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Research Article

Reliable Individual Change in Post Concussive Symptoms in the Year Following Mild Traumatic Brain Injury: Data from the Longitudinal, Population-Based Brain Injury Incidence and Outcomes New Zealand in the Community (Bionic) Study

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Keywords

- Post concussive symptoms
- Mild brain injury
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Abstract

Objective: Post concussive syndromes (PCS) is common after mild-TBI, yet are not well studied on a population level. This study examined PCS symptoms, including reliable change over time in a population-based sample up to one year post-TBI.

Methods: Prospective follow-up of 527 adults (≥16 years) with mild TBI (mTBI) and assessment data (Rivermead Post concussion Questionnaire; RPQ) at baseline, 1, 6, and/or 12-months post-TBI. Change in mean scores and clinically significant change across RPQ items for each person was calculated between assessment time points using a reliable change index (RCI).

Results: While prevalence of all symptoms reduced over time, >30% of participants reported fatigue, slowed thinking, and forgetfulness 12-months post-injury. Using the RCI, <12% of individuals improved from baseline to 1-month, 50% from 1 to 6-months, and 4.2% from 6 to 12-months.

Conclusions: Improvements in PCS post-mTBI were most obvious between 1 and 6-months, suggesting lengthy recovery trajectory. A third of patients experience residual cognitive problems 12-months following a mTBI, and while many individuals improve post-TBI, a large proportion remain stable or worsen.

INTRODUCTION

Post-concussive syndrome (PCS) refers to a cluster of symptoms that can occur after brain injury of any severity. These symptoms are commonly grouped into cognitive complaints (e.g., reduced memory, attention, and concentration), somatic (headaches, fatigue, dizziness, sensitivity to noise and light), and affective complaints (depression, irritability, frustration, and anxiety) [1].

Immediately after injury 80-100% of those with mild TBI (mTBI) will describe one or more symptoms of PCS [2,3]. In 80-90% of cases, individuals' symptoms are said to resolve within 2 weeks [4-8]. While the frequency and intensity of PCS symptoms are generally thought to improve over time, even at 3 months post-injury many studies report high rates of these symptoms. For example in a highly cited study [9], 78% of a mild TBI sample experienced headaches, and 60% experienced a decline in memory at 3 months.

In other studies, symptoms may remain for three to six months [10], but evidence indicates that many cases are completely resolved within 6 months [11].

While Levin et al., report that although nearly all patients initially reported cognitive problems, somatic complaints, and emotional malaise (e.g., 47% headaches, 22% decreased energy and 22% complaints of dizziness), these post-concussion symptoms had substantially resolved by the 3-month follow-up examination. The authors concluded that a single uncomplicated minor head injury produces no permanent disabling neurobehavioral impairment in the majority of patients without pre-existing neuropsychiatric disorder and substance abuse.

In contrast, others report [12] that 50% of mTBI sufferers report dizziness and headache, and 75% report fatigue 5-6 months post-injury. In a dual cohort study comparing those with mTBI and a matched other-injury group Kraus et al [13] found 83% of mTBI had at least one symptom at 6 months post-injury and on average they had 4.3 complaints with dizziness, vision problems, memory problems, and alcohol intolerance occurring more frequently in the mTBI than the other-injury cohort. Even at 1 year post-injury Dikmen et al. [2], reports that 44% of hospitalized cases of mTBI note the presence of 3 or more symptoms that were new or worse after injury, though as a hospitalized sample this sample is likely to represent the more sever end of the mild TBI spectrum. Roe [14] reports that 23% of a cohort with mTBI met PCS symptom criteria at 6 and 12 months post injury, with cognitive symptoms being more prominent than physical or behavioural symptoms. Other authors [15] have concluded that PCS lasts, on average, for over 3 years. In our earlier study, which used a sub sample of the current sample (N=341), and which was drawn from a population-based sample with mTBI, 47.9% reported experiencing four or more post-concussive symptoms1 year post-injury [16].

