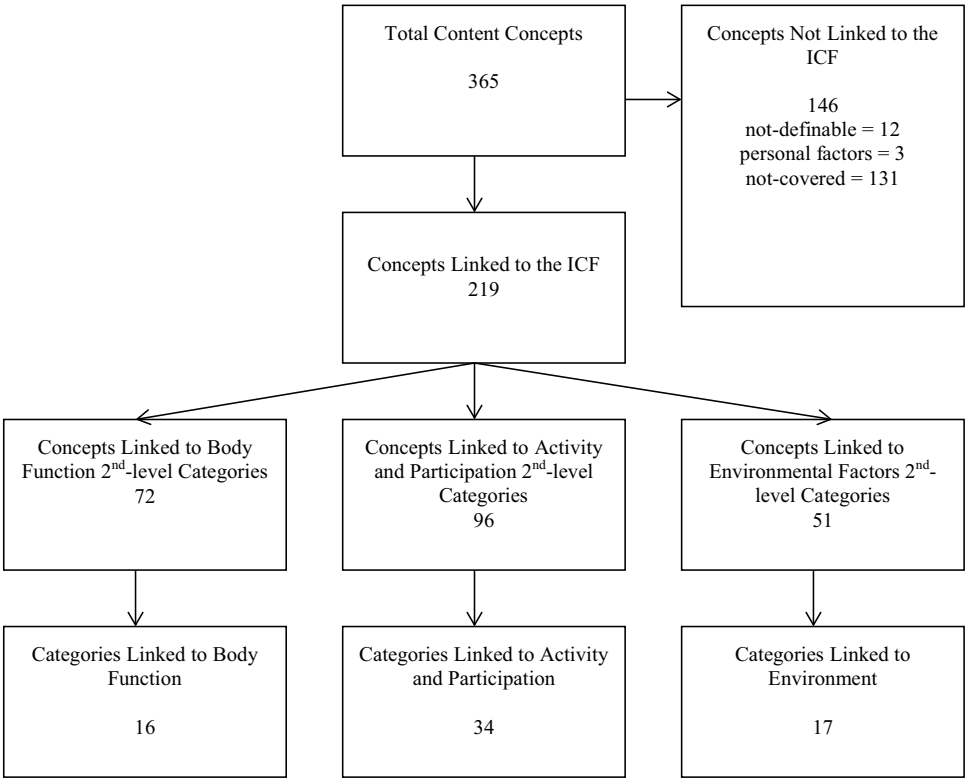

Fig. 4 Number of meaningful constructs identified in the four QOL measures and their distribution across the major components of the ICF. The component *body structures* is not part of the figure, because none of the measures contained concepts that were linked to this component

solving problems, and making decisions. Each concept was explored with one only question, and reported in terms of satisfaction with the ability to read, problem-solve everyday practical problems, learning new information, and the ability to make decisions.

General tasks and demands

The implication of general tasks and demands on QOL was evaluated from varying perspectives. Patients were asked to report concerns about any limitations in their everyday activities; to what extent they were having difficulty carrying out these activities; how much they were bothered by these limitations; and if their daily activities were affected by negative feelings.

Communication

Questions pertaining to communication were assessed as limitations at the level of activities and participation. Key concerns addressed were satisfaction with the ability to speak clearly, carry on and keep track of a conversation, and the ability to understand.

Mobility

Questions of mobility were expressed in terms of both the individual moving within their environment, and moving around using transportation. Significance of walking and the ability to get around was reported in terms of the satisfaction with ability to get out, general mobility difficulties, and the impact on the respondent's way of life. Transportation problems were identified as the ability to adequately access transportation, level of satisfaction, and how those difficulties restrict the respondent's life.

Self-care

The contribution of self-care to quality of life was evaluated non-uniformly across questionnaires at the level of an individual activity limitation. Patients were asked to report satisfaction with their level of independence, and their ability to

perform basic daily living skills, including bathing, and dressing, and general self-care.

Domestic life

Questions pertaining to impact of domestic activities explored three basic concepts, acquisition of necessities, household tasks, and assisting others. Significance of everyday actions and tasks was assessed as difficulties or satisfaction with the ability to shop, prepare meals, perform housework, or give help to family and others.

