

**Validation of the Symptoms of Post-Concussion Syndrome Questionnaire as a Self-Report Symptom Validity Test: A Simulation Study**

**Victoria Jayne Reece**

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## CONTENTS

|  |          |
|--|----------|
| INDEX OF APPENDICES  | 5        |
| THESIS ABSTRACT  | 7        |
| PREFACE  | 8        |
| <b>PAPER ONE: LITERATURE REVIEW</b>                              | <b>9</b> |
| ABSTRACT   | 10       |
| INTRODUCTION   | 11       |
| Rationale for the review   | 12       |
| Aim  | 12       |
| METHOD   | 13       |
| Selection of papers  | 13       |
| Evaluation tool  | 15       |
| RESULTS AND DISCUSSION   | 16       |
| Overview of papers   | 16       |
| Performance validity test outcomes and symptom reporting         | 16       |
| The utility of existing self-report PCS symptom measures as SVTs | 28       |
| The application of new and existing symptom validity tests       | 31       |
| Synthesis of findings  | 40       |
| CONCLUSION   | 42       |
| Clinical implications  | 42       |
| Recommendations for future research                              | 42       |
| REFERENCES   | 44       |
| APPENDICES   | 50       |

|   |           |
|---|-----------|
| <b>PAPER TWO: EMPIRICAL PAPER</b>                     | <b>55</b> |
| ABSTRACT  | 56        |
| INTRODUCTION  | 57        |
| Rationale, aim, and hypotheses                        | 61        |
| METHOD  | 63        |
| Design  | 63        |
| Participants  | 63        |
| Procedure   | 65        |
| Measures  | 66        |
| Statistical analysis                                  | 68        |
| Sample size calculation                               | 69        |
| Ethical and regulatory considerations                 | 69        |
| RESULTS   | 71        |
| Demographic variables                                 | 71        |
| Premorbid functioning, anxiety, and depression scores | 71        |
| Clinical scales                                       | 72        |
| SPCS symptom reporting                                | 74        |
| Utility of the SPCS                                   | 76        |
| DISCUSSION  | 80        |
| Clinical Implications                                 | 82        |
| Limitations   | 83        |
| CONCLUSION  | 84        |
| REFERENCES  | 85        |
| APPENDICES  | 91        |

|   |            |
|---|------------|
| <b>PAPER THREE: REFLECTIVE ACCOUNT</b>          | <b>143</b> |
| ABSTRACT  | 144        |
| INTRODUCTION                                    | 145        |
| SELECTING A RESEARCH TOPIC AND DEVELOPING IDEAS | 145        |
| LITERATURE REVIEW                               | 146        |
| EMPIRICAL PAPER                                 | 147        |
| CLOSING REFLECTIONS                             | 150        |
| REFERENCES                                      | 151        |

## INDEX OF APPENDICES

### **PAPER ONE: LITERATURE REVIEW**

A – Evaluation tool

B – Scoring sheet for evaluation tool

### **PAPER TWO: EMPIRICAL PAPER**

C – Symptoms of Post-Concussion Syndrome (SPCS) questionnaire

D – Recruitment email

E – Participant Information Sheet (clinical)

F – Participant Information Sheet (non-clinical)

G – Consent form (clinical)

H – Consent form (non-clinical)

I – Debrief

J – Vignette

K – Independent peer review approval and indemnity insurance

L – NHS Research Ethics Committee approval

M – Health Research Authority approval

N – NHS Research and Development approval

O – SPSS output: Demographic group differences

P – SPSS output: Premorbid functioning, anxiety, and depression comparisons

Q – SPSS Output: Within group premorbid functioning, anxiety, and depression correlations (malingering group)

R – SPSS Output: Within group premorbid functioning, anxiety, and depression correlations (control group)

S – SPSS Output: Kruskal-Wallis H test and contingency tables for TOMM, SRSI, and WMT

T – SPSS Output: Kruskal-Wallis H for SPCS

U – SPSS Output: Kruskal-Wallis H of pseudo items

V – SPSS Output: ROC curves and classification statistics

**OTHER**

W – Author Submission Guidelines

## THESIS ABSTRACT

Symptoms of post-concussion syndrome (PCS) can occur after a mild traumatic brain injury (mTBI). Whilst specific neuropsychological tests can be used to determine cognitive disturbances, there is a reliance on the use of self-report measures to record the presence and severity of other PCS symptoms. Self-reported symptoms can be subject to over report and exaggeration, particularly in individuals involved in litigation (Mittenberg, Patton, Canyock & Condit, 2002; Larrabee, 2003).

Paper one investigated the research evidence relating to what is known about the validation of self-reported symptoms of PCS. A total of nine papers were identified and appraised, the findings were synthesised according to the following topic areas: performance validity test outcomes and symptom reporting, the application of PCS self-report measures as symptom validity tests (SVTs), and the application of new and existing SVTs. Paper two followed from a recommendation to investigate a new measure that involved the endorsement of both genuine symptoms and atypical symptoms of PCS. This paper aimed to explore the utility of the Symptoms of Post-Concussion Syndrome questionnaire (SPCS). A simulation design was employed using control participants instructed to respond genuinely, and participants instructed to malingering. An optimal cut off score of >25 was established for the measure which produced promising diagnostic classification statistics (sensitivity .90, specificity 1.00, positive predictive power = 100%, negative predictive power = 93.75%). Further validation of the proposed cut off score with a clinical sample is required. Finally, paper three provides a reflective account of the process of completing this thesis, and a discussion of the challenges that were encountered along the way.

Total word count: 19,549 (excluding references and appendices)

## PREFACE

Paper one and paper two in this thesis will be submitted to the *Journal of Clinical and Experimental Neuropsychology*, which has an emphasis of interest on validity studies of psychometric procedures used in neuropsychological assessment of persons with known or suspected brain damage.

Both papers have been written in accordance with the author guidelines (Appendix W) with the following exceptions:

- Main tables and figures have been included in the main text of the thesis in order to improve readability.
- All papers have been formatted in accordance with the guidelines provided by Staffordshire and Keele Universities for the submission of professional theses.

The third paper in this thesis is not intended for publication.

## **Paper One: Literature Review**

How Can the Self-report of Post-Concussion Syndrome Symptoms be Validated?

## ABSTRACT

**Introduction:** Symptoms of post-concussion syndrome (PCS) can occur after a mild traumatic brain injury (mTBI). Diagnosis relies in part on the self-report of symptoms which can be subject to over-report and exaggeration. This article aimed to review the literature for what is known about the validation of self-reported symptoms of post-concussion syndrome (PCS).

**Method:** To identify articles that investigated symptom validity tests and/or factors that affect the legitimate self-report of PCS symptoms, a computerised literature search using EBSCO host (including All Health, Life Sciences and Psychology and Sociology databases) and Web of Science data bases was undertaken using the search terms - POST CONCUSS\* or POSTCONCUSS\* or POST-CONCUSS\*, MALINGER\*, and SYMPTOM VALIDITY. Papers were reviewed using an evaluative tool which contained items relating to reporting, generalisability, validity, and power. The findings from each paper were synthesised to better understand what is known about the self-report of symptoms in PCS.

**Results:** A total of nine papers were selected for review. Research papers concerning the following topic areas were appraised and discussed: performance validity test outcomes and symptom reporting, the application of PCS self-report measures as SVTs, and the application of new and existing SVTs.

**Conclusion:** This review found that the self-report of PCS symptoms can most reliably be validated using SVT measures that function as clinical prediction rules and have high sensitivity, specificity, positive predictive power and negative predictive power values. The merits of papers concerned with the utility of self-report measures of PCS symptoms as SVTs, as well as measures designed for the sole purpose of identifying over reporting, were discussed. Recommendations for future research included exploring the utility of a measure that looks at both over reporting of PCS symptoms and the endorsement of spurious or atypical symptoms not associated with PCS.

*Word count – 9639 (inclusive of 294 word abstract)*

## **How Can the Self-report of Post-Concussion Syndrome Symptoms be Validated?**

### **What is Post-Concussion Syndrome?**

Post-Concussion Syndrome (PCS) is a set of psychological, somatic and cognitive symptoms that may occur after experiencing a concussion. Diagnostic criteria established by The International Statistical Classification of Diseases and Related Health Problems (ICD-10) states that in order to receive a diagnosis of PCS a patient must have had a head injury “usually sufficiently severe to result in loss of consciousness”, and then within four weeks, develop at least three of the following symptoms; headache, dizziness, fatigue, irritability, sleep problems, concentration problems, memory problems, problems tolerating stress/emotion/alcohol (World Health Organisation, 1992).

Neuropsychological tests are used to measure cognitive deficits that can result from PCS, for example, memory problems. Self-report questionnaires are used alongside these tests to measure the presence and severity of other reported symptoms.

When considering a diagnosis of PCS, clinicians must also evaluate the possibility of malingering and symptom exaggeration. Malingering refers to the intentional production of false or exaggerated psychological or physical symptoms, motivated by external incentives, for example, financial compensation (Bush, Ruff, Troster, Barth, et al., 2005). It is estimated that around 40% of individuals involved in litigation for head injury are malingering symptoms (Mittenberg, Patton, Canyock & Condit, 2002; Larrabee, 2003). Undetected malingering can have clinical implications on receiving an accurate diagnosis, injury management, and can also lead to increases in health costs as well as blocking services for individuals experiencing genuine clinical symptoms (Logan, Goldman, Zola & Mackey, 2014).

### **What is symptom and performance validity?**

In an article by Bush and colleagues in 2005, symptom validity is defined as ‘the accuracy or truthfulness of the examinee’s behavioural presentation, self-reported symptoms, or performance on neuropsychological measures.’ (Bush et al., 2005). This definition has since been refined, however. Confirmatory factor analysis by Van Dyke, Millis, Axelrod and Hanks (2013) revealed that cognitive performance,

symptom self-report, performance validity and symptom validity are distinct factors. This suggests that failure in one validity domain does not invalidate the other domain, and so performance validity and symptom validity should be evaluated separately. It was recommended by Larrabee (2012) that the terms 'performance validity test' (PVT) and 'symptom validity test' (SVT) be used as opposed to "effort" or "response bias". It is proposed that performance validity refers to the degree to which an individual's neuropsychological test performance is reflective of their actual cognitive ability. Symptom validity, however, is the degree to which an individual's symptomatic complaint in response to self-report measures is reflective of their true experience of symptoms.

### **Rationale for the current review**

Much controversy exists around the diagnosis of PCS (Al Sayegh, Sandford, & Carson, 2010). This is due to disagreements over the aetiological mechanism and the finding that symptoms of PCS also occur in individuals who have no history of head injury (Iverson, 2005). There has been much debate concerning the degree to which psychological factors and organic factors are responsible. The World Health Organisation (Carroll et al., 2004) conducted a systematic review of the prognosis for mild traumatic brain injury (mTBI) and concluded that persistent PCS symptoms following an mTBI involves a complex interplay of biological, psychological, and social factors, including compensation and litigation issues. An editorial article in the British Journal of Psychiatry (King, 2003) cited the possibility that, at different times after injury, 'windows of vulnerability' emerge which increase the role of psychological factors. Such factors include when the patient begins to doubt the possibility of recovery or when issues surrounding compensation claims predominate. As such, there is a need to systematically identify and evaluate the literature to understand the ways in which the validity of self-reported symptoms of PCS can be determined.

### **Aim**

This review aims to explore and critically appraise the literature concerning what is known about the validation of self-reported symptoms of PCS. It focuses on synthesising the findings of the reported outcomes from the identified literature.

## **METHOD**

### **Selection of papers**

The final literature search was completed on 17/02/2017. To identify potential papers for review, a search strategy to search paper abstracts used the following search terms: POST CONCUSS\* or POSTCONCUSS\* or POST-CONCUSS\*, MALINGER\*, and SYMPTOM VALIDITY. As can be seen in Figure 1, this produced 41 results in EBSCO Host (which included the following databases: Psycinfo, AMED, MEDLINE, SPORTDiscus, AgeLine, and CINAHL) and 22 results in Web of Science. Duplicate results were removed and the remaining abstracts were then reviewed to select the final nine papers that were to be appraised for this literature review. Samples of the papers were checked against the inclusion/exclusion criteria by another member of the research team to ensure the same papers were retained.

### **Inclusion criteria**

Papers that met the following criteria were considered for review:

- Papers that specifically referred to testing the validity of self-reported symptoms of PCS.
- Papers that specifically referred to testing the utility of SVTs with PCS populations.
- Papers that collected data using clinical samples or simulation designs with healthy participants.

### **Exclusion criteria**

Papers that met any of the following criteria were excluded from the review:

- Papers that concerned testing the validity of self-reported symptoms of TBI symptoms, without specifically referring to PCS.
- Opinion papers or commentaries.
- Poster presentations or conference proceedings that were not formally published as an empirical research paper.

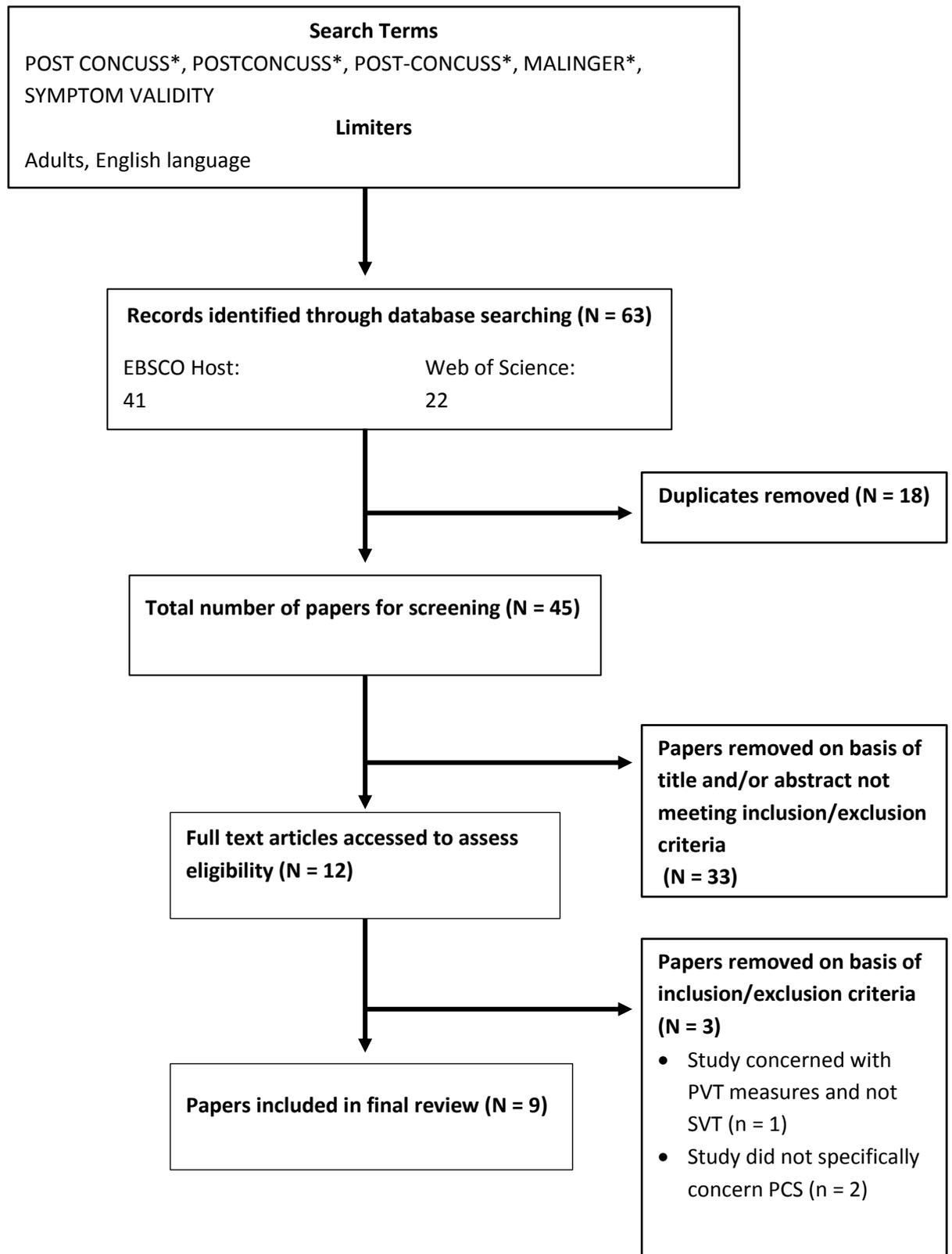


Figure 1. Literature review screening process flow chart

## **Evaluation tool**

In order to provide a critical appraisal of the papers included in this review an evaluation tool was developed as no single tool addressed the various study designs and methods of analysis (see appendix A). The evaluation tool was developed from two sets of appraisal checklists. Three items were adapted from the Critical Appraisal Skills Programme (CASP) Evaluate a Clinical Prediction Rule Checklist (2013) and 11 items were adapted from Downs and Black (1999). The tool has a total of 14 evaluative questions relating to reporting, applicability of findings, internal and external validity, and power. There are some questions on the tool that specifically relate to the evaluation of clinical prediction rules. Not all of the research papers in this review produce a clinical prediction rule, and so in order to allow for comparisons between research papers, these items on the tool have been designed to be optional, and thus only contribute to a paper's evaluation score should it be applicable. It is believed that a percentage score will be more meaningful to the reader and this approach also allows for comparisons to be made across all the research papers included in this review.

## **RESULTS AND DISCUSSION**

The literature search retrieved a total of nine papers that met the inclusion and exclusion criteria. Two studies (Lange, Iverson, Brooks, & Ashton Rennison, 2010; Iverson, Lange, Brooks & Ashton Rennison, 2010) examined the effect of poor performance validity on the self-report of symptoms, two studies (Tsanadis, Montoya, Hanks, Millis, Fichtenberg, & Axelrod 2008; Van Dyke, Axelrod & Schutte, 2010) concerned investigations into the utility of existing self-report PCS symptom measures as SVTs, and five studies (Greiffenstein, Baker, Gola, Donders, & Miller, 2002; Cooper, Nelson, Armistead-Jehle, & Bowles, 2011; Lange, Edmed, Sullivan, French, & Cooper 2013; Sullivan, Lange, & Edmed, 2016; Parks, Gfeller, Emmert, & Lammert, 2016) explored the application of new and existing symptom validity tests when assessing for PCS, using both known groups and simulation designs (Table 1). The reviewed papers have therefore been presented in three sections in order to synthesise findings, examine limitations, and draw conclusions from three different methods of assessing the validity of self-reported symptoms.