The above literature is inconsistent about the nature of PCS in the long-term after mTBI, there is a paucity of data describing the effects of mTBI across multiple assessment times, and all but one study used hospital samples [16], with the result being that the literature therefore does not account for the proportion of mTBI cases that go untreated and undetected, potentially leading to the overestimation of long-term effects. Finally, the majority of the literature which does examine change in symptoms over time is limited to describing the prevalence of specific symptoms or the mean number of symptoms across a group of individuals. There is no reference in the literature to the clinical significance of change over time on an individual level in relation to PCS. This final point is of central importance if one wants to take the findings of large scale studies and apply these to individual change over time within a rehabilitative context.

The aim of this analysis was to describe change in PCS symptoms of a population-based sample of adults (≥16 years; N=527) across the first year post-mTBI. The mean and presence of each symptom at each time point (baseline, 1, 6, and 12 months) as well as the statistical significance of change over time are presented. In addition, the proportion of individuals with clinically significant change in PCS symptoms is calculated using an update on Jacobsen and Traux's [17] formula, which is a significant addition to the existing literature. Tabulated data presented here includes all the figures required for clinicians to apply the formula for reliable change to individual cases. This builds upon our previous work which identified that nearly half of those who experience mTBI continue to experience persistent symptoms 1 year later, indicating that these persistent symptoms need to be identified and acknowledged by clinicians, with information and support provided to facilitate recovery and prevent re-injury [18].

METHOD

Study population

This study was conducted as part of a longitudinal, population-based mTBI incidence cohort study known as *Brain Injury Incidence and Outcomes in the New Zealand Community* (BIONIC). Full details of the methodology and TBI incidence findings have been published separately [19,20]. Within the main BIONIC study, all cases of TBI that occurred during a one year period (1 March 2010 through 28 February 2011) in the Hamilton and Waikato Districts of New Zealand (NZ) were identified.

TBI was defined by the World Health Organisation criteria, as an acute brain injury resulting from mechanical energy to the head from external physical forces [21]. Information on all potential TBI cases based on self-report and information obtained from medical records was reviewed by a diagnostic adjudication group to determine if each case met the inclusion criteria for TBI for this study.

All confirmed TBI cases were invited to participate in follow-up assessments at baseline (within 2 weeks of the injury) and at 1, 6 and 12-months to monitor their recovery. Assessments were completed in person at the participant's place of residence or at another mutually convenient location such as a private room at a GP practice, library or at the university. The TBI incidence study included people of all TBI severities; however 95% of TBIs identified were classified as mild (defined as a Glasgow Coma Score of 13-15 and/or Post-traumatic Amnesia of <24 hours). Data on mild TBI cases aged ≥16 years was extracted for these analyses. Cases were retained in the analysis where data on PCS symptoms were available for at least one follow-up assessment. In total there were 527 cases of adult mild TBI who provided consent and who had data for at least one follow-up assessment. See (Figure 1) flowchart of recruitment.

PROCEDURE

Ethical approval was obtained from the Northern Y Health and Disability Ethics Committee of NZ (NTY/09/09/095) and the Auckland University of Technology Ethics Committee (09/265). All participants included in the analysis provided informed written consent.

Baseline assessments included general demographic information, details of the injury and treatment received, and details of comorbidities, current work status and prior TBI. In regards to the present analysis, post concussive symptoms were assessed using the *Rivermead Post Concussion Symptoms Questionnaire (RPQ)* [22,23] which was specifically developed to assess the severity of symptoms experienced after a brain injury. For each item, the participant is presented with a particular symptom (e.g., "headaches", "forgetfulness, poor memory") and