Interpersonal interactions and relationships

Most questionnaires addressed the significance of interpersonal relationships on a patient's quality of life. The impact of these relationships was assessed with questions related to satisfaction with frequency of interaction, amount of support provided, and general happiness with friends, family, and intimate partners. At an intimate level, patients were asked to express their satisfaction with their level of sexual activity, sexual fulfillment, any perceived difficulties, amount of support provided, and their general happiness with the relationship.

Major life areas

Questions related to the impact of major life areas, such as education, work, and economic life, were well represented across all questionnaires. The impact of education was evaluated by questions about problems and satisfaction with participation in education. Work questions included asking patients about their capacity for work, how much, and whether they are satisfied with their ability to work. In terms of economic life, patients were asked to report on their ability to run personal finances, their worry about money, and any financial difficulties.

Community, social, and civic life

Social impact was represented across all QOL questionnaires in terms of community life, religious participation, recreation and leisure, sports, and hobbies. Questions asked patients to report on their satisfaction with both their contribution to the community, and opportunities to be able to participate social activities. Two general questions summarized the topic, asking how much respondents are satisfied with and enjoy their free time.

HRQOL themes linked to the ICF TBI core set—environmental factors

Products and technology

A rudimentary exploration of the impact of products on individuals post-concussion was identified in only two questionnaires, with broad ranging questions. From a personal consumption perspective, individuals were asked to report their satisfaction with the kind and amount of food they eat. From an overall quality of life perspective, individuals were asked to report on the use of medical substance or aids, including how much medication is needed to function in daily life. Patients were also asked to report on their satisfaction with their home, its level of comfort, and whether it met their needs. A single question assessed the patient's satisfaction with their financial situation.

Natural environment and human-made changes to environment

The extent to which patients consider noise where they live to be a concern represented a unique contribution of the environment to quality of life. No questions regarding environmental facilitators were posed in any of the questionnaires identified.

Support and relationships

The impact of support and relationships were divided along the contribution of family and friends, or health care providers. Questions regarding the support of family and friends were posed in terms of the amount and satisfaction with the help provided to an individual. The role of health professionals was reported as both how much medical treatment is necessary to function, and the ability to access it.

Attitudes

The influence of others' attitudes towards the patient was explored generically at both an interpersonal and societal level. Patient satisfaction with the level of respect and attitude of others towards them did not specify the relationship between individuals, leaving the questions open to interpretation.

Services, systems, and policies

Consequences of the quality and accessibility of services, such health and social care services, was assessed in only one questionnaire, in both its long and short form.

Personal factors

Three meaningful concepts identified were coded as 'personal factors (pf) as they clearly pertained to individual traits acknowledged to influence health, but not codified by the ICF. The significance of personal beliefs in terms of giving meaning to life, and the strength to face and understand difficulties was explored.

Linked to ICF, not included in the ICF comprehensive TBI core set

Several questions were identified on both the generic and TBI-specific QOL outcome measures that were not included in the ICF Comprehensive TBI Core Set. These questions covered a total of four categories across the components of *body functions, activities and participation*, and *environmental factors. Body functions* questions regarding *experience of self and time functions* were posed in terms of both appearance and sense of worth. Satisfaction with appearance was explored with respect to self-perception and body image, whereas satisfaction with one's sense of value and self-esteem dealt with the contribution of sense of worth to quality of life. A single question dealing with changes in quality of life resulting from problems with hearing represented the *sensory functions and pain* chapter. Within the component *activities and participation*, several nonspecific questions were posed within the chapters of *mobility, self-care, interpersonal interactions and relationships, major life areas*, and *community, social, and civic life* that broadly encompassed second-level categories within the ICF Comprehensive TBI Core Set. These were linked to second-level categories otherwise identified within the outcome measures, or as unspecified. One question assessing satisfaction with the ability to repair things represented the only unique contribution to the *activities and participation* component. The consequence of the *natural environment and human-made changes to environment* on quality of life was investigated by both long and brief versions of one questionnaire only. General questions regarding satisfaction with the health, comfort, appeal, and safety and security of where one lived conceptualized the global impact of the physical environment. Concern regarding climate, pollution, noise, and living conditions represented specific questions of environmental factors. Several questions clearly dealt with the contribution of *environmental factors* to quality of life; however, there was insufficient information to assign them to a precise category.