The total percentage scores for each of the papers, along with the main strengths and limitations are presented in Table 2. For further detail concerning the appraisal of individual items on the evaluation tool for each paper, refer to Appendix B.

### **Performance validity test outcomes and symptom reporting**

Two papers in the review focussed on the effect of scores on performance validity measures on the self-report of PCS symptoms. Lange, Iverson, Brooks and Ashton Rennison (2010) examined the influence of poor effort on self-reported PCS symptoms following mild traumatic brain injury (mTBI). The study evaluated responses from 63 participants seen in a specialty clinic for individuals who are slow to recover from an mTBI. Participants were divided into two groups based on their performance on the Test of Memory Malingering (TOMM; Tombaugh, 1996), a forced-choice performance validity test routinely used in neuropsychological assessments, where a 'fail' is suggestive of malingering. It was hypothesised that

Table 1

*Characteristics of selected papers*

| <b>Reference</b>  | <b>Country</b> | <b>Purpose/Aims</b>  | <b>Measure(s)</b>  | <b>Participants &amp; Method</b>  | <b>Findings</b>   |
|---|----------------|--|--|---|---|
| <b>(1) Lange, Iverson, Brooks, &amp; Ashton Rennison (2010)</b> | Canada         | To examine the influence of poor performance validity on self-reported symptoms of PCS following mTBI  | Post-Concussion Scale (PCS; Lovell et al., 2006)<br>British Columbia Cognitive Complaints Inventory (BC-CCI, Iverson, 2003a, 2003b; Iverson & Remick, 2003)<br>Test of Memory Malingering (TOMM; Tombaugh, 1996) | 63 patients from a concussion clinic<br>Participants were divided into two groups based on their performance on the TOMM (fail n = 15, pass n = 48). Group differences in responses to self-report measures were then investigated. | Significant main effects and large effect sizes were found for the PCS and BC-CCI total scores. Participants in the TOMM fail group scored higher than those in the TOMM pass group highlighting the importance of considering the influence of poor performance validity when assessing for PCS. |
| <b>(2) Iverson, Lange, Brooks &amp; Rennison (2010)</b>         | Canada         | To examine the “good old days” bias in patients who sustained mTBI. To explore the effect of performance validity on the report of pre-and post-injury PCS symptoms. | British Columbia Post-concussion Symptom Inventory (BC-PSI, Iverson & Gaetz, 2004; Iverson & Lange, 2003; Iverson et al., 2007)<br>Test of Memory Malingering (TOMM; Tombaugh, 1996)                             | 90 mTBI participants and 177 control participants.<br>mTBI participants provided pre- and post-injury ratings on the BC-PSI. Ratings were also compared to healthy controls.  | mTBI participants endorsed fewer pre-injury symptoms in comparison to the control group. Individuals who failed the TOMM tended to retrospectively report fewer pre-injury and more post-injury PCS symptoms than those individuals who passed the TOMM.  |

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| <p><b>(3) Tsanadis, Montoya, Hanks, Millis, Fichtenberg, &amp; Axelrod (2008)</b></p> | <p>USA</p> | <p>To explore the frequency and type of PCS symptoms reported by individuals with moderate-severe TBI and to investigate the effects of poor performance validity on the report of symptoms.</p> | <p>The Postconcussive Symptom Questionnaire (PCSQ; Lees-Haley, 1992)</p>  | <p>158 participants at a rehabilitation hospital. Participants were divided into two groups – moderate to severe brain injury (M-S TBI) (n = 133), and a mTBI group who exhibited poor performance validity (n = 25). Participants' responses on the PCSQ were compared for between group differences.</p>  | <p>Significant differences in item endorsement on the PCSQ were found. The mTBI poor performance validity group reported more symptoms with greater severity in comparison to the M-S TBI group.</p>   |
| <p><b>(4) Van Dyke, Axelrod, &amp; Schutte (2010)</b></p>                             | <p>USA</p> | <p>To investigate the utility of the PCSQ and its short form versions as a symptom validity measure.</p>   | <p>The Post-concussive Symptom Questionnaire (PCSQ; Lees-Haley, 1992) and its short forms. Minnesota Multiphasic Personality Inventory-2 Fake Bad Symptom Validity Scale (FBS; Lees-Haley, English, &amp; Glenn, 1991) and the Response Bias Scale (RBS; Gervais, Ben-Porath, Wygant, &amp; Green, 2007).</p> | <p>95 participants referred to a veteran's medical centre. 25 individuals were identified to be over reporting by the FBS and RBS. Total scores on the PCSQ were calculated and investigated with multiple regression analysis to determine construct validity. ROC curve analysis was conducted to determine the predictive value of the PCSQ.</p> | <p>Multiple regression analyses revealed that self-report symptom validity scales predicted significant variance in PCSQ total scores. The PCSQ cut off score of &gt;27 produced .36 sensitivity, .94 specificity, .69 PPP, and .80 NPP.</p> |

|   |     |   |  |   |  |
|---|-----|---|--|---|--|
| <b>(5) Greiffenstein, Baker, Gola, Donders, &amp; Miller (2002)</b> | USA | To determine whether the FBS captured atypical reporting styles better than other infrequent-symptom scales in the context of PCS. Explore the construct validity of the FBS. | The Fake Bad Scale (FBS; Lees-Haley, English & Glenn, 1991) The Minnesota Multiphasic Personality Inventory – Second edition (MMPI-2; Butcher et al., 1989)  | 159 litigating patients with illogical symptom histories termed the atypical minor head injury group (AMHI). A comparison group made of 68 patients with documented moderate-severe closed head injury (MSCHI). All participants were administered a battery of tests and the correlational and diagnostic properties of the FBS were examined. | The results indicated that when applying the original cutting score of 20+, the FBS was sensitive (.87) to atypical head injury symptoms, however specificity (.53) for the measure was lower, and the FBS items may reflect true long-term outcome in more severe TBI. The FBS appeared superior to other infrequency scales in differentiating atypical from real brain injury outcomes. |
| <b>(6) Cooper, Nelson, Armistead-Jehle, &amp; Bowles (2011)</b>     | USA | To investigate the psychometric properties of the mBIAS as a screening measure of symptom exaggeration for PCS.   | The mild Brain Injury Atypical Symptoms (mBIAS; Cooper et al., 2011), The Posttraumatic Checklist-Military (PCL-M; Blanchard et al., 1996), The Neurobehavioral Symptom Inventory (NSI; Ciccerone & Kalmar, 1995). | Subjects were 403 consecutive referrals to a brain injury clinic at a large military medical centre. Factor analysis was performed on all items from the mBIAS, PCL-M, and NSI. Item endorsement on the mBIAS was used a marker for symptom over-reporting. Diagnostic properties of the mBIAS were explored.                                   | Factor analysis revealed that the mBIAS scale items represented a unique factor. Psychometric properties of the mBIAS revealed that a total score of 8 on the measure was optimal for the detection of symptom over-reporting (sensitivity = .94, specificity = .92).  |

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| <b>(7) Parks, Gfeller, Emmert, &amp; Lammert (2016)</b>        | USA       | To examine the accuracy of the SIMS in detecting participants instructed to simulate feigned PCS, PTSD and comorbid PCS and PTSD symptoms. | The Structured Inventory of Malingered Symptomatology (SIMS; Widows & Smith, 2005), The Neurobehavioral Symptom Inventory (NSI; Ciccerone & Kalmar, 1995), The PTSD Checklist Civilian (PCL-C; Weathers et al., 1994).                                  | 83 volunteer students were assigned to one of three experimental groups (1) feigned PCS (n = 26), (2) feigned PTSD (n = 26), (3) feigned PCS & PTSD (n = 26). The sensitivity values at several cut off scores were examined.  | The SIMS produced the highest sensitivity values for the feign PCS group (.89). Other classification statistics were not available due to the study design not having a control group condition.   |
| <b>(8) Lange, Edmed, Sullivan, French, &amp; Cooper (2013)</b> | Australia | To examine the utility of the mBIAS to detect symptom exaggeration using a simulation design.  | The mBIAS (Cooper et al., 2011), the Minnesota Multiphasic Personality Inventory-2, Restructured Form (MMPI-2-RF; Ben-Porath & Tellegen, 2008), the NSI (Ciccerone & Kalmar, 1995), the PCL-C (Weathers et al., 1994), the SIMS (Widows & Smith, 2005). | 85 undergraduate students were assigned to one of three experimental groups (1) feign PCS (n = 29), (2) feign PTSD (n = 32), (3) controls (n = 24). Participants received instructions according to their group condition. The diagnostic properties of the mBIAS were explored. | Participants instructed to feign PCS and PTSD had significantly higher scores on the mBIAS than control participants. An optimal cut off score of >6 on the mBIAS was indicative of “possible exaggeration” and produced .62 sensitivity, .88 specificity, .73 PPP, and .81 NPP in controls vs. feign PCS comparisons. |

|  |                  |   |  |  |   |
|--|------------------|---|--|--|---|
| <b>(9) Sullivan, Lange, &amp; Edmed (2016)</b> | <b>Australia</b> | <b>To evaluate the utility of the NSI Validity-10 to detect symptom exaggeration using a simulation design.</b> | <b>The mBIAS (Cooper et al., 2011), MMPI-2-RF (Ben-Porath &amp; Tellegen, 2008), the NSI Validity-10 (Vanderploeg, Cooper, Belanger, Donnell, Kennedy, Hopewell, &amp; Scott, 2014), the PCL-C (Weathers et al., 1994), the SIMS (Widows &amp; Smith, 2005).</b> | <b>Secondary analysis was performed on data from Lange et al. (2013)</b> | <b>An optimal cut off score for the NSI Validity – 10 was identified as <math>\geq 10</math> which was indicative of “probable exaggeration” and produced .93 sensitivity, 1.00 specificity, 1.00 PPP, and .96 NPP in controls vs. feign PCS comparisons.</b> |
|--|------------------|---|--|--|---|

Table 2

*Research article strengths, limitations and percentage scores*

| Reference | Percentage score | Strengths   | Limitations   |
|-----------|------------------|---|---|
| (1)       | 70%              | Clearly described aims & hypotheses, use of measures, recruitment and sampling of participants, statistical methods and main findings.  | Type 1 error (not corrected); Made assumptions about PVT outcomes and symptom validity; Issues with generalisability; Relied on results of single PVT measure.  |
| (2)       | 56%              | Clearly described aims & hypotheses, use of measures, statistical methods and main findings; Considered perceptions of pre-injury symptoms.   | Made assumptions about PVT outcomes and symptom validity; Issues with generalisability and internal validity; Relied on results of single PVT measure.  |
| (3)       | 70%              | Clearly described aims & hypotheses, use of measures, recruitment and sampling of participants, and main findings.  | Mod-severe TBI participants used as a comparison group; Between group differences were explored, but there was no exploration of the clinical utility of the measure; Made assumptions about PVT outcomes and symptom validity.                         |
| (4)       | 67%              | Study design allowed for diagnostic classification statistics to be calculated; Provided two cut off scores to determine symptom validity; Examined variance explained by the measure using multiple regression analysis confirming construct validity. | Veteran sample; Poor specificity values increasing the risk of false positives, lack of multiple methods to measure both cognitive and psychological domains; Measure may not be reliable in assessing validity of PCS in clinical population.          |
| (5)       | 57%              | Clear aims and hypotheses; Clear description of group demographics and construction of groups; Reported diagnostic classification statistics.   | Significant issues with study design/internal validity; Main outcome measures were not clearly described; High false positive rates, due to poor specificity; Not clear if measure is actually detecting differences in injury severity or malingering. |
| (6)       | 71%              | Used factor analysis to confirm that measure  | Exclusively military sample; Lack of control group for  |

|            |     |   |  |
|------------|-----|---|--|
|            |     | was representing a unique factor; Diagnostic classification statistics included with high sensitivity and specificity values.   | comparison; No convergent validity; Study cannot state that failure on the measure was a function of conscious attempts to exaggerate symptoms   |
| <b>(7)</b> | 67% | Promising initial findings for use of measure as an SVT; Clear aims/hypotheses, description of measure, statistical methods used, and main findings.  | No control group for comparison; Design did not allow for full diagnostic classification statistics to be calculated; Potential issues with generalisability due to simulation design.                         |
| <b>(8)</b> | 87% | Utilised simulation design to allow for greater control in determining internal validity of the measure; Clear description and replicable method; reported diagnostic classification statistics including base rates. | Reported sensitivity value relatively low; Statistical methods were not clearly outlined; Potential issues with generalisability due to simulation design; Requires further validation with a clinical sample. |
| <b>(9)</b> | 87% | Clear description of development of measure. Provided classification statistics and diagnostic efficiency statistics for 25%, 35% and 45% base rates; High sensitivity and specificity reported.                      | Statistical methods were not clearly outlined; Potential issues with generalisability due to simulation design; Requires further validation with a clinical sample.  |

patients who failed the TOMM would endorse a greater degree of self-reported symptoms than those patients who passed the TOMM. Self-report symptoms were measured by the Post-Concussion Scale (Lovell et al., 2006) and the British Columbia Cognitive Complaints Inventory (BC-CCI: Iverson, 2003a, 2003b; Iverson & Remick, 2003).

It was reported that significant main effects and large to very large effects sizes were found for the total scores on the Post-Concussion Scale ( $p = .002$ ,  $d = 0.79$ ) and BC-CCI ( $p = .011$ ,  $d = 0.98$ ). Participants in the TOMM fail group endorsed more symptoms than those in the TOMM pass group on both self-report measures. Lange et al. (2010) concluded that the results of their study highlight the influence of poor effort on self-report inventories and stated that it is critical to consider issues of poor effort and possible symptom exaggeration when making a diagnosis of PCS.

Iverson and colleagues (Iverson, Lange, Brooks, & Ashton Rennison, 2010) explored the “good old days” bias in a PCS population. The “good old days” bias was a term developed to describe the tendency of patients with injuries, or general trauma, to underestimate past problems and overestimate the degree of change that has occurred post injury. In this study, 90 patients receiving compensation benefits following a mild traumatic brain injury (mTBI) completed the TOMM and the British Columbia Post-concussion Symptom Inventory (BC-PSI; Iverson, Zasler & Lange, 2007), a 16-item measure designed to assess the presence and severity of PCS symptoms. Participants were asked to make current as well as retrospective symptom ratings on the BC-PSI based on the month prior to sustaining their mTBI. Responses were compared to a control group that consisted of 177 healthy adults. It was found that participants who failed the TOMM (28.8%) not only reported a higher number of post injury symptoms ( $p < .001$ ;  $d=1.15$ ), they also gave a more positive impression with regards to their experience of pre-injury symptoms ( $p < .001$ ;  $d=2.32$ ) compared to patients who had passed the TOMM. Comparisons with the healthy control group revealed that all mTBI ratings of pre-injury symptoms, regardless of performance validity findings, were significantly lower than those reported by the control group ( $p < .001$ ;  $d=0.65$ ). However, a large effect size was found when comparing the

control group to the mTBI TOMM fail patients ( $p < .001$ ;  $d=0.82$ ) whereas a medium effect size was found for the mTBI TOMM pass patients ( $p < .022$ ;  $d=0.46$ ).

Iverson et al. (2010) concluded that post-injury symptom reporting and the “good old days” bias was associated with performance validity testing results. The findings were explained as representing a systematic bias in which an individual is trying to create an impression of being more able and better functioning than the average person prior to their injury, and then exaggerating their symptoms following injury.

### ***Quality Assessment***

As can be seen in Table 2, using the evaluation tool, Lange et al. (2010) was given a percentage score of 70%, and Iverson et al. (2010) scored 56% with regards to the applicability of findings, internal and external validity, and power.

One major limitation of these two papers is the suggestion that performance validity influences symptom validity. Conclusions are made about how performance validity testing, is important in establishing the legitimacy of self-reported symptoms of PCS, yet it is known that failure in one of these domains does not necessarily invalidate the results in the other (Van Dyke, et al., 2013). Although in Lange et al. (2010) and Iverson et al. (2010), the TOMM failure group endorsed more symptoms in comparison to participants who passed the TOMM, this did not necessarily mean that participants’ responses on the self-report measures were indicative of symptom invalidity. Conclusions can, therefore, only be made regarding the association of performance validity with the self-report of symptoms, and not causation.

### ***Participants***

All participants recruited in Lange et al. (2010) were receiving financial compensation. As a result it could be argued that the findings are not generalisable to the broader mTBI population due to the “litigation effect” as reported by Lees-Haley (1988). Issues with generalisability were also raised

in Iverson et al. (2010). It was stated that the sample should not be considered generalisable to all people who have sustained mTBIs as they were a highly selected and non-representative sample, who were also receiving compensation and were seen through a private clinic.

Both papers reported potential issues of systematic bias. In Lange et al. (2010) it was stated that only 63 out of 151 patients actually received neuropsychological screening at the specialty clinic, and the data from these 63 patients then went on to be analysed in the study. Similarly in Iverson et al. (2010), 62 out of 90 patients actually received neuropsychological screening. The samples that were used in the two studies may have represented sub-groups and a systematic bias of patients who were more likely to undergo neuropsychological screening, due to reporting more symptoms in the first instance, for example.

### *Internal Validity*

Comparison analyses in Iverson et al. (2010) of the mTBI group's reports of pre-injury symptoms to that of the control group, a large effect size was found for mTBI TOMM fail participants, however, a medium effect size was also found for the mTBI TOMM pass participants. Although the observed effect size was smaller for the TOMM pass than the TOMM fail, if the underestimation of pre-injury symptoms was solely associated with performance validity, a significant effect should not have been observed in participants classified as having legitimate performance validity, i.e. the TOMM pass group. This may suggest that experiencing an mTBI also has an impact on the "good old days" bias.

There may be an issue with the statistical methods that were used in Lange et al. (2010) to compare the TOMM pass and TOMM fail groups. The authors reported that Mann-Whitney U tests were performed to look at group differences in symptom reporting on each item of the Post-Concussion Scale and BC-CCI. It is acknowledged that the probability of Type 1 error increases when multiple statistical comparisons are made and adjustments to the p value would help to correct for this. However, the authors then go on to state their decision not to apply a more conservative p value as this was

considered too stringent given the sample size. The results reported by Lange and colleagues (2010), therefore, may have been affected by an increased probability of a Type 1 error.