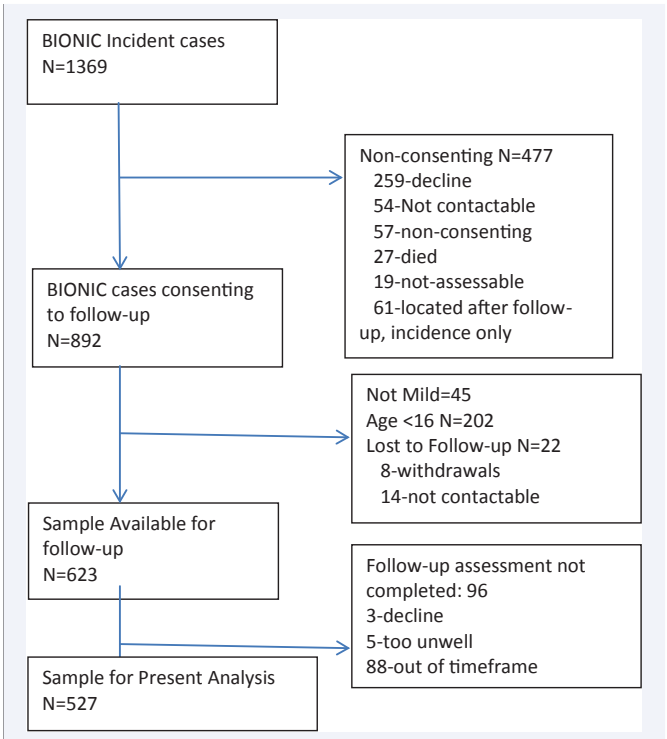

Figure 1 Flowchart of recruitment. Recruitment and selection of cases for the present study.

they are asked to compare their experience of that symptom within the last 24hours with their experience before the injury. Each symptom is rated on a scale from 0= Not experienced at all; 1= No more of a problem; 2 = A mild problem; 3= A moderate problem; to 4= A severe problem. For the purposes of this analysis, item scores of 0 or 1 were classified as "not present" while scores of 2 or more were considered "symptom present". The first three symptoms of the RPQ (headaches, nausea/vomiting, dizziness) are referred to as RPQ-3 or RPQh (RPQ head) [24], and are thought to represent the early (within 2 weeks of injury) symptoms associated with post-concussion syndrome; whilst the remaining 13 items are thought to reflect symptoms that are more likely to persist.

STATISTICAL ANALYSES

Preliminary analyses using t-tests and chi square (as appropriate to the data) were conducted to compare incident cases who consented and had follow-up data (N = 527) to those who did not consent (N = 644).The frequency of individuals expressing each symptom at each time of assessment are then presented, as are the means and standard deviations of each symptom at each time of assessment. Statistical significance of change over time (baseline to 1 month, 1 to 6 months, and 6 to 12 months) was determined through producing a within-subject t-test for each symptom. Reliable change was calculated for each individual using an extension of the original RCI [17] that takes into account practice effects [25]. Change was examined from baseline to 1 month, 1 to 6 months, and 6 to 12 months. This was calculated as $((X_2 - X_1) - (M_2 - M_1))/SDD$ where X_1 is the observed individual's pre-test score, X_2 is the observed post-test score, M_1 and $M_2$are the group mean pre and post-test scores, and SDD is the standard deviation of the group test-retest difference. The correction for practice effects is the addition of the constant that is based on group level average change [24]. Participant scores that are +/-1.69 indicate reliable improvement and reliable decline, respectively.

RESULTS

Sample Characteristics

Preliminary analysis was conducted to compare those incident cases who consented to follow-up assessment and had follow-up data (N = 527) and those who did not consent (N = 644). The groups did not differ significantly in terms of gender, area of residence (Hamilton (urban) versus Waikato (rural) region), or mechanism of injury (p >.05). However, the groups did differ significantly (all p values <.0001) in terms of age (with consenting individuals being significantly younger, mean ages = 25.68 and 30.83, respectively) and ethnicity (consenting having a larger proportion of non-Europeans, 24.14 versus 9.63%).

In regards to mechanism of injury within the present sample, the greatest proportion (30.3%) were due to a fall, followed by assault (22.7%), traffic crash (16.4%), recreational activities (11.0%) and work-related injury (2.2%). The remaining 17.4% of injuries did not fall into any of these categories.

Symptom Prevalence

Figure (2) presents the prevalence of each PCS symptom at each time of measure. As can be seen in Figure (2), the most frequent symptoms rated as 2 or more on the RPQ immediately after injury were not limited to items of the RPQ-3 (i.e., dizziness, nausea/vomiting, headaches), and included fatigue, headaches, taking longer to think, forgetfulness, and dizziness; all of which were present in at least 50% of the sample. The least common symptoms were double vision, and nausea/vomiting, both of which occurred in less than 25% of the sample. Looking at the prevalence rates over time it can be seen that all symptoms reduced over time. At one year post injury more than 30% of the sample continued to report problems with fatigue, taking longer to think, and forgetfulness. Double vision and nausea/vomiting remained the least prevalent symptoms, being reported in less than 10% of participants.