HRQOL themes linked to the ICF TBI core set—other

Not definable

From a general health perspective, patients were asked to report on how bothered they were by the effects of the brain injury and other injuries sustained at the same time in addition to their overall satisfaction with health. Clarification was only provided by one question to distinguish between the impact of injury on physical versus mental health. Likewise, no specific physical or mental health condition questions were identified among the questionnaires. The significance of perceived productivity was evaluated in terms of level of satisfaction with their abilities, their ability to do what they need to do, and what they have achieved since the brain injury.

Not covered

Questions not covered by the ICF tapped into the broader concepts of life, well-being, experiences, information, and quality of life. Satisfaction with the extent the patient perceived the meaning and purpose of life, along with variety in life, was evaluated in two separate questionnaires. The concept of well-being was assessed in terms of the ability to relax and enjoy life, feelings of safety and security, and attitude about the future. Experiential questions included comfort of living conditions, the way patients saw their future, perceived needs, and the extent to which they feel in charge of their own life. The significance of both the availability and opportunities to acquire day-to-day information was also evaluated. Additionally, patients were asked to report on their overall quality of life with respect to its deterioration post-injury and an overall rating of satisfaction.

Discussion

The primary objective of this study was to explore how HRQOL is being measured in concussion-specific research with existing outcome measures. The large number of concepts extracted from existing outcomes supports the complexity and challenge of measuring HRQOL post-concussion. Likewise, the wide variance in breadth and depth of concepts between outcome measures highlights the inconsistency with which the construct of HRQOL is defined and measured across studies. The working conceptual model developed from these concepts provides an emerging framework for future qualitative investigation of those issues that

post-concussion patients identify as being most relevant to their HRQOL.

While the ICF is not a substitute for an outcome measure, it is useful to understand *what* is being measured [28].

A list of agreed upon ICF categories thought to be relevant to TBI patients have been developed through collaborative efforts between the WHO and several international organizations [29]. These ICF Core Sets for TBI have been developed using the same linking guidelines applied in this study. This standardized terminology of the ICF has been recommended as a means of comparing the content validity of health status measures, and as the foundation for the development of new outcome measures [29].

The application of the ICF in this systematic review as a standard reference to link concepts to second-level categories provides deeper insight into the content of the HRQOL outcome measures currently being used in concussion research. Most of the concepts linked to the ICF at the second-level category. Only 12 concepts were considered to have insufficient detail to assign them to a specific chapter, and were coded as 'not definable.' These concepts included general health, as well as global concepts of ability and duties. Approximately one-third of concepts did not fall within the biopsychosocial framework of the ICF and were considered "not covered." These included more existential questions such as the meaning and purpose of life, life satisfaction, attitudes about the future, and general safety and security. Although these concepts were unable to be linked to the ICF, they were maintained and integrated into the working conceptual model of HRQOL for individuals with PPCS. The large number of questions not covered by the ICF support the notion that HRQOL is a multifaceted construct determined by concepts other than just limitations in functioning and disability. This highlights the need for a concussion-specific HRQOL measure that taps into concepts not covered by measures of health status.

This systematic review identified a large number of categories across the different components of *body function, activities and participation, environment*, and *personal factors* regarded as most relevant to assess. The absence of any concepts linked to the component *body structure* is consistent with our current understanding of concussion as a functional disturbance, not a structural injury to the brain induced by biomechanical forces [30]. No pharmaceutical or physical therapies have been demonstrated to cause a structural change correlated to an improvement in recovery; therefore, it seems reasonable not to assess *body structure* in relation to HRQOL.

Most questionnaire items were related to the ICF component *activities and participation*. Collectively, all nine chapters were represented in this review, although the breadth and depth of subcategory coverage differed between outcome measures. The QOLIBRI covered the most chapters within *activities and participation*, with seven out of nine. This is unsurprising, as the QOLIBRI is the only TBI-specific HRQOL outcome measure suitable for use in clinical settings and research studies. Chapters four (*mobility*), six (domestic life), eight (*major life areas*), and nine (community, social, and civic life) were covered by all four outcome measures. The WHOQOL-100 covered six of the chapters in the greatest detail, especially problems associated with d230 *carrying out daily routine*, d470 *transportation*, and d770 *interpersonal relationships*. This reflects the generic nature of the instrument and its ability to cover a breadth of issues due to the large number of questions.