### *Measures*

Both Lange et al. (2010) and Iverson et al. (2010) made use of only a single PVT measure in order to assign participants to pass or fail groups. Previous research has questioned the TOMM's sensitivity to correctly identify individuals who are giving poor or inadequate effort (DenBoer & Hall, 2007). It is possible that some participants may have been misidentified in the study, although the authors argue that this would not have changed the overall results of the study. Out of the 63 participants in Lange et al. (2010), just 15 (23.8%) were identified as failing the TOMM, and 16 (25.8 %) out of the 62 evaluated patients failed the TOMM in Iverson et al. (2010). This is not in keeping with previous research suggesting that around 40% of mTBI claims were indicative of probable malingering (Mittenberg, et al., 2002; Larrabee, 2003). The small sample size in the TOMM fail groups draws to question whether the sample was representative of patients with mTBI, who are seeking compensation and fail performance validity tests. Furthermore, issues with the sensitivity of the TOMM may explain the medium effect size found in Iverson et al. (2010) in the comparison of pre-injury ratings between the control group and mTBI TOMM pass group, as it is possible that some participants were misclassified.

### **The utility of existing self-report PCS symptom measures as SVTs**

The findings of two papers included in the review were concerned with the utility of an existing self-report measure, routinely used to assess the severity PCS symptoms. The Post-Concussive Symptom Questionnaire (PCSQ; Lees-Haley, 1992) is a 44 item self-report questionnaire that was initially developed to better understand the base rate occurrence of symptoms associated with PCS. Tsanadis, Montoya, Hanks, Millis, Fichtenberg and Axelrod (2008) used the PCSQ to examine differences in symptom reporting in two patient groups; individuals diagnosed with moderate to severe brain injury (n = 133), and individuals meeting criteria for mild traumatic brain injury

(mTBI) who exhibited no evidence of neurological injury and had failed tests of effort (n = 25). Tsanadis and colleagues (2008) found that participants in the poor effort mTBI group who were involved in litigation reported a higher degree of post concussive symptoms (psychological, cognitive, and somatic) than the moderate to severe TBI group. The authors stated that this was suggestive of symptom exaggeration and over reporting, and raised questions about PCS as a valid clinical diagnostic syndrome. The study highlighted observed differences in the reporting of symptoms of PCS between the two groups, but did not go on to suggest how the PCSQ could be used to establish the validity of symptom reporting.

Research by Van Dyke, Axelrod and Schutte (2010) looked into the utility of the PCSQ as an SVT in 95 individuals referred to a veterans medical centre for neuropsychological evaluation. Firstly, the construct validity of the PCSQ was investigated with multiple regression analyses against other measures of cognitive performance, general distress, and self-report symptom validity. Secondly, ROC curve analyses were conducted to explore the predictive value of the PCSQ in identifying individuals who had failed other measures of validity; the Minnesota Multiphasic Personality Inventory-2 Fake Bad Symptom Validity Scale (FBS; Lees-Haley, English, & Glenn, 1991) and the Response Bias Scale (RBS; Gervais, Ben-Porath, Wygant, & Green, 2007). Van Dyke and colleagues (2010) aimed to investigate the utility of the PCSQ and two other short forms of the measure (PCS-19, Millis, Hanks, Fitchenberg, & Axelrod, 2007; and PCS-NIM, Tsanadis, Montoya, Millis, Hanks, Fitchenberg, & Axelrod, 2007).

It was found that cognitive impairment did not account for significant variance in any of the versions of the PCSQ (PCSQ total = 2%, PCS-19 = 4%, & PCS-NIM = 2%). Measures of symptom validity were found to account for the most variance in the model (PCSQ total = 42%, PCS-19 = 43%, & PCS-NIM = 43%). Receiver Operating Characteristic (ROC) curve analyses revealed that for the PCSQ total a cut-off score of >27 produced the highest specificity (.94) and the best hit rate (.79), this was at the expense of lower sensitivity (.36), however. A cut-off score of >22 produced optimal sensitivity (.80) and specificity (.77). Similar classification rates were found across the

short form versions of the PCSQ, indicating that no one index is statistically superior. Van Dyke and colleagues (2010) therefore suggested that the short form versions perform just as well in comparison with the benefit of having 19 items rather than 44. It was concluded that the PCSQ and its short forms perform well as SVTs.

### ***Quality Assessment***

Tsanadis et al. (2008) received a percentage score of 70%. The study was well reported and gave a clear overview of the impact of injury severity and litigation status on the self-report of post concussive symptoms. The study by Van Dyke et al. (2010) was evaluated as 67%.

### ***Participants***

Tsanadis et al. (2008) used a moderate-severe TBI group as a comparison with the mTBI sample. There was no information regarding the self-awareness of symptoms collected in the study which could be considered problematic as symptom reporting requires self-awareness as well as self-report. It could be argued that the moderate to severe TBI group participants had deficits in self-awareness and thus their ability to accurately report symptoms would have been compromised, which could explain the differences observed between the two groups.

A main limitation of Van Dyke et al. (2010) was the generalisability of the findings, given the exclusively military veteran sample. Of the 95 participants, 92% were male. There is also some concern over the referral questions that were included in the sample. 54% of participants were referred to the service for TBI, 13% mild cognitive impairment, 5% cerebrovascular disease, 2% multiple sclerosis, and 2% hypoxia. Psychiatric referrals were also included which accounted for 23% of the sample. The data from the TBI participants was not reported separately to the rest of the sample. Although the paper by Van Dyke et al. (2010) meets the inclusion criteria of this literature review, as it concerns the self-report of PCS symptoms with a clinical sample, it is problematic to draw conclusions about the suitability of the PCSQ (and its short form versions) as an SVT in the

assessment of PCS, due to the variety of conditions and presentations included in the sample.

### *Design and statistical analysis methods*

The research design and analysis methods of Tsanadis and colleagues (2008) did not allow for a clinical prediction to be made. Inferences concerning the differences between group scores were developed and it was argued that the findings provided evidence that the self-report of PCS symptoms, in the presence of poor effort and involvement with litigation, may be viewed as negative impression management. However, as discussed earlier, caution should be taken when considering the relationship between performance validity, and symptom validity.

The research design used in Van Dyke et al. (2010) allowed for the findings to be used to examine the PCSQ for its utility as an SVT using diagnostic and classification statistics, which demonstrated some promising early evidence for its use as a brief measure. The lack of multiple methods of measuring both cognitive and psychological domains is considered a limitation of Van Dyke et al. (2010), as shared-methods variance may have affected the results. Cognitive symptoms were measured only by neuropsychological assessment measures whereas symptom validity and general distress were measured by self-report measures. The variance that was explained by the regression model could have been attributed to the measurement methods rather than the constructs that the measures were assumed to represent. Van Dyke and colleagues (2010) commented however, that the small amount of variance that was explained by the addition of distress measures to the model suggested that the findings were not spurious.

### **The application of new and existing symptom validity tests**

Five papers evaluated the application of measures designed to assess the validity of the self-report of PCS symptoms. Cooper, Nelson, Armistead-Jehle, & Bowles (2011) developed the 5-item Mild Brain Injury Atypical Symptoms Scale (mBIAS) to detect symptom exaggeration when embedded

within commonly used screening instruments used in PCS and PTSD (Post Traumatic Stress Disorder) populations. The mBIAS consists of the following items, (1) being unable to hear anything [complete deafness] for periods of time; (2) seeing only in black and white; (3) completely losing your voice for more than a minute; (4) complete loss of feeling in both arms; (5) difficulty swallowing due to a lump in the throat. Respondents are required to rate the extent to which the symptoms have disturbed them over the last two weeks on a 5-point likert scale (1= not at all, 5= extremely). A total score is then obtained. Cooper et al. (2011) used consecutive referrals to a brain injury clinic at a military medical centre to explore the psychometric properties of the mBIAS as an SVT with mTBI and neurologic patients. The purpose of the inclusion of a range of neurological conditions as well mTBI was to reduce the potential for false errors on the mBIAS by ensuring that item endorsement was not commonly shared with severe diffuse impairments. Patients completed measures of symptoms of PTSD, and PCS as well as the mBIAS items which were interspersed within the content of the other measures to minimise the likelihood of detection.

Factor analysis revealed that the mBIAS items measure a unique dimension in symptom reporting and so mBIAS responses should not be confounded by the presence of PTSD or PCS. Cooper et al. (2011) stated that given that the items on the mBIAS were extremely unlikely to be caused by mTBI, any endorsement of items should be considered as a marker for symptom over-reporting. The cut-off score with the best balance of sensitivity and specificity, positive predictive power and negative predictive power, however, appeared to be an mBIAS score of  $\geq 8$ . This led to a sensitivity value of .94, and a specificity value of .92. Cooper and colleagues (2011) concluded that the findings show strong initial support for the use of the mBIAS in military post-deployment populations.

Greiffenstein, Baker, Gola, Donders and Miller (2002) aimed to use archival data to conduct further research into the Fake Bad Scale (FBS; Lees-Haley, English & Glenn, 1991) to determine whether it was specific to persons trying to malingering a personal injury in the context of PCS. The FBS is a 43-item self-report measure that was constructed to detect simulation of

emotional distress in the context of compensation seeking. A cut-off score of 20 more was proposed to determine the validity of self-reported symptoms. Participants included a pool of 159 litigating patients with illogical symptom histories, termed the atypical minor head-injury (AMHI) group, the authors had also assessed this group as having 'persistent post-concussion syndrome'. The AMHI group was compared to a group of 68 patients with documented moderate-severe closed head injury (MSCHI). All patients had been administered a battery of PVTs and SVTs, including the FBS. The results indicated that when applying the original cutting score of 20+, the FBS was sensitive (.87) to atypical head injury symptoms, however, specificity (.53) was 53%, indicating a false positive rate of 47%. Greiffenstein and colleagues (2002) commented that the MSCHI participants were also involved in seeking compensation and so part of this group may have engaged in symptom promotion or exaggeration in excess of their legitimate injuries. Following correlations of FBS scores and indices of neurological status, it was found that FBS items overlapped with objective neurological abnormalities that may be seen within a moderate-severe head injury group. It was therefore concluded that the original FBS cut-score of 20+ may incorrectly identify individuals with more severe head injury as over reporting symptoms, as some FBS items may reflect true long-term outcome in severe cerebral dysfunction. An alternative cut-off score of 24+ was suggested for this patient group. The FBS does however, appear to be a valid measure of detecting spurious symptom reporting in the context of PCS patients seeking compensation.

*Analogue simulation designs:*

Within the group of papers evaluating the application of existing SVTs to assess the validity of self-reported symptoms of PCS, a subsection emerged concerning the use of analogue simulation designs. Analogue simulation designs use non-clinical participants who are assigned to different experimental conditions (e.g. control group and instructed to malingering group) and responses on the test measure(s) of interest are compared and analysed. The American Academy of Clinical Neuropsychology Consensus Conference Statement on the neuropsychological assessment of effort,

response bias and malingering (Heilbronner, Sweet, Morgan, Larrabee, Millis & Conference Participants, 2009) states that simulation designs represent rigorous and clinically relevant research designs. Such designs provide tight experimental control for examining “proof of concept”, including when validating new diagnostic or screening measures (Streiner, 2003).

The Structured Inventory of Malingered Symptomatology (SIMS: Widows and Smith, 2005) is a 75-item SVT designed as a screening measure to detect exaggerated psychological and neurological symptoms. Parks, Gfeller, Emmert and Lammert (2016) aimed to examine the accuracy of the SIMS in detecting participants instructed to simulate feigned PCS symptoms, PTSD symptoms, and comorbid PCS and PTSD symptoms. 78 undergraduate students were recruited and randomised into one of three experimental groups: (1) feigned PCS symptoms, (2) feigned PTSD symptoms, and (3) feigned PCS and PTSD. Participants were asked to imagine they had been in a car accident in which they were unharmed. As a result of the accident they were involved in a personal injury lawsuit and were required to undergo psychological testing and if found to have sustained an injury could receive compensation. Participants were also provided with a list of symptoms for their respective disorder. All participants were administered the SIMS (Widows & Smith, 2005), the Neurobehavioral Symptom Inventory (NSI: Cicerone and Kalmar, 1995) – a checklist for PCS symptoms, and the PTSD Checklist Civilian Version (PCL-C: Weathers, Litz, Huska, and Keane, 1994) – a symptom checklist for the assessment of PTSD.

Parks and colleagues (2016) explored the sensitivity of the SIMS with the different experimental groups. A cut-off score for the SIMS total score of >14 detected the greatest number of participants in the feigned PCS group (.89). The authors concluded that the SIMS has potential for use in clinical settings where PCS symptoms are assessed and there is a need for symptom validity testing.

Lange, Edmed, Sullivan, French and Cooper (2013) used an analogue simulation study design to examine the utility of the mBIAS to detect feigned

PCS and PTSD. For a full description of the mBIAS, see the discussion of Cooper et al. (2011) above. 85 healthy undergraduate students were recruited. Participants completed a battery of self-report measures following random allocation to one of three experimental conditions: control group, feigned symptoms of PCS, and feigned symptoms of PTSD. The battery of self-report measures included the mBIAS (Cooper et al., 2011), the PCL-C (Weathers et al., 1994), the NSI (Cicerone & Kalmar, 1995), The Minnesota Multiphasic Personality Inventory-2, Restructured Form (MMPI-2-RF; Ben-Porath & Tellegen, 2008), and the SIMS (Widows & Smith, 2005). In this study the mBIAS, NSI and PCL-C were combined into a single measure. This was done in an effort to minimise the likelihood of item detection. Prior to completing the self-report measures, participants received written instructions for their experimental condition. For the PCS and PTSD conditions the instructions consisted of a case scenario that described their motivations for feigning and diagnostic criteria for either PCS or PTSD. A test phase was also incorporated to ensure participants had sufficient understanding of the disorder they were instructed to feign.

All participants were informed of an incentive of \$100 depending on their performance. Control participants were informed that they could win the prize based on the honesty of their responses. While the PCS and PTSD groups were told that winners would be selected based on the quality of their feigned performance, in actual fact, prize winners were randomly selected.

A series of group comparisons were undertaken to examine the differences in group responses to the psychometric measures. Lange et al. (2013) acknowledged the probability of type 1 error increasing with multiple comparisons and so significant between group differences were interpreted using a criteria of  $p < .01$ . Participants in the feign PCS and feign PTSD groups were found to have consistently higher scores on all of the self-report measures in comparison to the control group, with large to very large effect sizes. Analyses on the mBIAS responses revealed that feign PCS participants had higher total scores ( $p < .01$ ;  $d = 1.02$ ) and a significantly higher number of symptoms endorsed as 'severe' or higher ( $p < .01$ ;  $d = .84$

to  $d = 1.59$ ). One of the five mBIAS items in particular received higher scores [“being unable to hear anything (complete deafness) for periods of time”].

Classification statistics identified the optimal cut-off score for “highly probable exaggeration” for the feign PCD group as  $\geq 8$ . This produced very high positive predictive power (1.00) and specificity (1.00), and moderate negative predictive power (.73), sensitivity, however was low (.31). An optimal cut-off score for “possible exaggeration” was determined as  $\geq 6$ . This produced a moderate-high positive predictive power (.73) and adequate specificity (.88) and negative predictive power (.81). Sensitivity improved with this cut-off to .62. Lange et al. (2013) concluded that the “highly probable exaggeration” cut-off score is only reliable as a tool to “rule in” symptom exaggeration, but is not reliable as a measure to “rule out”. The second cut-off score of  $\geq 6$  however, can be used as a tool to “rule out” symptom exaggeration. That is, a clinician can have reasonably high confidence that an individual scoring below the cut-off score is not exaggerating. This cut-off score will identify a considerably larger proportion of individuals feigning PCS symptoms than the first cut-off score.

Sullivan, Lange & Edmed (2016) performed secondary analysis on the data from Lange et al. (2013) to explore the utility of the Neurobehavioral Symptom Inventory Validity – 10 index (NSI Validity-10; Vanderploeg, Cooper, Belanger, Donnell, Kennedy, Hopewell, & Scott, 2014) to detect symptom exaggeration in PCS and PTSD. The same participants and procedures as described in Lange et al. (2013) were used. New NSI validity measures were created in 2014 by Vanderploeg et al. This included the LOW6, which was made up of 6 low-frequency items; The Negative Impression Management-5 (NIM5), made up of 5 negative impression management items; and the NSI Validity-10 which was made up of 10 items from the LOW6 and NIM5 (one overlapping item was counted once).

An optimal cut-off score for “highly probable exaggeration” was  $\geq 10$  which in the feign PCS condition produced very high positive predictive power (1.00), specificity (1.00), negative predictive power (.96), and sensitivity (.93). The optimal cut-off score for “possible exaggeration” was  $\geq 8$

which gave high positive predictive power (.93), specificity (.96), negative predictive power (.98), and sensitivity (.97). These results suggested that the NSI Validity -10 was a very effective measure at accurately identifying feigned PCS.

### ***Quality Assessment***

#### *Participants*

There was some concern about the selection of participants in Lange et al. (2013) and Sullivan et al. (2016). Participants across all groups were selected for the final sample based on their responses on the SIMS and the MMPI-2-RF validity scales. Control group participants were excluded from the study if their responses did not suggest a genuine response style. Participants in the experimental conditions however, were also excluded if their responses did not suggest that they had over reported or exaggerated symptoms enough (scoring beyond the cut-offs on both measures). It is possible that by narrowing the sample in this way, only participants with the most extreme reporting styles were retained, and less extreme, more subtle 'feigners' were not represented. This could have impacted on the likelihood of finding statistically significant results as the control group and experimental conditions became more polarised. It is important, particularly in analogue simulation designs, that a broad range of response styles be included in the analysis, as this is more likely to be reflective of the range of malingering presentations in real life settings.

The sample used in Cooper et al. (2011) was composed of active duty service members, which may have led to some issues with the generalisability of findings to clinical settings as the motivation to feign symptoms may differ. As part of an analogue simulation design, Lange et al. (2013), Sullivan et al. (2016), and Parks et al. (2016) recruited neurologically healthy participants. There may be some issues with the generalisability of the findings from this population to clinical settings. Potential issues surrounding the generalisability of using these designs are discussed in more detail below.