Table (1) presents the means and standard deviations obtained on each symptom at each time of assessment, including examination of the significance of within-subject change over each time period. As seen in Table (1), from baseline to 1 month post-injury all symptoms on the RPQ reduced, with all but nausea/vomiting, sleep disturbance, poor concentration, and double vision improving significantly. From 1 to 6 months all of these except poor concentration, which reduced significantly, remain non-significant. In addition light sensitivity, noise sensitivity, forgetfulness and being irritable/easily angered no longer improved significantly. From 6 to 12 months, all symptoms continued to reduce with the exception of depression which increased, though this was not significant. Those symptoms which showed significant within-subject reductions over this time frame included noise sensitivity, fatigue, irritability, frustration/impatience, forgetfulness, poor concentration, and slowed thinking.

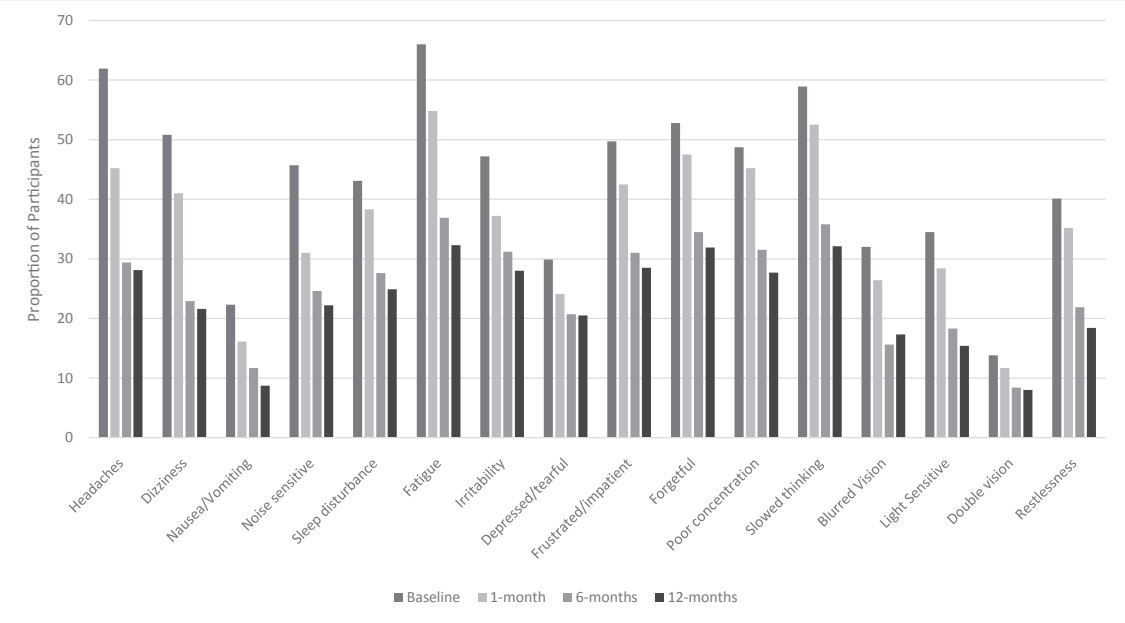

Figure 2 Percentage of the sample who indicates a symptom was present at each time of assessment
Note: The above differ from the adom et al. [18], reflecting different samples.

Table 1: Means and SDs on RPQ items at each assessment and significance of differences between assessments.