By far the most frequent category examined within the component *body functions* was b152 emotional functions, followed remotely by b280 *sensation of pain*. No question on higher-level cognitive functions (b164), a common concern among individuals with PPCS, was identified in any of the outcome measures. Within *body functions*, chapter four (functions of the cardiovascular, immunological, and respiratory systems), chapter five (functions of the digestive, metabolic, and endocrine systems), and chapter six (functions of the genitourinary and reproductive systems) were not represented by any of the identified outcome measures. This is unremarkable given the generic nature of the HRQOL outcome measures. Furthermore, limitations in these domains remain outside the scope of commonly reported issues post-concussion.

The ICF contextual factors *environment* and *personal factors* were poorly represented among the included outcome measures, despite their potential to have an impact on HRQOL. A content comparison revealed little overlap between outcome measures, with none of chapters being covered by more than two different outcome measures. No single outcome measure was linked to all five chapters within the *environmental factors*. The *environmental factors* covered in the greatest detail were e299 *natural environment and human-made changes to environment* and e399 *support and relationships, unspecified*. These categories were linked to concepts such as 'where one lives' and 'support received from others' which were assessed in terms of satisfaction.

Each outcome measure was used only once or twice, with none being applied in the majority of the included studies. The QOLIBRI, the only TBI-specific HRQOL outcome measure, was only included in one recently published study, as was the WHOQOL-100. The PQOL, EQ-5D, and WHOQOL-BREF were each only used in two out of the nine included studies. This demonstrates the lack of a universally accepted HRQOL outcome measure for patients with PPCS, suggesting that current measures may not meet the specific needs of this population.

HRQOL is a complex construct represented by a heterogeneous constellation of concepts, including, but not limited to, functioning, disability, and health. Existing

outcome measures tap into these concepts to varying degrees. For example, general concepts contained within the 37-item QOLIBRI include cognitive abilities, emotional health, daily functional activities, social relationships, and physical health [31]. These concepts have been linked to 42 second-level ICF categories in a study carried out by two independent researchers using established linking rules [10, 32]. Individuals with PPCS may present with some of the concepts, but not others, and the concepts endorsed by different individuals may vary, since they are not necessarily related to one another. Using a clinical example, one individual may report that the cognitive impairments due to their concussion, such as poor memory and concentration, have a negative impact on their HRQOL. Another individual may report that their inability to ride a bicycle due to post-concussion balance impairments negatively impacts their HRQOL. However, one can have cognitive impairments without balance impairments after a concussion, and vice versa. This has several significant implications. First, concepts assessed by the ICF *cause* changes in HRQOL, rather than being affected by it [33]. Therefore, within the hierarchical taxonomy of the ICF, HRQOL should be considered a higher-level construct determined by a composite of the components *body functions, body structures, activities and participation, environment*, and *personal factors*, rather than being a subset of any of them. Second, because the concepts affect HRQOL, rather than being affected by it, they are not necessarily causally related. If the concepts are not correlated, concepts included on outcome measures will not cover relevant concepts that have been omitted [34]. Practically, this means that outcome measures need to possess high content validity to ensure that they adequately represent the construct of HRQOL. This study describes the concepts contained in existing outcome measures being used to assess HRQOL in patients with PPCS. While these concepts represent current best-thought, the extent of the items' content validity has yet to be confirmed in this population. Furthermore, it is unclear whether additional concepts need to be identified that are relevant to individuals with PPCS. Comprehensive content validity, as evidenced by PPCS patient involvement in the generation of questionnaire items, as well as the evaluation of patient understanding through cognitive interviewing, is lacking in existing outcome measures [35]. A qualitative study using patient focus groups is necessary to elicit concepts relevant to individuals with PPCS in order to prevent any missing, redundant, or irrelevant concepts, and identify any gaps in existing outcome measures in order to understand what *needs* to be measured. Support for the development of a concussion-specific HRQOL outcome measure would be provided if concepts identified by individuals with PPCS were not well represented by existing outcome measures.