### *Generalisability of analogue simulation designs.*

The implications of using an analogue simulation study design, as seen in Lange et al. (2012), Parks et al. (2016), and Sullivan et al. (2016) is discussed. An advantage of using an analogue simulation design is that there is greater experimental control than with other samples. Lange and colleagues (2010) acknowledged however, that the most ecologically valid study design when validating a new psychometric measure would be to use clinical subjects alongside known groups in a simulation design. As such, it could be argued that these studies lack ecological validity and generalisability. Compared with previously proposed cut-off scores developed from research using clinical populations, the cut-off scores identified by Sullivan et al. (2016) were very low. Previous studies with clinical criterion designs, suggest cut-off scores of  $\geq 23$  to detect over reporting of symptoms (Lange, Brickell, Lippa, & French, 2015; Vandeploeg et al., 2014). It could be argued that these studies were not specifically investigating the feigning of PCS symptoms, however, and so a lower cut-off score may be acceptable and appropriate when identifying feigned self-reported PCS symptoms. Sullivan et al. (2016) argue that different measures used to diagnostically categorise the participant groups may explain the differences in cut-off scores found in the clinical studies.

Several studies have found that simulators instructed to malingering do not significantly differ from clinical populations seeking secondary gain (Meyers, 2007; Mittenberg, Theroux-Fichera, Zielinski, & Heilbronner, 1995; Rohling, Meyers, & Millis, 2003).

### *Study Design*

There were issues with the study designs employed in Cooper et al. (2011) and Parks et al. (2016). Neither study recruited a control group for comparison. This meant that for Parks et al. (2016) additional classification statistics (i.e. specificity, positive and negative predictive power) could not be calculated. Specificity and predictive power calculations are required to ensure that a measure does not incorrectly identify genuine responders as having invalid self-report of symptoms. The authors acknowledged this

limitation and stated that the reported findings are part of an early step in validating the SIMS for use as an SVT with PCS populations. Classification statistics were still calculated in Cooper et al. (2011) however, as it was assumed that any endorsement of items on the mBIAS was a marker for over reporting. The study design did not include the use of any established SVTs which could have allowed for convergent validity comparisons. Consequently, Cooper et al. (2011) cannot state with confidence that over-reporting on the mBIAS is a function of conscious attempts to exaggerate symptoms. The findings in the study cannot be used to establish why a patient may endorse items on the mBIAS and be identified to have elevated scores.

The design employed by Greiffenstein et al. (2002) appears to confuse the findings of the effectiveness of the FBS to determine symptom validity. It is reported that alongside the FBS, other measures of validity were also collected. The results of these measures however, were not used to classify participants into either a feigning or genuine responders group. The reported classification statistics were based on differentiating the AMHI group from the MSCHI group, yet the MSCHI were also involved in litigation and may have also engaged in symptom promotion, and this may explain the poor specificity values that were found. This also draws into question whether the FBS was classifying individuals based on invalid symptom reporting or rather, if it was differentiating based on the severity of expressed symptoms. The finding that FBS items overlapped with neurological symptoms that may be seen with more severely injured patients supports this hypothesis. The reliability and validity of the FBS as an SVT is therefore, questionable. It is noted that Greene (2000) questions the validity of the FBS stating that “additional research is needed to determine whether the FBS scale is specific to persons trying to malingering in personal injury because of its low correlations with other infrequency scales” (pp. 76-77). Further research with an alternative comparison group, or a simulation design that warrants greater experimental control may help to determine what the FBS is in fact measuring.

## **Synthesis of Findings**

The papers in this literature review were presented in three sections according to the types of measures used to establish the validity of self-reported symptoms of PCS. The findings from these three sections are synthesised below.

### ***Performance validity test outcomes and symptom reporting***

The two research papers (Lange et al., 2010; Iverson et al., 2010) that explored the relationship between performance validity and symptom reporting in PCS provided little information in the way of determining valid self-report due to performance validity and symptom validity being distinct from one another. Clinicians may carry out PVTs as part of a standard neuropsychology assessment, and this will provide information about the validity of performance on other neuropsychological measures. In order to establish the validity of self-reported symptoms, however, SVTs are needed. Self-reported symptoms cannot be reliably validated using outcomes from PVT measures to assume symptom validity.

### **The utility of existing self-report PCS symptom measures as SVTs**

There is scope for existing self-report measures, such as the PCSQ (Tsanadis et al., 2008; Van Dyke et al., 2010), to be utilised to assess the validity of self-reported PCS symptoms. Study designs that compare the effectiveness of self-report measures with existing SVTs and provide cut-off scores with classification statistics enable greater clinical application than designs that solely identify between group differences. Van Dyke et al. (2010) proposed a cut-off score on the PCSQ of >22, which provided adequate specificity (.94), however, sensitivity (.36) was poor, meaning that many cases of invalid self-report of PCS symptoms would go undetected.

### **The utility of new and existing SVTs**

The FBS was found to have promising concordant validity with other established SVT measures (Greiffenstein et al., 2002) and was effective at detecting atypical persistent PCS patients from a moderate-severe closed

head injury comparison group. However, as the comparison group were also involved in litigation, it is not clear if the FBS was in fact measuring symptom validity. As a high rate of false positives were found it is likely that the FBS was measuring symptom validity and that the two groups did not represent a malingering group and a genuine responders group, however, positive correlations were also found with features of true long term outcome of more severe injuries.

Initial research into the mBIAS presented promising findings regarding its use as an SVT to determine the validity of self-reported PCS symptoms (Cooper et al., 2011), however due to the study design it could not be stated with confidence that the mBIAS measured conscious attempts to exaggerate PCS symptoms. A simulation study using the mBIAS allowed for greater control to investigate the internal validity of the measure (Lange et al., 2013). Although acceptable levels of specificity were attained, the sensitivity (.62) of the mBIAS in detecting the self-report of feigned PCS symptoms was disappointing, suggesting that the measure may not be as effective at determining symptom validity as Cooper et al. (2011) suggested. The SIMS (Parks et al., 2016) provided a better sensitivity value of .89, supporting its use as an SVT screening measure in PCS. Further classification statistics could not be calculated however, due to the lack of a comparison group.

Of the papers reviewed in this section, the NSI Validity – 10 was found to be the most effective measure at validating the self-report of PCS symptoms (Sullivan et al., 2016). The classification statistics revealed that a cut off score of  $\geq 8$  produced high sensitivity (.97), specificity (.96), PPP (.93), NPP (.98).

## **CONCLUSION**

This review identified, critically appraised and synthesised the literature to understand how the self-report of PCS symptoms can be validated. A review of the literature led to the identification of nine research articles. Appraisal of these research papers resulted in three main sections of the review, each section concerned different categories of measures to validate the self-report of PCS symptoms. These included the effect of PVT outcomes on symptom reporting, the application of self-report PCS symptom measures as SVTs, and the application of new and existing SVTs.

### **Clinical Implications**

According to statistics released by Headway (2012), each year around 1 million people attend accident and emergency services in the UK following a head injury. Approximately 85% of these are cases of mTBI. At least half of these patients will experience some PCS symptoms, and although most will recover completely within 3 months of injury, around a third experience persisting PCS symptoms beyond this time (King, 2003). Due to the reliance on the self-report of symptoms in the diagnosis of PCS, determining symptom validity is of great importance. This is particularly pertinent for services involved with neuropsychological assessment for the purposes of litigation. Knowledge of effective measures of SVTs that can detect feigned symptoms of PCS is essential and these measures should be included in standard psychometric batteries when considering a diagnosis of PCS.

### **Future Research**

All of the SVT measures that were investigated through this review were concerned with the endorsement of either genuine symptoms or atypical symptoms of PCS. An area for future research could involve an investigation into the design of a measure that includes both genuine symptoms of PCS and atypical pseudo symptoms in order improve the effectiveness of the measure to detect different styles of malingering. As discussed earlier, simulation designs appear to be suitable for establishing the utility of new measures as greater experimental control can help to determine reasons

behind symptom endorsement. As with the validation of any psychometric measure, however, evidence of suitability with the intended clinical population is also of importance in order to ensure generalisability.

The British Psychological Society (2009) reported that there is little UK research literature on validity testing and that there is a need for this to be developed. This literature review has revealed that in terms of studies investigating the validation of the self-report of PCS symptoms, no UK research currently exists.

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## Appendix A

### Evaluation Tool

|   |   |     |    |     |
|---|---|-----|----|-----|
| Reporting                                 | <p><b>Is the hypothesis/aim/objective of the study clearly described?</b></p>   | Yes | No |     |
|   | <p><b>Are the main outcomes to be measured clearly described in the introduction or methods section?</b><br/><i>If the main outcomes are first mentioned in the Results section, the question should be answered No.</i></p>                            | Yes | No |     |
|   | <p><b>Are the characteristics of the participants included in the study clearly described?</b><br/><i>In cohort studies and trials, inclusion and exclusion criteria should be given.</i></p>   | Yes | No |     |
|   | <p><b>Are the statistical methods used clearly described?</b></p>   | Yes | No |     |
|   | <p><b>Are the main findings of the study clearly described?</b><br/><i>Simple outcome data should be reported for all major findings so that the reader can check the major analyses and conclusions.</i></p>   | Yes | No |     |
|   | <p><b>Can the performance of the clinical prediction rule be calculated?</b><br/><i>Performance results can be presented as: sensitivity, specificity, positive predictive power, negative predictive power, ROC curve, calibration curves etc.</i></p> | Yes | No | N/A |
| <p><b>Are the findings applicable</b></p> | <p><b>Would the clinical prediction rule be reliable and results interpretable if used in assessing post concussion syndrome?</b><br/><i>Consider if your setting is too different from that of the study.</i></p>                                      | Yes | No | N/A |

|   |   |     |    |                     |     |
|---|---|-----|----|---------------------|-----|
|   | <p><b>Is the clinical prediction rule acceptable in assessing post concussion syndrome?</b><br/><i>Ease of use, availability, reasonable from a clinical point of view, cost</i></p>  | Yes | No | N/A                 |     |
|   | <p><b>Would the results of the clinical prediction rule modify any decision about the management of a patient undergoing PCS assessment?</b></p>  | Yes | No | N/A                 |     |
| <b>External &amp; Internal Validity</b> | <p><b>Were the subjects asked to participate in the study representative of the entire population from which they were recruited?</b><br/><i>The study must identify the source population for participants and describe how they were selected. Participants would be representative if they comprised the entire source population, an unselected sample of consecutive patients, or a random sample.</i></p> | Yes | No | Unable to determine |     |
|   | <p><b>Were study subjects in different groups recruited from the same population?</b><br/><i>For example, patients for all comparison groups should be selected from the same hospital. The question should be answered unable to determine for cohort and case control studies where there is no information concerning the source of patients included in the study.</i></p>                                  | Yes | No | Unable to determine | N/A |
|   | <p><b>Were study subjects in different groups recruited over the same time period?</b></p>  | Yes | No | Unable to determine | N/A |
|   | <p><b>Were subjects randomised into different groups?</b><br/><i>Studies which state that subjects were randomised should be answered yes except where method of randomisation would not ensure random allocation. For example alternate allocation would score no because it is predictable.</i></p>   | Yes | No | Unable to determine | N/A |
| <b>Power</b>                            | <p><b>Did the study have sufficient power to detect a clinically important effect where the probability value for a difference being due to chance is less than 5%?</b></p>   | Yes | No | Unable to determine |     |

## Appendix B

### Scoring sheet for evaluation tool

|   | Lange et al. (2010) | Iverson et al. (2010) | Tsanadis et al. (2008) | Van Dyke et al. (2010) | Cooper et al. (2011) | Greiffenstein et al. (2002) | Parks et al. (2016) | Lange et al. (2013) | Sullivan et al. (2016) |
|---|---------------------|-----------------------|------------------------|------------------------|----------------------|-----------------------------|---------------------|---------------------|------------------------|
| <b>Is the hypothesis/aim/objective of the study clearly described?</b>  | ✓                   | ✓                     | ✓                      | ✓                      | ✓                    | ✓                           | ✓                   | ✓                   | ✓                      |
| <b>Are the main outcomes to be measured clearly described in the introduction or methods section?</b><br><i>If the main outcomes are first mentioned in the Results section, the question should be answered No.</i>                            | ✓                   | ✓                     | ✓                      | ✓                      | ✓                    | ✗                           | ✓                   | ✓                   | ✓                      |
| <b>Are the characteristics of the participants included in the study clearly described?</b><br><i>In cohort studies and trials, inclusion and exclusion criteria should be given.</i>   | ✓                   | ✓                     | ✓                      | ✗                      | ✓                    | ✓                           | ✓                   | ✓                   | ✓                      |
| <b>Are the statistical methods used clearly described?</b>  | ✓                   | ✓                     | ✗                      | ✓                      | ✓                    | ✓                           | ✓                   | ✗                   | ✗                      |
| <b>Are the main findings of the study clearly described?</b><br><i>Simple outcome data should be reported for all major findings so that the reader can check the major analyses and conclusions.</i>   | ✓                   | ✓                     | ✓                      | ✓                      | ✓                    | ✓                           | ✓                   | ✓                   | ✓                      |
| <b>Can the performance of the clinical prediction rule be calculated?</b><br><i>Performance results can be presented as: sensitivity, specificity, positive predictive power, negative predictive power, ROC curve, calibration curves etc.</i> | N/A                 | N/A                   | N/A                    | ✓                      | ✓                    | ✓                           | ✗                   | ✓                   | ✓                      |

|  |     |     |     |   |   |     |     |   |   |
|--|-----|-----|-----|---|---|-----|-----|---|---|
| <p><b>Would the clinical prediction rule be reliable and results interpretable if used in assessing post-concussion syndrome?</b><br/> <i>Consider if your setting is too different from that of the study.</i></p>  | N/A | N/A | N/A | x | x | ✓   | x   | ✓ | ✓ |
| <p><b>Is the clinical prediction rule acceptable in assessing post-concussion syndrome?</b><br/> <i>Ease of use, availability, reasonable from a clinical point of view, cost</i></p>  | N/A | N/A | N/A | ✓ | ✓ | ✓   | ✓   | ✓ | ✓ |
| <p><b>Would the results of the clinical prediction rule modify any decision about the management of a patient undergoing PCS assessment?</b></p>   | N/A | N/A | N/A | ✓ | x | x   | x   | ✓ | ✓ |
| <p><b>Were the subjects asked to participate in the study representative of the entire population from which they were recruited?</b><br/> <i>The study must identify the source population for participants and describe how they were selected. Participants would be representative if they comprised the entire source population, an unselected sample of consecutive patients, or a random sample.</i></p> | x   | x   | ✓   | ✓ | ✓ | ✓   | UTD | x | x |
| <p><b>Were study subjects in different groups recruited from the same population?</b><br/> <i>For example, patients for all comparison groups should be selected from the same hospital. The question should be answered unable to determine for cohort and case control studies where there is no information concerning the source of patients included in the study.</i></p>                                  | ✓   | N/A | ✓   | ✓ | ✓ | UTD | ✓   | ✓ | ✓ |

|   |            |            |            |            |            |            |            |            |            |
|---|------------|------------|------------|------------|------------|------------|------------|------------|------------|
| <b>Were study subjects in different groups recruited over the same time period?</b>   | ✓          | ✘          | UTD        | UTD        | UTD        | UTD        | ✓          | ✓          | ✓          |
| <b>Were subjects randomised into different groups?</b><br><br><i>Studies which state that subjects were randomised should be answered yes except where method of randomisation would not ensure random allocation. For example alternate allocation would score no because it is predictable.</i> | N/A        | N/A        | N/A        | N/A        | N/A        | N/A        | ✓          | ✓          | ✓          |
| <b>Were the statistical tests used to assess the main outcomes appropriate?</b><br><br><i>The statistical techniques used must be appropriate to the data. Keep in mind the possibility of type 1 error. Were measures put in place to account for this (e.g. Bonferroni correction)?</i>         | ✘          | ✘          | ✓          | ✓          | ✓          | ✘          | ✓          | ✓          | ✓          |
| <b>Did the study have sufficient power to detect a clinically important effect where the probability value for a difference being due to chance is less than 5%?</b>  | UTD        | ✓          | ✓          |
| <b>TOTAL SCORE</b>  | <b>70%</b> | <b>56%</b> | <b>70%</b> | <b>67%</b> | <b>71%</b> | <b>57%</b> | <b>67%</b> | <b>87%</b> | <b>87%</b> |

## **Paper Two: Empirical Paper**

Validation of the Symptoms of Post-Concussion Syndrome Questionnaire as a Self-report Symptom Validity Test: A Simulation Study

## **Abstract**

**Introduction** – Symptoms of post-concussion syndrome (PCS) can be categorised into somatic, cognitive and emotional domains. Whilst specific neuropsychological tests can be used to determine cognitive disturbances as a result of PCS, there is a reliance on the use of self-report measures to record the presence and severity of other PCS symptoms, which can be subject to over report and exaggeration of symptoms. The Symptoms of Post-Concussion Syndrome questionnaire (SPCS) is a new measure designed to detect symptom exaggeration and over report in PCS. This study aimed to explore the utility of the SPCS as symptom validity test.

**Method** – A simulation design was employed using control participants instructed to respond genuinely (n = 30), and participants instructed to malingering (n = 30). All participants completed a battery of measures that included established performance and symptom validity tests, alongside the new measure. Classification statistics were calculated to determine the effectiveness of the SPCS at distinguishing participants instructed to malingering from controls. Three different scoring methods were explored; a total SPCS score, total pseudo symptoms SPCS score, and a pseudo symptom endorsement frequency score.

**Results** – Participants instructed to malingering had significantly higher scores on the SPCS compared with controls. An optimal cut off score of >25 was established for the ‘total SPCS score’ scoring method (sensitivity .90, specificity 1.00, positive predictive power = 100%, negative predictive power = 93.75%).

**Conclusion** – The findings provide strong initial support for the use of the SPCS as a symptom validity measure. Its properties are promising, and classification statistics compare favourably with other established measures. However, further validation of the proposed cut off score with a clinical sample is required.

**Word count – 7,867 (inclusive of abstract – 273)**

**Validation of the Symptoms of Post-Concussion Syndrome (SPCS)**  
**Questionnaire as a Self-report Symptom Validity Test: A Simulation**  
**Study**

**INTRODUCTION**

Following a mild head injury (MHI), some patients experience post-concussion symptoms (such as headaches, irritability, anxiety, fatigue, memory difficulties and impaired concentration). Post-concussion syndrome (PCS) has been defined as a clinical state where 3 or more symptoms persist for more than 3 months (ICD-10 Version: 2016, World Health Organisation). Symptoms of PCS can be categorised into somatic, cognitive or emotional domains, as presented in Table 1. Neuropsychological tests measure deficits in cognitive functioning that can result from PCS. Alongside these tests there are various self-report measures that record and assess the development and severity of PCS symptoms.