	Baseline N=197		1-month N=261		SDD Baseline to 1 month	Significance of change to 1 month	6-months N=420		SDD 1 to 6 months	Significance of change 1 to 6 months	12-months N=527		SDD 6 to 12 months	Significance of change 6 to 12 months
	Mean	SD	Mean	SD		Df1=1, Df2=137	Mean	SD		Df1=1, Df2=174	Mean	SD		Df1=1, Df2=352
11 .headache	1.91	1.266	1.52	1.277	1.167	F=26.084,p<.001	1.09	1.150	1.173	F=9.977, p=.002	.97	1.143	1.052	F=3.693,p=.055
2. dizziness	1.44	1.230	1.20	1.182	1.169	F=12.212,p=.001	.76	1.024	1.191	F=6.444,p=.012	.68	1.042	.958	F=3.572,p =.060
3. nausea, vomiting	.71	1.080	.56	1.001	1.080	F=2.740,p=.100	.46	.842	.882	F=.599,p=.440	.37	.742	.907	F=2.516,p=.114
4. noise sensitivity	1.37	1.369	.97	1.168	1.215	F=7.848,p=.006	.82	1.149	1.060	F=3.180,p=.076	.70	1.099	1.12	F=6.943,p=.009
5. sleep disturbance	1.43	1.341	1.33	1.291	1.257	F= 3.598,p=.060	1.06	1.191	1.349	F=2.824,p=.095	.99	1.198	1.56	F=1.434,p=.232
6. fatigue	2.05	1.360	1.77	1.309	1.235	F=7.992,p=005	1.28	1.270	1.110	F=10.245,p=.002	1.13	1.260	1.030	F=6.942,p=.009
7. irritable, easy to anger	1.53	1.296	1.26	1.218	1.293	F=13.109, p<.001	1.15	1.197	1.241	F=.627,p=.430	1.02	1.135	1.086	F=6.782,p=.010
8. depressed, tearful	1.01	1.116	.84	1.089	.978	F=8.246,p=.005	.79	1.053	1.080	F = .123,p=.727	1.06	1.137	1.010	F=2.025,p=.156
9. frustrated, impatient	1.52	1.272	1.39	1.219	1.238	F=5.788,p= .017	1.21	1.179	1.300	F = 8.792,p=.003	.73	1.042	1.073	F=7.719,p=.006
10. forgetful	1.73	1.291	1.56	1.287	1.272	F=6.471,p=.012	1.22	1.239	1.124	F=1.810,p=.180	1.13	1.251	.994	F=7.461,p=.007
11. poor concentra-tion	1.60	1.335	1.47	1.242	1.278	F=2.555,p= .112	1.14	1.217	1.200	F=5.142,p=.025	1.05	1.185	1.070	F=6.946,p=.009
12. longer to think	1.82	1.307	1.51	1.239	1.031	F=16.371,p<.001	1.21	1.220	1.173	F=8.409,p=.004	1.06	1.198	.963	F=7.059,p=.008
13. blurred vision	.99	1.204	.84	1.138	1.093	F=11.220,p=.001	.60	.997	1.023	F=4.590,p=.034	.58	1.034	.979	F=.003,p=.957
14. light sensitivity	1.11	1.247	.89	1.184	.966	F=4.473,p=.036	.68	1.092	1.099	F=.572,p=.450	.57	1.048	1.058	F=3.277,p=.071
15. double vision	.41	.908	.41	.879	.757	F=2.476,p=.118	.32	.736	.844	F=.128,p=.721	.28	.729	.759	F=.595,p=.441
16. restlessness	1.30	1.300	1.11	1.148	1.115	F=9.321,p=.003	.88	1.037	1.059	F = 6.974,p=.009	.75	1.011	.905	F=8.307,p=.004

Abbreviations: SDD = standard deviation of difference between time points. This, along with group means can be used to calculate reliable change using the formula provided (see Statistical Analysis section).

Table (2) presents the results of calculations of the reliable change index, indicating the number and percentage of individuals whose performance reliably improved (scores reduced), reliably declined, or stayed the same. Overall, just fewer than 12% of individuals reliably improved from baseline to one month assessment, 50% improved from 1 to 6 months, and 4.2% significantly improved from 6 to 12 months. The greatest proportion of individuals (> 86%) showed no reliable change in symptom scores from baseline to 1 months and from 6 to 12months.