Study limitations

While all attempts were made to be comprehensive by including a number of different electronic databases and gray literature search, the possibility exists that some studies were not identified by the search strategy employed. Additionally, studies were limited to those published in English or French. Only one study was excluded during the abstract review for failing to meet this criterion, so although the chances are low that significant data loss occurred due to these stringent language criteria, the possibility must be acknowledged. Decisions on study relevance were unblinded, raising the possibility of reviewer bias in the selection of included studies. Furthermore, concepts contained within the outcome measures were linked to second-level ICF categories by a single researcher. Data extraction performed by two independent reviewers may have yielded different results.

Lastly, the results are only as valid as the content validity of the tools that were used to assess the construct of HRQOL in individuals with PPCS. The lack of direct patient input into the development of any of these tools in a concussion-specific population underscores the need to substantiate the relevance of these concepts. The working conceptual model developed from these concepts should be considered an emerging framework for an iterative process to validate these concepts and identify additional concepts through future qualitative studies with patients and clinical experts (Fig. 5).

Conclusions

Previous studies have examined the concepts contained within a sample of various outcome measures using the ICF as a framework, without differentiating between severities of TBI or specifying HRQOL [36, 37]. This systematic review identified and quantified concepts of HRQOL used in concussion-specific research, using the ICF as a standard reference. The ICF provides a practical tool to identify limitations in health from an objective perspective. Where it is limited is in its ability to assess non-health-related concepts that contribute to HRQOL, or to assess whether functional limitations and disability are relevant to the subjective patient experience. The wide breadth of coverage identified in this review reflects the complexity of concussion and the heterogenic constellation of problems associated with prolonged recovery. The wide range of concepts covered by different outcome measures also demonstrates a lack of universal agreement in terms of what should be measured in this population. The results of this study provide a framework for a working conceptual model of HRQOL in individuals with

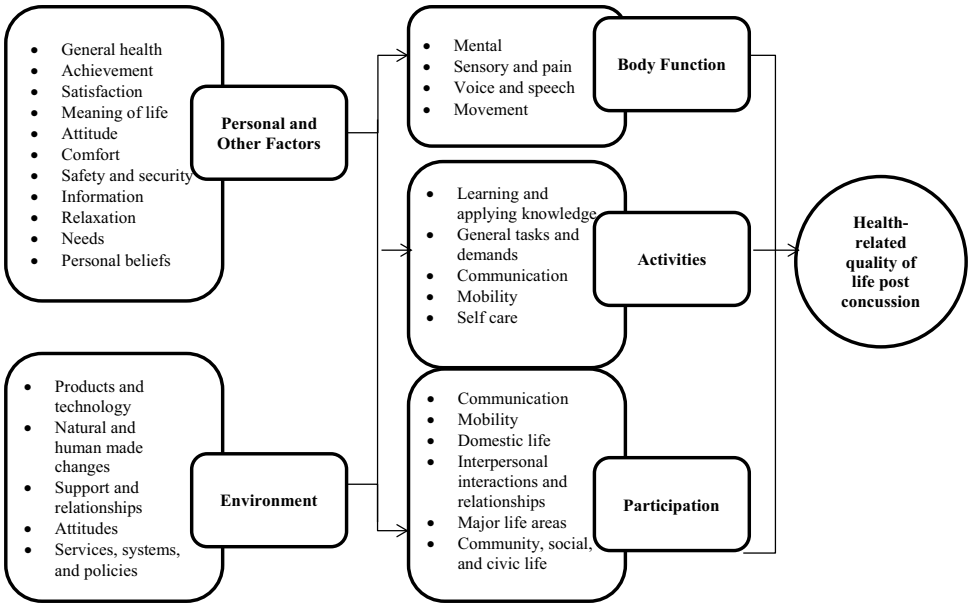

Fig. 5 Working conceptual model of HRQOL in individuals with PPCS

PPCS. A qualitative study exploring the patient's subjective perspective is necessary to ensure robust content validity of the identified concepts. Further work is needed to build upon this study and deepen our understanding of whether the concepts identified are relevant to patients with PPCS.

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Conflict of interest The authors declare no conflict of interest with respect to the research, authorship, and/or publication of this article.

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