The detection of malingering or symptom exaggeration is an important component in the assessment of PCS. This may occur for a number of reasons, for example, consciously feigning or exaggerating illness to gain personal benefits and fulfilling “sick role” ideations, or to gain financial compensation (Binder & Rohling, 1996). It was estimated that 39% of litigants making MHI claims were suggestive of probable malingering (Mittenberg, Patton, Canyock, & Condit, 2002). A similar estimate of 40% was found by Larrabee (2003).

Assessing the effort, or validity of performance, on cognitive tests is strongly encouraged when interpreting assessment results (Heilbronner et al., 2009). Clinical prediction rules can be used to estimate the probability of a specific outcome, and help clinicians to determine whether an individual is feigning or exaggerating symptoms (Toll, Janssen, Vergouwe and Moons, 2008). Tests of validity can provide clinicians with cut off scores to identify potential under performers and malingerers. Guidance on neuropsychological assessment published by the British Psychological Society (2009) states that measures of response validity should be given routinely as part of a clinical assessment of cognitive function.

Table 1

*Typical PCS symptoms (adapted from Snell, Macleod, and Anderson, 2016)*

| <b>Somatic</b>             | <b>Cognitive</b>                            | <b>Psychological</b> |
|----------------------------|---|----------------------|
| <b>Fatigue</b>             | Difficulty concentrating                    | Anxiety              |
| <b>Headache</b>            | Memory problems                             | Depression           |
| <b>Nausea</b>              | Slowed thinking                             | Irritability         |
| <b>Vestibular symptoms</b> | Word finding difficulties                   | Emotional outbursts  |
| <b>Light sensitivity</b>   | Difficulties with planning and organisation | Personality changes  |
| <b>Noise sensitivity</b>   |   |                      |
| <b>Sleep disturbance</b>   |   |                      |
| <b>Balance problems</b>    |   |                      |
| <b>Tinnitus</b>            |   |                      |

Following a need to clarify between self-report symptom validity measures and cognitive performance validity measures, it was recommended by Larabee (2012) that the terms performance validity test (PVTs) and symptom validity test (SVT) should be reported rather than terms such as “effort” or “response bias”. More specifically, PVTs are concerned with assessing the extent to which an individual’s performance on cognitive tests reflects their actual ability, so the accuracy or truthfulness of their cognitive profile according to neuropsychological measures. Whereas, SVTs are concerned with the extent to which an individual’s symptomatic complaints, as measured by self-report questionnaires, is reflective of their true experience of symptoms. They aim to detect the over report and exaggeration of symptoms.

Performance validity and symptom validity should be viewed as separate validity domains. Confirmatory factor analysis research carried out by Van Dyke, Millis, Axelrod and Hanks (2013) evaluated the factor structure underlying PVTs and SVTs, alongside measures of cognitive performance and symptom self-report not designed to measure validity. Out of the six models that were tested, a three-factor model, whereby cognitive performance, performance validity, and self-reported symptoms (including standard self-report measures and SVTs) were separate factors was the best fitting. This suggests that failure in one domain does not equate to failure in the other and that performance and symptom validity should be tested separately. Also of note was that SVTs and symptom report measures loaded on to the same factor. This may suggest that all self-report instruments measure symptom self-report and symptom validity on a continuum.

Symptom validity in PCS can be assessed in a number of ways. The utility of self-report questionnaires originally designed to measure the severity of PCS symptoms have been investigated for use as SVTs. Tsanadis, Montoya, Hanks, Millis, Fichtenberg and Axelrod (2008) examined total scores of the Postconcussive Symptom Questionnaire (PCSQ; Lees-Haley, 1992) with a mild TBI and poor performance validity group in comparison with scores from a moderate to severe TBI group. The mild TBI group reported more symptoms with greater severity than the moderate to severe TBI group. It was argued that this was suggestive of symptom exaggeration and over reporting, and Tsanadis et al. (2008) used the results to question the validity of PCS diagnoses. A cut off score of >27 on the PCSQ was established by Van Dyke, Axelrod and Schutte (2010) to determine symptom validity in a military veteran sample.

Other SVTs that have been validated for use with PCS include the Fake Bad Scale (FBS; Lees-Haley, English & Glenn, 1991), a 43-item self-report validity scale on the Minnesota Multiphasic Personality Inventory-2 (MMPI-2; Butcher, Dahlstrom, Graham, Tellegen, & Kaemmer, 1989) designed to detect the simulation of emotional distress in compensation seeking individuals. It was also used to detect the over report of symptoms in a

neurological sample. In a group of individuals with persistent PCS the FBS was found to be an effective measure of spurious symptom reporting (Greiffenstein, Baker, Gola, Donders and Miller, 2002) Some FBS items however, may have overlapped with true long-term outcomes in severe cerebral dysfunction and so specificity and false positive values for this measure are relatively poor in individuals with more severe presentations.

The Structured Inventory of Malingered Symptomatology (SIMS; Widows and Smith, 2005) is a stand-alone SVT that has been researched in personal injury litigants due to TBI or exposure to trauma (Wisdom, Callahan & Shaw, 2010) and with simulators of whiplash injury (Merten, Diederich, & Stevens, 2008). Most recently Parks, Gfeller, Emmert and Lammert (2016) examined the validity of the SIMS in detecting feigned symptoms of PCS and PTSD. It was found that the SIMS total score produced the highest sensitivities for feigned PCS symptoms, supporting its use as an SVT screening measure in PCS. However, due to a lack of control condition in the design, no specificity or predictive values could be calculated, meaning that the extent to which the SIMS is able to discriminate individuals feigning PCS from those responding genuinely, is unknown.

The five-item Mild Brain Injury Atypical Symptoms Scale (mBIAS; Cooper, Nelson, Armistead-Jehle, & Bowles, 2011) is an embedded measure that contains atypical symptoms not normally associated with PCS. Factor analysis revealed that the mBIAS items measure a unique dimension in symptom reporting and so responses should not be confounded by the presence of PCS. Cut off scores were presented to determine symptom exaggeration in individuals with mTBI, although any endorsement of items should be considered a marker for exaggeration. However, as this was not a known groups design and no established SVTs were administered alongside the mBIAS, Cooper and colleagues (2011) could not state with confidence whether over-reporting on the mBIAS could have been a function of conscious attempts to exaggerate symptoms, or if it was possible that the five items could have been endorsed in patients with co-occurring physical or sensory conditions. Lange and colleagues (Lange, Edmed, Sullivan, French, & Cooper, 2013) ran an analogue simulation study with the mBIAS, which

allowed for greater internal validity and control, and found that it was effective at distinguishing between controls and participants feigning PCS. Two cut off scores were suggested, “highly probable exaggeration” and “possible exaggeration”, although sensitivity was low for the higher cut off value (.31).

The Neurobehavioral Symptom Inventory Validity – 10 (NSI Validity-10; Vanderploeg, Cooper, Belanger, Donnell, Kennedy, Hopewell, & Scott, 2014) was found to produce very high classification statistics for distinguishing participants feigning PCS symptoms from controls in an analogue simulation design (Sullivan, Lange & Edmed, 2016). However, the suggested cut off scores were substantially lower than those found to be effective in previous research using a clinical TBI sample (Lange, Brickell, Lippa, & French, 2015; Vanderploeg, Cooper, Belanger, Donnell, Kennedy, Hopewell, & Scott, 2014).

Professional concern has been reported regarding information about validated tests being accessible through the Internet (Bauer & McCaffrey, 2005). The coaching of litigants to detect and deceive performance and symptom validity tests has also been reported (Youngjohn, 1995; Wetter & Corrigan, 1995). This has resulted in PVTs and SVTs having a limited ‘shelf life’. Providing a wide range of tests and the development of new tests may help to maintain test security (Bianchini Mathias, & Greeve, 2001).

### ***Rationale, aims and hypotheses***

The development of new measures to detect symptom exaggeration and over reporting is important when assessing PCS, particularly in the context of a medico legal setting. Previous measures used to validate the self-report of PCS symptoms have been concerned with the endorsement of either genuine symptoms or atypical symptoms of PCS. The Symptoms of Post-Concussion Syndrome (SPCS) questionnaire was developed by the research team as a new SVT for use in the assessment of PCS (see Appendix C). The SPCS is a 35-item self-report measure designed to detect the over report and exaggeration of PCS symptoms. It includes both genuine symptoms of PCS and atypical pseudo symptoms in order increase the likelihood of

detecting malingering. When developing a new measure, and validating new diagnostic and screening tools, evidence from analogue simulation designs should be collected (Rogers, 2008; Streiner, 2003). The American Academy of Clinical Neuropsychology Consensus Conference Statement on the Neuropsychological Assessment of Effort, Response Bias, and Malingering (Heilbronner, Sweet, Morgan, Larrabee, Millis & Conference Participants, 2009) states that analogue simulation designs provide tight experimental control as well as being a practical and cost-effective method for examining “proof of concept” for new tests.

The purpose of this study was to evaluate the utility of the SPCS to detect the malingering of PCS symptoms using a simulation design. This will be established by determining whether the test has sufficient psychometric properties (sensitivity, specificity and predictive power values) to correctly identify instructed malingerers completing the measure, whilst also not incorrectly identifying control participants. Different scoring methods will be explored and reported. The psychometric properties and effectiveness of the SPCS will also be compared to an established SVT and two established PVTs.

The following hypotheses were made:

- 1) Participants who are instructed to mangle will have higher scores on all PVTs and SVTs in the test battery, including the SPCS, than controls who are instructed to respond genuinely.
- 2) The SPCS will be effective in discriminating between participants instructed to mangle and those participants instructed to respond genuinely.
- 3) The SPCS will perform as well as established tests of performance and symptom validity at discriminating between participants instructed to mangle and those participants instructed to respond genuinely.

## METHOD

### *Design*

A Between subjects analogue simulation design was used. Control participants instructed to respond genuinely, and participants instructed to malingering were recruited from a neurologically healthy student population.

### *Participants*

#### *Recruitment of participants*

#### Neurologically healthy sample

Participants were recruited from universities in the West Midlands via a recruitment email notification that was disseminated to all students via faculty and/or school leads (see Appendix D). Potential participants expressed their interest to the lead researcher and were sent an information sheet containing further details about the research project (see Appendices E & F) and participants were given the opportunity to book an available time slot to take part. Information concerning participants' sex, age, and years of education was collected. Participants were asked if they had any current or historical neurological condition(s) or if they had suffered a current or historical head injury (including a history of concussion). Any participants who responded positively to either of the two screening questions were not included in the research.

The following inclusion/exclusion criteria applied to the neurologically healthy sample:

#### Inclusion criteria:

1. Individuals must be aged 18+
2. Individuals must be fluent in English language

#### Exclusion criteria:

1. Individuals with any historical or current neurological condition, including traumatic brain injury or previous concussion.
2. Individuals with a diagnosis of a learning disability.

#### Clinical sample:

It was originally intended for a clinical sample of individuals with mild TBI, who fit the criteria for a diagnosis of PCS, to also be included in this research project. However, constraints on the inclusion/exclusion criteria (as agreed by the NHS REC) prohibited individuals who were seeking compensation or were receiving benefits, which would have significantly reduced the number of potential participants. Furthermore, clinicians who were approached to assist with recruitment to the study shared that due to funding pressures in NHS neuro-rehabilitation services, very few individuals with mild TBI were picked up in comparison to moderate-severe TBI. An identified specialist Accident & Emergency Neuropsychology partnership service failed to respond to requests to participate.

The following inclusion/exclusion criteria applied to potential participants in the clinical sample:

#### Inclusion criteria:

1. Individuals must be aged 18+
2. Individuals must have a traumatic brain injury (TBI) – sub-acute to chronic phase of recovery (determined by the clinician working with the individual) receiving community based rehabilitation (3 months post injury)
3. Individuals must be fluent in English language

#### Exclusion criteria:

1. Individuals seeking or intending to seek compensation or disability benefits in relation to their head injury.
2. Individuals that are in the acute phase of recovery (determined by the clinician working with the individual)
3. Individuals that have a co-morbid neurological condition (determined by the clinician working with the individual)
4. Individuals that had a pre-morbid learning disability

*Participant demographics:*

60 neurologically healthy students from universities in the West Midlands were recruited to take part in the study. Demographic information for participants was as follows: 71.67% female, with a mean age of 30.67 (SD 10.79), and 17.45 (SD 2.78) years of education. All participants were fluent in English language and did not have any historical or current neurological condition, including TBI or previous concussion.

***Procedure***

Neurologically healthy participants were randomly allocated to either the control, or instructed to malingering group. Random assignment of participants was conducted by use of a random number generator computer programme. All participants were informed that the study was investigating methods of assessment in post-concussion syndrome. Participants in the instructed to malingering condition were provided with a vignette (see Appendix J) detailing their role in the study. The vignette involved a fictional scenario in which participants were to imagine that they had been involved in a car accident. They were told that they lost consciousness for about 15 minutes and awoke spontaneously without being woken by others. Over time they feel normal again and were unharmed by the accident. Due to the accident, however, they were involved in a lawsuit against the driver of the other car and are required to undergo psychometric testing. Participants were informed that if they were found to have suffered injuries as a result of the accident they would receive a large settlement. The vignette instructs participants to fake the symptoms of a brain injury in order to gain compensation. Control group participants were instructed to respond honestly. All participants were then administered a battery of assessment measures (detailed below).

Following completion of the test battery, participants received a debrief in which they were informed of the actual purpose of the study (see debrief statement in Appendix I). Passive deception was used concerning the established performance and symptom validity tests in order to preserve their function of detecting symptom exaggeration and over reporting.

### ***Measures***

The Hospital Anxiety and Depression Scale (HADS; Zigmond and Snaith, 1983) is a 14-item self-report questionnaire designed to determine levels of anxiety and depression. Each item on the measure is scored from 0-3. Seven of the items relate to anxiety and seven to depression. Two separate scores are generated simultaneously of between 0-21 for both anxiety and depression.

The Test of Premorbid Functioning (TOPF-UK; Wechsler, 2011) is a reading test composed of a list of 70 words that have atypical grapheme to phoneme translations. It is designed to estimate premorbid intelligence and memory abilities. The TOPF-UK can be described as a “hold test”, in that it relies on abilities thought to be unaffected by decline associated with neurological damage. Examinees are presented with the word list and instructed to pronounce each word aloud. Each correct pronunciation is awarded a score of one, and the test is discontinued after five incorrect pronunciations.

The Test of Memory Malingering (TOMM; Tombaugh, 1996) is a test of performance validity that is commonly used by neuropsychologists (Sharland & Gfeller, 2007). It employs a forced-choice recognition paradigm using line drawings of 50 common objects. Examinees are presented each drawing for three seconds. The test phase of the measure then involves participants correctly identifying the drawing they had been shown previously when it is presented alongside a distractor drawing. The examiner provides verbal feedback and corrects the participant if they make an incorrect choice. The trial serves a dual function as a test of performance validity and also as an additional learning trial. Participants are then shown the same 50 line drawings followed by another test phase. After approximately 15 minutes, participants are presented with a retention test in which the 50 line drawings are again presented alongside more distractor drawings. Total scores from each trial are obtained from the number of original line drawings that were correctly identified. Cut off scores are then utilised to determine the likelihood that an individual is malingering.

The Word Memory Test oral form (WMT; Green & Astner, 1995) is a test of performance validity that detects sub optimal performance in relation to an individual's immediate and delayed memory performance. Participants are read a list of 20 word pairs, after the list has been read through twice, there is an immediate recognition trial. Participants are tested using a forced-choice recognition paradigm whereby they are read new word pairs containing only one of the words belonging to the original list and they are asked to select the word from the original list. A delayed recognition test then follows 30 minutes later containing different foil words. Scoring of the WMT involves a consistency calculation from the responses on the immediate and delayed recognition tests. The WMT also includes a multiple choice task, where participants are given the first word in each word pair and must select the correct word to match it from eight options. A paired associates task involves the examiner telling the participant the first word and asking for the second word in each word pair. Delayed free recall requires participants to state as many words as possible from the original list in any order. Long delayed free recall is the same task but after a further 20 minute delay. Scores below 82.5% on the immediate recognition, delayed recognition and consistency indices are indicative of invalid performance.

The Self-Report Symptom Inventory (SRSI; Merten, Merckelbach, Giger, & Stevens, 2016) is a 107 item self-report SVT that combines genuine clinical and pseudo symptoms scales. It contains the following five subscales covering genuine commonly endorsed symptoms: cognitive, depressive, pain, non-specific somatic, and PTSD/anxiety. The pseudo symptoms scales concern cognitive/memory, neurological motor, neurological sensory, pain, anxiety/depression. All items are presented in a true/false format and participants are required to respond to each statement. Over-reporting of symptoms is gauged in two ways: by looking at the sum scores of endorsed pseudo symptoms and by inspecting the ratio between the number of endorsed genuine symptoms and that of endorsed pseudo symptoms.

The Symptoms of Post-Concussion Syndrome questionnaire (SPCS) is a 35 item self-report questionnaire (see Appendix C). Items include 20 common symptoms of PCS as well as 15 pseudo symptoms. The symptom items

were selected and developed from the over reporting scales in the Minnesota Multiphasic Personality Inventory – Second edition (MMPI-2; Butcher et al., 1989) with the support of a Consultant Clinical Neuropsychologist with extensive experience of working with TBI presentations. Pseudo symptoms were selected as bizarre, atypical or uncommon complaints that in the eyes of laypersons, appear to belong to PCS. Participants report the severity of symptoms by rating the extent that the symptoms have disturbed them over the last two weeks on a four-point Likert scale (0 = not experienced, 1 = minor nuisance, 2 = moderate problem, and 3 = severe problem). A total score is obtained by summing the rating for all 35 items. A separate pseudo symptoms score can also be obtained by summing the endorsement of the 15 pseudo symptoms items. A pseudo symptoms frequency score can also be calculated by totalling the frequency of endorsed pseudo symptoms items. This study will investigate which of these scoring methods produces the more precise sensitivity, specificity and predictive values, and will report their respective cut off scores.