DISCUSSION

The main goal of treatment in any neurological condition is improvement in the patient's symptoms. Yet the measurement of reliable change at the individual level in people with mTBI remains an area of significant challenge. This study was conducted to examine stability or change in symptom reporting in people with mTBI on the most commonly used self-report measure of post-concussive symptoms, the RPQ.

In the present study, the most frequent symptoms immediately after injury were fatigue, headaches, taking longer to think, forgetfulness, and dizziness; while the least common were double vision, and nausea/vomiting. The first three symptoms of the RPQ (headaches, nausea/vomiting, dizziness) are referred to as RPQ-3, also known as RPQh (RPQ head) [26], and are thought to represent the early (immediately following injury) symptoms associated with post-concussion syndrome. Our findings suggest that despite research suggesting that it represents a distinct construct and subscale of the RPQ [27], the RPQ-3 does not include the symptoms most frequently reported in the acute stage, nor are they the ones that are least reported over time.

Statistically, many of the symptoms reduced significantly over time, with all symptoms improving with the exception of nausea/vomiting, sleep disturbance, poor concentration, and double vision from baseline to 1 month. While fewer symptoms reached significance, the majority continued to improve to 6 months. Further, 7 of the 16 symptoms showed the greatest change indicative of improvement between 6 and 12 months (noise sensitivity, fatigue, irritability, frustration/impatience, forgetfulness, poor concentration, and slowed thinking).

Differences at a group mean level over time do not address the clinical question of identifying the extent to which people can be expected to reliably improve or decline. Indeed, despite these statistically significant changes, when using the reliable change index fewer than 12% of individuals reliably improved from baseline to one month assessment, 50% from 1 to 6 months, and 4.2% from 6 to 12 months. This suggests that it is important to consider clinically meaningful change rather than changes that are statistically significant, per se. Indeed, it is important to note that in the 1 to 6 month period where the most individuals did experience significant improvement, a further 33% of individuals had significant increases in symptom reporting.

It is recommended that manufacturers of tests provide

Table 2: Number and percentage of individuals whose change was a reliable increase, decrease, or where there was no reliable change.

	Change baseline to 1 month N=138			Change 1 to 6 months N=175			Change 6 to 12 months N = 353		
	Reduced	No Change	Increased	Reduced	No Change	Increased	Reduced	No Change	Increased
1.headaches	7(5.1%)	126(91.3%)	5(3.6%)	23(13.1%)	150(85.7%)	3(1.7%)	32(9.1%)	297 (84.4%)	24 (6%)
2. dizziness	4(2.9%)	128(92.8%)	6(4.3%)	4(2.3%)	159(90.9%)	12(6.9%)	26(7.4%)	309 (87.5%)	18 (5%)
3. nausea, vomiting	17(12.3%)	115(83%)	6(4.3%)	12(6.9%)	154(88.0%)	8(4.6%)	215.9%)	317 (89.8%)	15 (4.2%)
4. noise sensitivity	7(5.1%)	123(89.1%)	8(5.8%)	3(1.7%)	162(92.6%)	10(5.7%)	35(9.9%)	299 (84.7%)	21(5.9%)
5. sleep disturbance	6(4.3%)	128(92.8%)	4(2.9%)	8(4.6%)	154(88.0%)	13(7.4%)	10(2.8%)	314 (89.0%)	29 (8%)
6. fatigue	7(5.1%)	124(89.9%)	7(5.1%)	4(2.3%)	163(93.1%)	8(4.6%)	33(9.3%)	301 (85.2%)	19(5.4%)
7. irritable, easily angered	7(5.1%)	121(87.7%)	10(7.2%)	18(10.3%)	140(80.0%)	17(10%)	30(8.5%)	303(85.8%)	20 (5.7%)
8. depressed or tearful	14(10.1%)	121(87.7%)	3(2.2%)	12(6.9%)	152(86.9%)	11(6.3%)	25(7.1%)	303(85.8%)	25 (7.1%)
9. frustrated, impatient	6(4.3%)	122(88.4%)	10(7.2%)	8(4.6%)	164(93.7%)	3(1.7%)	7(1%)	323 (91.5%)	23 (6%)
10. forgetfulness	6(4.3%)	124(89.9%)	8(5.8%)	2(1.1%)	162(92.6%)	11(6.3%)	30(8.5%)	304 (86.1%)	19 (5.4%)
11. poor concentration	8(5.8%)	125(90.6%)	5(3.6%)	6(3.4%)	160(91.4%)	9(5.1%)	25(7.1%)	310 (87%)	18 (5%)
12. longer to think	4(2.9%)	129(93.5%)	5(3.6%)	4(2.3%)	160(91.4%)	11(6.3%)	27(8%)	306 (86.7%)	20(5.7%)
13. blurred vision	21(15.2%)	114(82.6%)	3(2.2%)	19(10.9%)	152(86.9%)	4(2.3%)	21(5.9%)	311 (88.1%)	21(5.9%)
14. light sensitivity	14(10.1%)	119(86.2%)	5(3.6%)	5(2.9%)	160(91.4%)	10(5.7%)	28(8%)	302 (85.6%)	23 (6%)
15. double vision	6(4.3%)	128(92.8%)	4(2.9%)	7(4%)	158(90.3%)	10(5.7%)	15(4.2%)	323 (91.5%)	15(4.2%)
16. restlessness	17(12.3%)	115(83%)	6(4.3%)	21(12%)	145(82.9%)	9(5%)	15(4.2%)	324 (91.8%)	14 (3%)
total score	15(11.6%)	119(86.2%)	4(2.9%)	87(50%)	29(16%)	58(33%)	15(4.2%)	321 (90.9%)	17 (4.8%)