### ***Statistical analysis***

To address the hypotheses, different statistical analyses were performed. Comparisons of scores on the performance and symptom validity tests were made between the control and instructed to malingering groups. The psychometric properties of the SPCS were established by running a Receiver Operating Characteristic (ROC) curve analysis. ROC curves are often encountered in research papers that evaluate a new application of a clinical test. A ROC curve analysis provides information concerning a test's sensitivity, specificity and predictive power. ROC curve analysis was used to graphically represent how changes in cut-off values for the total SPCS score and the pseudo symptoms SPCS score impacted the resulting sensitivity and specificity values. Sensitivity indicates how often the test will be positive in the existence of over-reporting of symptoms. Specificity indicates how often the test will be negative in those responding truthfully. Clinical prediction rules should also have good negative predictive power (NPP) and positive predictive power (PPP), which refer to the level of confidence in the accuracy of a negative (pass) and positive (fail) result respectively. NPP and PPP

were calculated using a base rate of malingering set at 40%, in keeping with the findings reported by Larrabee (2003) and Mittenberg et al. (2012). To reduce the likelihood of false positives, only cut-off scores that produced specificity figures of above .95 were considered acceptable.

### ***Sample size calculation***

A sample size of approximately 60 participants (30 analogue malingerers and 30 controls) would afford a precision of 0.81 standardised units at a statistical power of 0.80. As participants in the control group condition are expected to perform at near ceiling levels on performance and symptom validity tests with relatively small standard deviations, a statistical power of 0.80 and a precision of 0.81 would be adequate to test between group differences. More specifically, in order to determine the standard error value, a confidence interval calculation was performed for a sample size of 60. This produced a standard error of 0.035 (degrees of freedom = 58).

### ***Ethical and regulatory considerations***

#### ***Risk and Management of risk***

Prior to taking part, participants were provided with participant information sheets (see Appendices E & F) stating that there were no anticipated major physical or emotional risks involved in taking part in the study. However, it was possible that participants may have been aware that they were unable to answer all of the questions or complete all of the tasks and may have felt despondent because they felt as though they were failing. Participants were given the option of not providing an answer to the questions that they deemed inappropriate, or difficult to answer, or for which they preferred not to give an answer. Participants were warned about this prior to engaging in the study and were informed that different people perform differently on all aspects of the tests. At the end of the session there was time set aside to allow for participants to discuss their experiences and ask any questions.

It is possible that participants may have felt uncomfortable with the use of passive deception with regards to the use of performance and symptom validity test measures. Participants were fully debriefed immediately after

completing the test battery, and all participants were given a debrief sheet (see Appendix I). Participants were given the opportunity to discuss the study with the researcher and were reminded of their right to withdraw from the study should they wish to do so. Participants were also given the contact details of the researcher and research supervisor should they wish to discuss the study further. Participants were also given an appropriate contact within their university in case of any adverse effects on their mental wellbeing as a result of their participation or exposure to the questions.

*Consent:*

Informed consent was obtained prior to participants engaging in the study (see consent form in Appendices G & H). The study did require the use of passive deception in relation to the function of the performance validity and symptom validity tests included in the test battery. Participants were fully debriefed following completion of the study and informed of the true purpose of the study and reminded of their right to withdraw their data up until the point of data analysis (three weeks after their participation).

*Ethical approval:*

The research proposal for this study was subject to an independent peer review at Staffordshire University and was approved on 03/05/16 (see Appendix K). The study was granted ethical approval from the West Midlands – Edgbaston Research Ethics Committee on the 08/09/16 (see Appendix L for a copy of the favourable opinion letter), and Health Research Authority (HRA) approval was granted on 05/12/16 (see Appendix M).

## RESULTS

### Demographic variables

The control group was made up of 73.3% female and 26.7% male participants with an average age of 31.53 (SD 11.54) and 16.83 (SD 2.57) years of education. The instructed to malingering group was composed of 70.0% females and 30.0% male participants with an average age of 29.8 (SD 10.12) and 18.07 (SD 2.89) years of education. Non-parametric between group comparisons revealed that there were no significant differences found for sex ( $\chi^2(1, N = 60) = .082, p = .774$ ), age ( $U = 390, p = .374$ ) or years of education ( $U = 562, p = .093$ ) between the control and instructed to malingering group.

### Premorbid functioning, anxiety, and depression scores

Descriptive statistics, group comparisons (nonparametric due to non-normal distributions) and Cohen's effect sizes are presented in Table 2. Statistically significant differences were observed for premorbid functioning scores ( $U = 297, p = .024$ ), as measured by the TOPF-UK, and anxiety scores ( $U = 808.5, p = <.001$ ) and depression scores ( $U = 839.5, p = <.001$ ), as measured by the HADS. These differences were not seen to be valid however, as the analogue malingerers were likely to have purposely performed with sub optimal performance on the TOPF-UK and over-reported symptoms of anxiety and depression in their role as malingerers on the HADS.

As statistically significant differences in TOPF-UK and HADS scores were observed between the control and instructed to malingering groups, correlations examining the relationship of TOPF-UK and HADS scores with SPCS scores were performed on control group and instructed to malingering group data separately, rather than as a whole data set.

Kendall's tau-b rank correlation co-efficient was performed to examine the relationship between SPCS scores and TOPF-UK premorbid functioning, HADS anxiety and HADS depression scores within the control group. There was a positive statistically significant relationship between the SPCS scores

and HADS anxiety scores;  $\tau(28) = .51$ ,  $p = 0.01$ ., and HADS depression scores;  $\tau(28) = .57$ ,  $p = 0.01$ . No significant relationship was found between the SPCS scores and TOPF-UK premorbid functioning scores;  $\tau(28) = -.23$ ,  $p = 0.10$ .

Correlations performed with the instructed to malingering group scores revealed positive statistically significant relationships of the HADS anxiety scores;  $\tau(28) = -.50$ ,  $p = 0.01$ , and HADS depression scores;  $\tau(28) = -.50$ ,  $p = 0.05$  with the SPCS scores. No significant relationship was found between premorbid functioning scores and SPCS scores;  $\tau(28) = -.21$ ,  $p = 0.11$ .

Table 2

*Descriptive statistics and group comparisons for the TOPF-UK and HADS by group*

| <i>Measure</i>         | <i><u>Control</u></i> |           | <i><u>Instructed to malingering</u></i> |           | <i>P</i> | <i>Cohen's effect size (d)</i> |
|------------------------|-----------------------|-----------|---|-----------|----------|--------------------------------|
|                        | <i>M</i>              | <i>SD</i> | <i>M</i>                                | <i>SD</i> |          |                                |
| <b>Total scores</b>    |                       |           |   |           |          |                                |
| <b>TOPF-UK</b>         | 53.77                 | 9.51      | 45.77                                   | 11.94     | .024     | .76                            |
| <b>HADS anxiety</b>    | 5.37                  | 2.83      | 13.27                                   | 4.68      | <.001    | 2.10                           |
| <b>HADS depression</b> | 1.30                  | 1.58      | 10.30                                   | 5.43      | <.001    | 2.57                           |

Note. N = 60; controls (n = 30), instructed to malingering (n = 30). Cohen's effect sizes = small (0.2), medium (0.5), large (0.8). TOPF-UK = Test of Premorbid Functioning; HADS = Hospital Anxiety and Depression Scale.

### **Clinical scales**

To explore the effect of experimental condition on the results of the established PVT and SVT measures a series of comparisons were performed on the TOMM, WMT and SRSI outcome results as the dependent variable, and the experimental condition (control or instructed to malingering group) as the independent variable. There were significant main effects

(using Kruskal-Wallis *H* tests) for the pass and fail frequencies on the TOMM, WMT, and SRSI measures (all  $p < .001$ ), as presented in Table 3.

Contingency frequencies of pass/fail rates on the TOMM, WMT and SRSI measures between the control and instructed to malingering groups are presented in Table 4.

Table 3

*Kruskal-Wallis H findings for TOMM, WMT, and SRSI*

| <b>Measure</b> | <b>Chi square</b> | <b>Df</b> | <b>p</b> |
|----------------|-------------------|-----------|----------|
| <b>TOMM</b>    | 34.16             | 1         | <.001    |
| <b>WMT</b>     | 39.33             | 1         | <.001    |
| <b>SRSI</b>    | 39.33             | 1         | <.001    |

*Note. N = 60; control (n = 30), instructed to malingering (n = 30). All p = <.001. TOMM = Test of Memory Malingering; WMT = Word Memory Test; SRSI = Self-Report Symptom Inventory.*

Table 4

*Contingency frequencies and percentages for the TOMM, WMT and SRSI pass/fail frequencies by group*

| <b>Measure</b> |      | <b>Control</b> | <b>Instructed to malingering</b> | <b>Total</b> |
|----------------|------|----------------|----------------------------------|--------------|
| <b>TOMM</b>    | Pass | 30 (100%)      | 8 (26.7%)                        | 38 (63.3%)   |
|                | Fail | 0 (0%)         | 22 (73.3%)                       | 22 (36.7%)   |
| <b>WMT</b>     | Pass | 30 (100%)      | 6 (20.0%)                        | 36 (60.0%)   |
|                | Fail | 0 (0%)         | 24 (80.0%)                       | 24 (40.0%)   |
| <b>SRSI</b>    | Pass | 30 (100%)      | 6 (20.0%)                        | 36 (60.0%)   |
|                | Fail | 0 (0%)         | 24 (80.0%)                       | 24 (40.0%)   |

*Note. N = 60; control (n = 30), instructed to malingering (n = 30). TOMM = Test of Memory Malingering; WMT = Word Memory Test; SRSI = Self-Report Symptom Inventory.*

The sensitivity, specificity and predictive values were calculated for the TOMM, WMT and SRSI using their respective cut off values with base rate set at 40%. The TOMM had a sensitivity value of .73, a specificity value of 1.00, PPP of 100% and NPP of 85%. The WMT had a sensitivity value of .80, a specificity value of 1.00, PPP of 100% and NPP of 88%. The SRSI had a sensitivity of .80, a specificity value of 1.00, PPP of 100% and NPP of 88%.

## SPCS symptom reporting

The effect of experimental condition on the SPCS symptom reporting was explored with a series of non-parametric between-groups comparisons (using Kruskal-Wallis H). The dependent variable for this comparison was one of the three SPCS scoring methods (total SPCS score, total pseudo symptom SPCS score, or pseudo symptom endorsement frequency score). The independent variable was the experimental condition. Descriptive statistics, group comparisons and effect sizes for the pseudo symptoms total score and frequency of pseudo symptom item endorsement are presented in Table 6. There were significant main effects for the total scores on the SPCS ( $X = 42.36$ ,  $p = <.001$ ) with an effect size of 3.03, the pseudo symptoms SPCS total scores ( $X = 30.87$ ,  $p = <.001$ ) with an effect size of 2.05, and the pseudo symptom endorsement frequency score ( $X = 29.65$ ,  $p = <.01$ ) with an effect size of 2.17.

Comparisons were also made for each of the pseudo symptom items. There were significant main effects found in 14 of the 15 pseudo symptoms included in the SPCS items and these are presented in Table 7.

Table 6

*Descriptive statistics, group comparisons and effect sizes for SPCS index scores*

| <u>Index</u>                 | <u>Control</u> |           | <u>Instructed to malingering</u> |           | <i>P</i> | <i>Cohen's effect size (d)</i> |
|------------------------------|----------------|-----------|----------------------------------|-----------|----------|--------------------------------|
|                              | <i>M</i>       | <i>SD</i> | <i>M</i>                         | <i>SD</i> |          |                                |
| <b>Total SPCS</b>            | 9.57           | 6.31      | 51.87                            | 21.65     | <.001    | 3.03                           |
| <b>Total pseudo symptoms</b> | 1.87           | 2.56      | 15.17                            | 10.40     | <.001    | 2.05                           |
| <b>Pseudo symptoms freq.</b> | 1.57           | 2.05      | 9.13                             | 4.90      | <.001    | 2.17                           |

*Note. N = 60; controls (n = 30), Instructed to malingering (n = 30). Cohen's effect sizes = small (0.2), medium (0.5), large (0.8). SPCS = Symptoms of Post-Concussion Syndrome questionnaire.*

Table 7

*Between groups comparison statistics (Kruskal-Wallis H) of pseudo symptom items.*

| <b>Pseudo Symptom items</b>                                 | <b>Test statistic</b> | <b>P</b> |
|---|-----------------------|----------|
| PS1 - Difficulty remembering personal details               | 33.62                 | <.001    |
| PS2 - Lump in the throat                                    | 1.90                  | .169     |
| PS3 - Sweating all over                                     | 20.25                 | <.001    |
| PS4 - Feeling hot all over                                  | 10.32                 | .001     |
| PS5 - Reduced sensitivity in fingers and toes               | 15.67                 | <.001    |
| PS6 - Legs feeling weak                                     | 15.70                 | <.001    |
| PS7 - Tingling sensation at the tip of the nose and/or lips | 17.70                 | <.001    |
| PS8 -Occasional numbness in hands and feet                  | 15.24                 | <.001    |
| PS9 - Hot or cold sensations on the skin                    | 5.79                  | .016     |
| PS10 - Mouth becoming dry                                   | 12.79                 | <.001    |
| PS11 - Everything tastes the same                           | 19.26                 | <.001    |
| PS12 - Frequent pins and needles                            | 25.10                 | <.001    |
| PS13 - Fainting spells                                      | 18.20                 | <.001    |
| PS14 - Difficulty remembering the gist of conversations     | 31.05                 | <.001    |
| PS15 - Difficulty recalling information about my childhood  | 29.55                 | <.001    |

## Utility of the SPCS

To determine the utility of the SPCS as a tool to identify malingerers from controls, diagnostic efficiency statistics (sensitivity, specificity, PPP, and NPP) were calculated for the total SPCS scores, pseudo symptom SPCS scores, and pseudo symptom endorsement frequency scores.

ROC curve analysis of the total SPCS scores provided an area under the curve (AUC) of .989, with a standard error measurement of .009 and the 95% confidence interval range from .972 to 1.00 suggesting highly accurate classification. Different cut off scores with their respective sensitivity and specificity values are presented in Table 6. Optimal cut-off scores were identified by examination and exploration of sensitivity, specificity and predictive power values. A cut score of >22 produced .93 sensitivity, .90 specificity, 95.07% NPP, and 86.11% PPP. However, to prevent false positive findings, specificity was set at 1.00, and a cut-off score of >25 was established which produced .90 sensitivity and 93.75% NPP and 100% PPP.

ROC curve analysis of the pseudo symptoms total score revealed an AUC of .914 with a standard error measurement of .40, and a confidence interval range of .835 to .992. Different cut-off scores with their respective sensitivity and specificity values are presented in Table 7. Optimal cut-off scores were identified by examination and exploration of sensitivity, specificity and predictive power values. Cut-off scores are presented in Table 6. A cut-off score of >7 produced .73 sensitivity, .96 specificity, 84.42% NPP, and 92.24% PPP.

ROC curve analysis of the frequency of pseudo symptoms score revealed an AUC of .906 with a standard error measurement of .041, and a confidence interval range from .825 to .986. Different cut-off scores with their respective sensitivity and specificity values are presented in Table 8. Optimal cut-off scores were identified by examination and exploration of sensitivity, specificity and predictive power values. A cut-off score of >7 produced .67 sensitivity, 1.00 specificity, 81.97% NPP, and 100% PPP.

Table 6

*Sensitivity and specificity values for different cut offs for the SPCS total score method on the SPCS measure*

| Cut off score | Sensitivity | 1-Specificity |
|---------------|-------------|---------------|
| >1            | 1.000       | .967          |
| >2            | 1.000       | .900          |
| >3            | 1.000       | .867          |
| >4            | 1.000       | .833          |
| >5            | 1.000       | .733          |
| >6            | 1.000       | .700          |
| >7            | 1.000       | .567          |
| >8            | 1.000       | .467          |
| >9            | 1.000       | .400          |
| >10           | 1.000       | .300          |
| >12           | 1.000       | .233          |
| >13           | 1.000       | .200          |
| >14           | 1.000       | .167          |
| >16           | 1.000       | .133          |
| >17           | .967        | .133          |
| >19           | .933        | .133          |
| >21           | .933        | .100          |
| >22           | .933        | .067          |
| >23           | .900        | .067          |
| <b>&gt;25</b> | <b>.900</b> | <b>.000</b>   |
| >28           | .867        | .000          |
| >29           | .833        | .000          |
| >32           | .800        | .000          |
| >36           | .767        | .000          |
| >38           | .667        | .000          |
| >41           | .633        | .000          |
| >45           | .600        | .000          |
| >46           | .567        | .000          |
| >48           | .533        | .000          |
| >51           | .467        | .000          |
| >56           | .400        | .000          |
| >59           | .333        | .000          |
| >63           | .267        | .000          |
| >67           | .233        | .000          |
| >70           | .200        | .000          |
| >73           | .167        | .000          |
| >81           | .133        | .000          |
| >88           | .100        | .000          |
| >92           | .033        | .000          |
| >95           | .000        | .000          |

Table 7

*Sensitivity and specificity values for different cut offs for the total pseudo symptoms scoring method on the SPCS measure*

| Cut off score | Sensitivity | 1-Specificity |
|---------------|-------------|---------------|
| .50           | .933        | .567          |
| 1.50          | .933        | .367          |
| 2.50          | .900        | .300          |
| 3.50          | .900        | .167          |
| 4.50          | .833        | .133          |
| 6.00          | .767        | .133          |
| <b>7.50</b>   | <b>.733</b> | <b>.033</b>   |
| 8.50          | .700        | .033          |
| 9.50          | .700        | .000          |
| 10.50         | .667        | .000          |
| 11.50         | .633        | .000          |
| 12.50         | .567        | .000          |
| 14.00         | .533        | .000          |
| 15.50         | .467        | .000          |
| 16.50         | .400        | .000          |
| 17.50         | .367        | .000          |
| 18.50         | .333        | .000          |
| 19.50         | .300        | .000          |
| 21.00         | .200        | .000          |
| 22.50         | .167        | .000          |
| 27.00         | .133        | .000          |
| 32.50         | .100        | .000          |
| 35.00         | .067        | .000          |
| 38.00         | .033        | .000          |

Table 8  
*Sensitivity and specificity values for different cut offs for the pseudo symptoms endorsement frequency scoring method on the SPCS measure*

| Cut off score | Sensitivity | 1-Specificity |
|---------------|-------------|---------------|
| .50           | .933        | .567          |
| 1.50          | .933        | .367          |
| 2.50          | .900        | .233          |
| 3.50          | .800        | .167          |
| 4.50          | .733        | .100          |
| 5.50          | .733        | .067          |
| 6.50          | .700        | .067          |
| <b>7.50</b>   | <b>.667</b> | <b>.000</b>   |
| 8.50          | .567        | .000          |
| 9.50          | .533        | .000          |
| 10.50         | .500        | .000          |
| 11.50         | .400        | .000          |
| 12.50         | .333        | .000          |
| 13.50         | .233        | .000          |
| 14.50         | .167        | .000          |

## DISCUSSION

This study aimed to examine the utility of a new measure, the SPCS, using data from an analogue simulation study. More specifically, this study explored the ability of the SPCS to discriminate between controls and participants instructed to malingering. The hypotheses were three-fold. Firstly, participants who are instructed to malingering would have higher scores on all PVTs and SVTs in the test battery, including the SPCS, than controls who are instructed to respond genuinely. Second, the SPCS would be effective in discriminating between participants instructed to malingering and those participants instructed to respond genuinely. Finally, the SPCS would perform as well as established tests of performance and symptom validity at discriminating between participants instructed to malingering and those participants instructed to respond genuinely. Overall, the main findings from this study supported these hypotheses.

As predicted in the first hypothesis, participants who were instructed to malingering had significantly higher scores (or test failure rates) on the TOMM, WMT, SRSI and SPCS. Main effects were found for three different SPCS index scores that were extracted from the data (total SPCS score, total pseudo symptom SPCS score, and pseudo symptom endorsement frequency score). Significant correlations were found between the SPCS total scores and ratings of anxiety and depression, indicating a positive relationship. No significant correlation was found however, between SPCS scores and premorbid functioning, indicating that intellectual and memory abilities did not bear any relationship with SPCS responses.

As part of the investigation into the utility of the SPCS measure, different scoring methods (total SPCS score, total pseudo symptom SPCS score, and pseudo symptom endorsement frequency score) were explored. The total SPCS score was calculated from summing all of the item responses. This scoring method produced cut-off values with the most favourable diagnostic efficiency statistics. A cut-off score of >25 was selected to identify “probable malingering” which produced high sensitivity (.90) and specificity (1.00). In

comparison the identified cut-off values for the total pseudo symptom SPCS score and pseudo symptom endorsement frequency scoring methods produced lower classification statistics of .73 and .67 sensitivity, and .96 and 1.00 specificity respectively. It is therefore, recommended that the total SPCS scoring method and cut-off value of >25 is used to distinguish malingerers from genuine responders as this produced the highest sensitivity value when specificity was set at >.95. However, a score that exceeds either of the two cut-offs for the pseudo symptom scoring methods should be considered a “red flag” for possible symptom exaggeration.

In comparison to other performance and symptom validity tests included in this study, classification statistics revealed that the total SPCS score was more effective at determining malingering of PCS symptoms from genuine responders. Thus suggesting it is a very effective SVT measure. It is important to acknowledge, however, that the SPCS cut off score was established with neurologically intact individuals, and the sensitivity of the measure may reduce with a clinical TBI population.

In this study it was found that the WMT, SRSI and SPCS measures were more effective than the TOMM at discriminating malingerers from control participants, yet, it was reported from a survey of practicing Neuropsychologists, that the TOMM is one of the most frequently used validity measures (Sharland & Gfeller, 2007). Previous concerns have been expressed about the sensitivity of the TOMM, and reports have been made of high false negative rates (Bauer, O’Byrant, Lynch, McCaffrey, & Fisher, 2007; DenBoer & Hall, 2007; Gervais, Rohling, Green & Ford, 2004; Tan, Slick, Strauss, & Hultsch, 2002; van Hout, Schmand, Wekking, Hageman, & Deelman, 2003).

As the SPCS is a new SVT there is no previous research specifically concerning its effectiveness as a measure to directly compare the findings from this study with. Investigative studies of other SVT measures however, indicate that the SPCS shows promising preliminary findings as a new measure. Classification statistics reported in this study compare favourably with those reported in previous literature. Research using an analogue

simulation to investigate the utility of the mBIAS (Lange et al, 2013), a measure which also involved ratings of pseudo symptoms to detect malingering, reported a “possible exaggeration” cut-off score that provided a sensitivity value of .62, specificity of .88, PPP of 73% and NPP of 81% (with base rate set at 35%) for the feign PCS condition. When specificity was set at 1.0, a “probable exaggeration” cut-off score provided a sensitivity value of just .31, PPP of 100% and NPP of 73% (with base rate set at 35%) for the feign PCS condition. Further findings on the NSI Validity-10 revealed more efficient classification statistics for the feign PCS condition with a “probable exaggeration” cut off providing a sensitivity value of .97, specificity of .96, PPP of 93%, and NPP of 98% (with base rate set at 35%) (Sullivan et al., 2016). Parks and colleagues (2016) reported that the SIMS had a sensitivity value of .89 when detecting feigned PCS symptoms, other classification statistics were not available. Research into PCS SVTs with clinical samples reported similar findings regarding classification statistics. Van Dyke and colleagues (2010) reported findings for the PCSQ tested for its use as an SVT. Sensitivity was found to be somewhat low for the suggested cut-off score (.36), whilst specificity was .94, PPP was 69.2%, and NPP was 80.5%. The optimal cut-off score for the mBIAS proposed in Cooper et al. (2011) produced better sensitivity of .94, and specificity of .92, PPP was 83%, and NPP was 97% (with base rate set at 30%).

### **Clinical implications**

The SPCS has been found to be an effective measure of distinguishing participants who were instructed to malingering from controls. The measure was also found to be more effective than existing PVT and SVT measures in this study. Clinically, the SPCS may be of benefit to Neuropsychologists working in mTBI services to detect potential cases of symptom exaggeration and over reporting. The SPCS can be completed in less than 5 minutes, and it is quick and straight forward to score and interpret which may be advantageous over other longer self-report measures, particularly in busy services where screening sessions may be time pressured. A patient’s neuropsychological profile should not be discounted upon the results of a single SVT, however, when used as a screening tool, the SPCS may be used as an indicator of

symptom exaggeration and prompt clinicians to be cautious about the interpretation of other self-report measures. A clinical validation of the recommended cut-off scores is required however, in order to provide confidence for use in a clinical setting.

### **Limitations**

A limitation in this research project was the lack of a clinical sample. Although a simulation design provides the most control for internal validity, it could be argued that analogue simulation designs lack ecological validity. The initial design for this study involved recruiting a clinical sample alongside neurologically healthy subjects, which may have resolved potential issues with generalisability. It is possible that further validation with a clinical population may reveal that the cut-off scores suggested in this paper need to be adjusted, and this should be explored in future research. Sullivan, Lange and Edmed (2016) found that an investigation into the utility of the NSI validity-10 using an analogue simulation design produced lower cut-off scores than was previously found in research involving clinical samples (Lange, Brickell, Lippa, & French, 2015; Vanderploeg, Cooper, Belanger, Donnell, Kennedy, Hopewell, & Scott, 2014). It is argued that the differences may be due to the use of different measures to define groups. It is worth noting that several studies have reported that simulators instructed to malingering may not significantly differ from clinical populations seeking secondary gain (Meyers, 2007; Mittenberg, Theroux-Fichera, Zielinski, & Heilbronner, 1995; Rohling, Meyers, & Millis, 2003).

Another limitation of this study is that there was no questionnaire measure confirming that exaggeration was induced in the instructed to malingering group condition. There is a possibility that some participants misunderstood instructions given to them and did not fake the symptoms of a brain injury. This may have impacted the findings in the study, however, this is unlikely as a high sensitivity value (.90) was calculated.

## **CONCLUSION**

In summary, this study provided preliminary support for, the SPCS, a new measure of symptom validity. Three different scoring methods were explored to identify the most effective way of utilising data from the measure. The total SPCS score was found to be most effective. However, a score above the cut off values of the pseudo symptoms total score and frequency score should also be considered a “red flag”. The SPCS showed promising preliminary results for use as a population screening tool. It allows for a rapid assessment of symptom validity which is beneficial to Neuropsychologists operating within services that are highly time pressured. There is a need for validation with a clinical sample, however, and this is a recommendation for future research. It is worth acknowledging that a patient’s neuropsychological profile should not be discounted upon the results of a single SVT, and the SPCS is not intended to be used for purely diagnostic purposes. Although SVTs and PVTs have an essential role in determining valid responding, ultimately, it is the role of the expert clinician to make any attributions of symptom exaggeration or malingering (Lockhart, 2015).

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## Appendix C

### Symptoms of Post-Concussion Syndrome (SPCS) questionnaire

#### Symptoms of Post-Concussion Syndrome Questionnaire

Following a head injury some people go on to develop symptoms that can disrupt normal life and cause concern. Read through the list of symptoms in the table below and tick the appropriate response.

| Symptom:   | Severity of experience: |                |                  |                |
|--|-------------------------|----------------|------------------|----------------|
|  | Not experienced         | Minor nuisance | Moderate problem | Severe problem |
| Difficulty concentrating                               |                         |                |                  |                |
| Difficulty remembering personal details (e.g. address) |                         |                |                  |                |
| Lump in throat   |                         |                |                  |                |
| Blurred vision   |                         |                |                  |                |
| Feeling depressed or tearful                           |                         |                |                  |                |
| Problems tolerating stress                             |                         |                |                  |                |
| Sweating all over                                      |                         |                |                  |                |
| Restlessness   |                         |                |                  |                |
| Feeling hot all over                                   |                         |                |                  |                |
| Anxiety  |                         |                |                  |                |
| Feelings of dizziness                                  |                         |                |                  |                |
| Reduced sensitivity in fingers and toes                |                         |                |                  |                |
| Difficulty controlling emotional outbursts             |                         |                |                  |                |
| Legs feeling weak                                      |                         |                |                  |                |
| Fatigue  |                         |                |                  |                |
| Difficulty sleeping                                    |                         |                |                  |                |
| Apathy/ loss of motivation                             |                         |                |                  |                |
| Nausea   |                         |                |                  |                |
| Headaches  |                         |                |                  |                |

Version 1.0 - 01<sup>st</sup> September 2015

|   | Not experienced | Minor nuisance | Moderate problem | Severe problem |
|---|-----------------|----------------|------------------|----------------|
| Tingling sensation at the tip of the nose and/or lips |                 |                |                  |                |
| Occasional numbness in hands and feet                 |                 |                |                  |                |
| Difficulty remembering general knowledge              |                 |                |                  |                |
| Hot or cold sensations on the skin                    |                 |                |                  |                |
| Noise sensitivity                                     |                 |                |                  |                |
| Difficulty remembering details of conversations       |                 |                |                  |                |
| Mouth becoming dry                                    |                 |                |                  |                |
| Everything tastes the same                            |                 |                |                  |                |
| Frequent 'pins and needles'                           |                 |                |                  |                |
| Light sensitivity                                     |                 |                |                  |                |
| Fainting spells                                       |                 |                |                  |                |
| Difficulty remembering the gist of conversations      |                 |                |                  |                |
| Taking longer to think                                |                 |                |                  |                |
| Word finding difficulties                             |                 |                |                  |                |
| Difficulty recalling information about my childhood   |                 |                |                  |                |
| Absent minded memory slips                            |                 |                |                  |                |

Version 1.0 - 01<sup>st</sup> September 2015

## Appendix D

### Recruitment Email

27/06/16

Version 1.0

Dear Student,

I am a student on the Clinical Psychology Doctorate at Staffordshire and Keele Universities, and I am conducting a study to fulfil the requirements of my thesis project. The study concerns post-concussion syndrome and how this can be assessed, more specifically I am interested in the validation of a new measure that has recently been developed. Participation involves completing a number of tasks that assess a range of memory and intellectual abilities, for example, you may be asked to do some puzzles or remember some pictures. Participants will also be asked to complete some questionnaires concerning the symptoms of post-concussion syndrome (e.g. difficulties with mood, tiredness and concentration). I am looking for participants who do not have a head injury in order to compare these results with the responses given by people who do have a head injury. I would be very grateful if you would be willing to take part in my study. If you are interested, please contact me at the address below. If you do so, you will have the chance to find out more about the study before coming to any decision. You would be under no obligation to take part.

My study is supervised by Dr Ken McFadyen and he can be contacted on [k.mcfadyen@staffs.ac.uk](mailto:k.mcfadyen@staffs.ac.uk). The use of email to recruit participants for this study has been approved by the Health Research Authority.

Victoria Bagnall  
Trainee Clinical Psychologist  
[b026528e@student.staffs.ac.uk](mailto:b026528e@student.staffs.ac.uk)

## Appendix E

### Clinical Participant Information Sheet

22/08/16

TBI participant information sheet

#### **A STUDY INVESTIGATING POST-CONCUSSIVE SYMPTOMS**

**Victoria Reece - DClinPsy Student**

*This study is being carried out as part of the completion of a doctorate in Clinical Psychology at Staffordshire and Keele Universities. Please read the information below and consider whether you would be interested in taking part in the study.*

#### **1. WHAT IS THE STUDY ABOUT?**

The study concerns post-concussion syndrome and how this can be assessed, more specifically I am interested in the validation of a new measure that has recently been developed. Post-concussion syndrome is the term used to describe a collection of symptoms that can last for several weeks or months after the concussion.

Participation involves completing a number of tasks that assess a range of memory and intellectual abilities, for example, you may be asked to do some puzzles or remember some pictures.

Participants will also be asked to complete some questionnaires concerning the symptoms of post-concussion syndrome (e.g. difficulties with mood, tiredness and concentration).

#### **2. WHAT WILL I HAVE TO DO?**

If you agree to take part in the study, you will be asked to:

- a) Provide brief information about yourself (e.g. age, occupation, level of education)
- b) Complete a battery of test measures that include a reading task, memory tests, and questionnaires concerning the symptoms of post-concussion syndrome, anxiety and depression.

The testing will take place within an NHS centre at a time that is convenient for you. If you wish a carer or another professional may be present during the testing, otherwise the testing will take place in a room with just the researcher and yourself.

It is anticipated that testing will take approximately 1 ½ -2 hours of your time.

### **1. WHAT ARE THE BENEFITS?**

It is important for professionals working with people who have suffered head injury to understand as much as possible about the tests they use. These tests should be good, accurate measures. If tests are accurate then professionals can develop new ways to help people with brain injuries.

It is important for us to investigate how individuals who do not have a head injury perform on the tasks involved in this study and compare these results with the responses given by people who do have a head injury. Although these tests may be of benefit to other people with head injury you will not gain any direct benefits from taking part in this research. It is, however, hoped you will find the tests interesting and stimulating.

### **2. WHAT ARE THE RISKS?**

There are no physical or emotional risks involved in taking part in this study. It is possible that you may be aware that you are unable to answer all of the questions or complete all of the tasks and this may feel despondent because you are feel as though you are failing. This is not the case as different people perform differently on all aspects of the tests. There is a possibility of psychological distress and discomfort as a result of participation/providing answers to the questions. At the end of the session there will be a chance to discuss your experience and ask any questions. You do not have to provide an answer to any questions that you may deem inappropriate, or difficult to answer, or for which you prefer not to give an answer.

### **3. WHAT IF I DO NOT WANT TO TAKE PART?**

You do not have to take part in the study and you can withdraw at any point without giving a reason. If you choose to withdraw after completing the study, all responses and information that you have given will be destroyed and will not be used in the analysis, please note however, that 3 weeks after taking part in the study your data will be anonymised and input to a statistical software program and so it will not be possible to identify your data and remove it. If you wish to withdraw your data after taking part in the study you must notify the researcher (contact details below) within 3 weeks of your participation. If you choose not to take part this will not influence any future treatment or care that you may receive from services.

**4. WHAT HAPPENS TO THE INFORMATION?**

All information is confidential and your responses to the tests will be given a code number. This code number will then be entered into a password-protected computer and transferred onto an encrypted memory stick and kept separate from your name.

**5. WHO ELSE IS TAKING PART?**

A number of different people will be taking part in this study including clients from a number of NHS services in the West Midlands and students from The Universities of Staffordshire and Keele.

**6. WHAT HAPPENS AT THE END OF THE STUDY?**

You will have a chance to ask any questions and to discuss your experience of the assessment. The investigator will explain about the research in more detail. After all the data is collected, it will be analysed and the results of the study will be written up as part of a Doctoral Degree in Clinical Psychology. A summary report will be available after July 2017 and you may receive a copy of this should you wish to do so.

**7. WHAT HAPPENS NOW IF I DECIDE TO TAKE PART?**

You will be asked to sign a consent form giving your permission to be a participant in the research. The assessment will then begin and is expected to last between 1 ½ - 2 hours.

**8. WHAT HAPPENS IF I CHANGE MY MIND DURING THE STUDY?**

You are free to withdraw from the study up to the point of the analysis phase of the study (3 weeks after taking part), prior to this any information will be shredded and not be included in the analysis. Your withdrawal will not influence your treatment or care in any way.

## Appendix F

### Non-Clinical Participant Information Sheet

23/08/16 Non-clinical information sheet

**A STUDY INVESTIGATING POST-CONCUSSIVE SYMPTOMS**  
**Victoria Reece - DClinPsy Student**

*This study is being carried out as part of the completion of a doctorate in Clinical Psychology at Staffordshire and Keele Universities. Please read the information below and consider whether you would be interested in taking part in the study.*

**1. WHAT IS THE STUDY ABOUT?**

The study concerns post-concussion syndrome and how this can be assessed, more specifically I am interested in the validation of a new measure that has recently been developed. Post-concussion syndrome is the term used to describe a collection of symptoms that can last for several weeks or months after the concussion.

Participation involves completing a number of tasks that assess a range of memory and intellectual abilities, for example, you may be asked to do some puzzles or remember some pictures. Participants will also be asked to complete some questionnaires concerning the symptoms of post-concussion syndrome (e.g. difficulties with mood, tiredness and concentration).

**2. WHAT WILL I HAVE TO DO?**

If you agree to take part in the study, you will be asked to:

- Provide brief information about yourself (e.g. age, occupation, level of education)
- Complete a battery of test measures that include a reading task, memory tests, and questionnaires concerning the symptoms of post-concussion syndrome, anxiety and depression.