information on change over time within clinical samples so that clinicians can calculate the RCI for individual patients. For example, using the current sample, if an individual with mTBI received a RPQ total score of 32 at one month post-injury and a score of 28 at 6 months, his or her RCI would be calculated as ([28-32]–[14.58-18.63])/ 10.417= -0.77; where 14.58 and 18.63 were the group means at times 2 and 1, respectively, and 10.417 is the standard deviation of the difference between tome 2 and time 1 for the group. Thus, although the score is improved, the criterion for reliable improvement (scores +/- 1.69) has not been met. This is particularly important for patients being seen in legal contexts (e.g., power of attorney) and when seeking funding to support services. Most randomized controlled trials rely on averaging or pooling data across individuals to determine mean change. The responsiveness of individuals to treatment effects can be lost in such analyses, yet such individual responsiveness is important to future efforts to develop and refine treatments.

Our findings are based on a large sample of individuals with mild TBI followed for 12 months post-injury. Limitations to the findings include its generalizability as consenting individuals were significantly younger, and more likely to self-identify as non-Europeans than those who did not consent. The present sample included a greater proportion of the original BIOINC sample as data for participants completing only one time point early in recovery were included, in contrast to the previous paper which only looked at participants who had longitudinal data at 6 and/ or 12 months [18] An additional limitation is that, while the RPQ is likely the most common measure used to quantify PCS in both research and clinical practice, it relies on self-report. Additional, qualitative research that could take a more holistic view of the impact and consequences for the lived experience of mTBI could add weight to our conclusions. Future research should also examine what characteristics of the individual and the injury are predictive of individual outcomes of mTBI. For example it is evidenced in the literature that individuals are more likely to experience Posttraumatic Stress Disorder (PTSD) following an intentional mTBI (e.g., assault), [28] and that the presence of PTSD exacerbates post-concussive symptoms; [29] yet the ability of injury mechanism or PTSD to predict individual change in PCS has yet to be explored.

Particular strengths include our relatively large sample, with repeated measures allowing examination of change over time not only in terms of prevalence of symptoms and mean symptoms reported by the sample, but also reliable change within each individual.

CONCLUSION

Slowed thinking, fatigue, irritability, and headaches appear to be the persistent symptoms following a mild TBI. Interventions targeting these symptoms in the acute phase may help to improve long term outcomes and recovery following mild TBI. The use of RCI rather than group change statistics presents a very different picture, with it clear that while many individuals improve post-TBI; a large proportion remains stable or worsens. Whilst the present paper provides these data for the RPQ after mild TBI, it is recommended that manufacturers of tests provide information on change over time within clinical samples so that clinicians and researchers can calculate the RCI for individual patients.

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