The testing will take place within a private room within the university or NHS centre at a time which is convenient for you.

It is anticipated that this will take approximately 1 ½-2 hours of your time.

Version 5.0 1

### **3. WHAT ARE THE BENEFITS?**

It is important for professionals working with people who have suffered head injury to understand as much as possible about the tests they use. These tests should be good, accurate measures. If tests are accurate then professionals can develop new ways to help people with brain injuries.

We intend to investigate how individuals who do **not** have a head injury perform on the tasks involved in this study and compare these results with the responses given by people who do have a head injury. Although these tests may be of benefit to some people with head injury you will not gain **any** direct benefits from taking part in this research. It is, however, hoped you will find this interesting and stimulating.

### **4. WHAT ARE THE RISKS?**

There are no physical or emotional risks involved in taking part in this study. It is possible that you may become aware that you cannot answer all of the questions or complete all of the tasks and this may feel as though you are failing. This is not the case as different people perform differently on all aspects of the tests. There is a possibility of psychological distress and discomfort as a result of participation/providing answers to the questions. At the end of the session there will be a chance to discuss your experience and ask any questions. You do not have to provide an answer to any questions that you may deem inappropriate, or difficult to answer, or for which you prefer not to give an answer.

### **5. WHAT IF I DO NOT WANT TO TAKE PART?**

You do not have to take part in the study and you can withdraw at any point without giving a reason. If you choose to withdraw after completing the study, all responses and information that you have given will be destroyed and will not be used in the analysis, please note however, that 3 weeks after taking part in the study your data will be anonymised and input to a statistical software program and so it will not be possible to identify your data and remove it. If you wish to withdraw your data after taking part in the study you must notify the researcher (contact details below) within 3 weeks of your participation.

**6. WHAT HAPPENS TO THE INFORMATION?**

All information is confidential and your responses to the tests will be given a code number. This code number will then be entered into a password-protected computer and transferred onto an encrypted memory stick.

**7. WHO ELSE IS TAKING PART?**

A number of different people will be taking part in this study including clients from a number of NHS hospitals in the West Midlands and students from The Universities of Staffordshire and Keele.

**8. WHAT HAPPENS AT THE END OF THE STUDY?**

You will have a chance to ask any questions and to discuss your experience of the assessment. The investigator will explain about the research in more detail. Data will then be analysed and the results of the study will be written up as part of a Doctoral Degree in Clinical Psychology. A summary report will be available after July 2017 and you may receive a copy of this should you wish to do so.

**9. WHAT HAPPENS NOW IF I DECIDE TO TAKE PART?**

You will be asked to sign a consent form giving your permission to be a participant in the research. The assessment will then begin and last between 1 ½ – 2 hours.

**10. WHAT HAPPENS IF I CHANGE MY MIND DURING THE STUDY?**

You are free to withdraw from the study up to the point of the analysis phase of the study (3 weeks after taking part), prior to this any information will be shredded and not be included in the analysis.

# Appendix G

## Clinical Consent Form

28/06/16

Consent form TBI

Participant Identification Number for this study:

### CONSENT FORM

#### A STUDY LOOKING AT MEASURES ASSESSING POST-CONCUSSION SYNDROME

Name of Researcher: Victoria Bagnall

Please  
initial box

1. I confirm that I have read the information sheet dated..... (version.....) for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.
2. I give permission for details concerning the nature of my head injury to be passed on to the research team.
3. I understand that my participation is voluntary and that I am free to withdraw from the study at any point in my participation and up to 3 weeks after taking part, without giving any reason, without my medical care or legal rights being affected.
4. I understand that the information collected about me will be used to support other research in the future, and may be shared anonymously with other researchers.
5. I agree to take part in the above study.

\_\_\_\_\_  
Name of Participant                      Date                      Signature

\_\_\_\_\_  
Investigator Name                      Date                      Signature

Version 3.0

IRAS number 200642

## Appendix H

### Non-Clinical Consent form

28/06/16

Consent form – non clinical

Participant Identification Number for this study:

#### CONSENT FORM

#### A STUDY LOOKING AT MEASURES ASSESSING POST-CONCUSSION SYNDROME

Name of Researcher: Victoria Reece

Please  
initial box

1. I confirm that I have read the information sheet dated..... (version.....) for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.

2. I understand that my participation is voluntary and that I am free to withdraw from the study at any point in my participation and up to 3 weeks after taking part, without giving any reason, without my medical or legal rights being affected.

3. I understand that the information collected about me will be used to support other research in the future, and may be shared anonymously with other researchers.

4. I agree to take part in the above study.

\_\_\_\_\_  
Name of Participant                      Date                      Signature

\_\_\_\_\_  
Investigator Name                      Date                      Signature

Version 3.0

## Appendix I

### Debrief

23/08/2016

Version 3.0

#### DEBRIEF STATEMENT

The information sheet you were provided with prior to taking part in this study stated that this study was about the process of assessing post concussion syndrome. Some information regarding the aims and purpose of this study was withheld from you however. This research study is concerned with testing people's application of effort in relation to the self-report of symptoms of post-concussion syndrome. Effort tests are used to detect when an individual is not trying their best or may be feigning symptoms due to some external reward (e.g. compensation). In this study we are looking at the validity of a new questionnaire (Post Concussion Syndrome Questionnaire) that could be used in the future to detect when individuals are not applying full effort and may be attempting to deceive the examiner. Testing of effort is an important aspect of neuropsychological work and often forms part of a comprehensive assessment. As information about validated effort tests has started to become accessible through the internet, it is necessary for Psychologists to research and validate new questionnaires for clinical use.

Thank you for your participation, there is now time allocated for you to discuss your experience of the study with the researcher. Alternatively please feel free to contact the research team (details below) if you have any further questions concerning the study. Please remember that you are free to withdraw from the study up to the point of the analysis phase of the study (3 weeks after your participation in the study), prior to this any information can be shredded and not be included in the analysis.

#### CONTACTS:

Mrs Victoria Reece  
Trainee Clinical Psychologist  
School of Psychology, Sport and Exercise  
Clinical Psychology Department  
Science Centre  
Staffordshire University  
Leek Road  
Stoke on Trent  
ST4 2DF

Email: [b026528e@student.staffs.ac.uk](mailto:b026528e@student.staffs.ac.uk)

Dr Ken McFadyen  
Academic Tutor  
School of Psychology, Sport and Exercise  
Clinical Psychology Department  
Science Centre  
Staffordshire University  
Leek Road  
Stoke on Trent  
ST4 2DF

01782 294387

Email: [k.mcfadyen@staffs.ac.uk](mailto:k.mcfadyen@staffs.ac.uk)

## Appendix J

### Vignette

23/08/16

version 2.0

#### Vignette

We would like you to imagine that you were driving about six months ago. When you were stopped at the traffic lights, another car hit your car. You hit your head on the steering wheel. You lost consciousness for about 15 minutes. You awoke in hospital spontaneously, without being woken by others. Generally over the next few months you start to feel normal again.

Imagine you are now involved in a lawsuit against the driver of the other car. If you are found to have experienced injuries as a result of the accident you will obtain a very large settlement. You have therefore decided to fake symptoms of a brain injury in order to get compensation. As part of the lawsuit you are required to undergo psychometric testing to ascertain whether you have had a brain injury. If this was an actual real life situation and you were able to successfully convince the examiner that you have a brain injury you would be likely to get a very large settlement.

You will now be presented with some psychometric tests and questionnaires. Remember, you have decided to fake the symptoms of a brain injury in order to get compensation.

## Appendix K

### Staffordshire University Independent Peer Review and Indemnity Insurance



Date: 07/02/2016

**To whom it may concern**

**Application for Independent Peer Review Approval**

**Researcher:** Victoria Bagnall

**Study Title:** Validation of the Symptoms of Post-Concussion Syndrome Questionnaire (SPSQ) as a self-report symptom validity test for individuals with an acquired head injury.

I can confirm that Staffordshire University supports this research project proposal being put forward by the above research project applicant, and that the University is willing to act as sponsor of the project if it received LREC approval.

Our support for this project takes account of the outcome of an independent peer review of its scientific merit undertaking within the University.

I can also confirm that the University has generic indemnity/insurance arrangements in place as stated on the attachment to this letter, that arrangements will be in place before the study starts for the research team to access resources and support to deliver the research as proposed, that arrangements to allocate responsibilities for the management, monitoring and reporting of the research will be in place before the research starts and that the duties of sponsors set out in the NHS Research Governance Framework for Health and Social Care will be undertaken in relation to this research.

A handwritten signature in red ink, appearing to read 'N. Chockalingam'.

Professor Nachiappan Chockalingam  
Chair,  
University Academic Ethics Committee

**INDEPENDENT PEER REVIEW APPROVAL FEEDBACK**

**Researcher Name** Victoria Bagnall  
**Title of Study** Determining the SPSQ as a symptom validity test  
**Award Pathway** DClinPsy  
**Status of approval:** **Approved**

This letter is formally to approve the minor amendment that you have requested to the proposal as it will be presented to the LREC. You will be dropping the Amsterdam Short Memory Test (Schmand) from your proposal and replacing it with the LIPP - symptom validity test.

**Action now needed:**

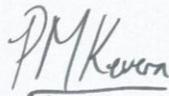
You must now apply to the Local NHS Research Ethics Committee (LREC) for approval to conduct your study. You must not commence the study without this second approval.

Please forward a copy of the letter you receive from the LREC to Peter Kevern at Blackheath Lane as soon as possible after you have received approval.

Once you have received LREC approval you can commence your study. You should be sure to do so in consultation with your supervisor.

You should note that any divergence from the approved procedures and research method will invalidate any insurance and liability cover from the University. You should, therefore, notify the Panel of any significant divergence from this approved proposal.

When your study is complete, please send the Faculty ethics committee an end of study report. A template can be found on the ethics BlackBoard site.

**Comments for your consideration:**



To Whom It May Concern

Our ref: SN/IND

13 July, 2015

Zurich Municipal Customer: Staffordshire University

This is to confirm that Staffordshire University have in force with this Company until the policy expiry on 31 July 2016 Professional Negligence Insurance incorporating the following essential features:

Policy Number: NHE-02CA03-0013

Services covered: The Services

Limit of Indemnity: £ 5,000,000 any one claim and *in the aggregate for all claims* first made against the Insured and notified to Zurich Municipal during the period of insurance

Excess : £ 5,000 any one claim

Retroactive Date: 05 March 2003

**Exclusions**

Standard insurance market exclusions apply, notably exclusion of Pollution other than sudden and accidental; punitive or exemplary damages; express warranties or guarantees; claims the cause of which occurred prior to the Retroactive Date.

*This is a brief summary and the full policy should always be referred to for exact details of cover.*

Yours faithfully

Underwriting Services  
Zurich Municipal  
Farnborough

Zurich Municipal  
Zurich House  
2 Gladiator Way  
Farnborough  
GU14 6GB

Telephone 0870 2418050

Direct Phone 01252 387849  
Direct Fax 01252 375893  
E-mail  
victoria.stockley@uk.zurich.com

Communications will be monitored  
regularly to improve our service and  
for security and regulatory purposes

Zurich Municipal is a trading name of  
Zurich Insurance Group Ltd

A public limited company incorporated in  
Ireland. Registration No. 13460  
Registered Office: Zurich House, Ballsbridge  
Park, Dublin 4, Ireland.

UK branch registered in England and Wales  
Registration No. BR7985.  
UK Branch Head Office: The Zurich Centre,  
3000 Parloway, Whiteley, Fareham,  
Hampshire PO15 7JZ

Authorised by the Central Bank of Ireland  
and subject to limited regulation by the  
Financial Conduct Authority. Details about  
the extent of our regulation by the Financial  
Conduct Authority are available from us on  
request.

1405270400 (08/13) SN/IND



To Whom It May Concern

Our ref: SN/IND

13 July, 2015

Zurich Municipal Customer: Staffordshire University

This is to confirm that Staffordshire University have in force with this Company until the policy expiry on 31 July 2016 Insurance incorporating the following essential features:

Policy Number: NHE-02CA03-0013

**Limit of Indemnity:**

|                       |              |                       |
|-----------------------|--------------|-----------------------|
| Public Liability:     | £ 25,000,000 | any one event         |
| Products Liability:   | £ 25,000,000 | for all claims in the |
| Pollution:            |              | aggregate during      |
|                       |              | any one period of     |
|                       |              | insurance             |
| Employers' Liability: | £ 25,000,000 | any one event         |
|                       |              | inclusive of costs    |

**Excess:**

|  |         |                   |
|--|---------|-------------------|
| Public Liability/Products Liability/Pollution: | £ 1,000 | any one event     |
| Employers' Liability:                          |         | Nil any one claim |

**Indemnity to Principals:**

Covers include a standard Indemnity to Principals Clause in respect of contractual obligations.

**Full Policy:**

The policy documents should be referred to for details of full cover.

Yours faithfully

Underwriting Services  
Zurich Municipal  
Farnborough

Zurich Municipal  
Zurich House  
2 Gladiator Way  
Farnborough  
Hampshire  
GU14 6GB

Telephone 0870 2418050  
Direct Phone: 01252 387849  
Direct Fax: 01252 375893  
E-mail  
victoria.stockley@uk.zurich.com

Communications will be monitored regularly to improve our service and for security and regulatory purposes

Zurich Municipal is a trading name of Zurich Insurance Group Ltd

A public limited company incorporated in Ireland. Registration No. 13460  
Registered Office: Zurich House, Ballsbridge Park, Dublin 4, Ireland.

UK branch registered in England and Wales Registration No. BR7985.  
UK Branch Head Office: The Zurich Centre, 3000 Parkway, Whiteley, Fareham, Hampshire PO15 7JZ

Authorised by the Central Bank of Ireland and subject to limited regulation by the Financial Conduct Authority. Details about the extent of our regulation by the Financial Conduct Authority are available from us on request

1080632403 (08/12/18)



**Certificate of Employers' Liability Insurance(a)**

(Where required by regulation 5 of the Employers' Liability (Compulsory Insurance) Regulations 2008 (the Regulations), a copy of this certificate must be displayed at all places where you employ persons covered by the policy or an electronic copy of the certificate must be retained and be reasonably accessible to each employee to whom it relates).

Policy No. NHE-02CA03-0013  
1. Name of policyholder Staffordshire University  
2. Date of commencement of insurance policy 01 August 2015  
3. Date of expiry of insurance policy 31 July 2016

We hereby certify that subject to paragraph 2:

1. The policy to which this certificate relates satisfies the requirements of the relevant law applicable in Great Britain, Northern Ireland, the Isle of Man, the Island of Jersey, the Island of Guernsey and the Island of Alderney (b)
2. (a) the minimum amount of cover provided by this policy is no less than £5 million (c)

Signed on behalf of Zurich Insurance plc (Authorised Insurer).

Signature

Stephen Lewis

Chief Executive Officer, Zurich Insurance plc (UK Branch)

Zurich Municipal is a trading name of Zurich Insurance plc  
A public limited company  
Incorporated in Ireland  
Registration No.13460 Registered Office Zurich House, Ballsbridge Park, Dublin 4 Ireland.  
UK branch registered in England and Wales Registration No. BR 7983  
UK Branch Head Office  
The Zurich Centre, 3000 Parkway, Whiteley, Fareham, Hampshire PO15 7JZ

**Notes**

- (a) Where the employer is a company to which regulation 3(2) of the Regulations applies, the certificate shall state in a prominent place, either that the policy covers the holding company and all its subsidiaries, or that the policy covers the holding company and all its subsidiaries except any specifically excluded by name, or that the policy covers the holding company and only the named subsidiaries.
- (b) Specify applicable law as provided for in regulation 4(6) of the Regulations.
- (c) See regulation 3(1) of the Regulations and delete whichever of paragraphs 2(a) or 2(b) does not apply. Where 2(b) is applicable, specify the amount of cover provided by the relevant policy.

Authorised by the Central Bank of Ireland and subject to limited regulation by the Financial Conduct Authority. Details about the extent of our regulation by the Financial Conduct Authority are available from us on request

## Appendix L

### NHS Research Ethics Committee Approval Letter



#### Health Research Authority

West Midlands - Edgbaston Research Ethics Committee

The Old Chapel  
Royal Standard Place  
Nottingham  
NG1 6FS

Telephone: 0207 104 8069

**Please note:** This is the favourable opinion of the REC only and does not allow you to start your study at NHS sites in England until you receive HRA Approval

08 September 2016

Miss Victoria Bagnall  
Trainee Clinical Psychologist  
South Staffordshire and Shropshire NHS Foundation Trust  
School of Psychology, Sport and Exercise, Clinical Psychology Department  
Science Centre, Staffordshire University, Leek Road, Stoke on Trent  
ST4 2DF

Dear Miss Bagnall

|                  |  |
|------------------|--|
| Study title:     | Validation of the Symptoms of Post-Concussion Syndrome Questionnaire (SPSQ) as a self-report symptom validity test for individuals with an acquired head injury. |
| REC reference:   | 16/WM/0300   |
| Protocol number: | n/a  |
| IRAS project ID: | 200642   |

Thank you for your submission of 30 August 2016, responding to the Committee's request for further information on the above research and submitting revised documentation.

The further information has been considered on behalf of the Committee by the Chair.

We plan to publish your research summary wording for the above study on the HRA website, together with your contact details. Publication will be no earlier than three months from the date of this opinion letter. Should you wish to provide a substitute contact point, require further information, or wish to make a request to postpone publication, please contact the REC Manager, Helen Poole at [NRESCommittee.WestMidlands-Edgbaston@nhs.net](mailto:NRESCommittee.WestMidlands-Edgbaston@nhs.net)  
**Confirmation of ethical opinion**

On behalf of the Committee, I am pleased to confirm a favourable ethical opinion for the above research on the basis described in the application form, protocol and supporting documentation as revised, subject to the conditions specified below.

#### **Conditions of the favourable opinion**

The REC favourable opinion is subject to the following conditions being met prior to the start of the study.

Management permission must be obtained from each host organisation prior to the start of the study at the site concerned.

*Management permission should be sought from all NHS organisations involved in the study in accordance with NHS research governance arrangements. Each NHS organisation must confirm through the signing of agreements and/or other documents that it has given permission for the research to proceed (except where explicitly specified otherwise).*

*Guidance on applying for NHS permission for research is available in the Integrated Research Application System, [www.hra.nhs.uk](http://www.hra.nhs.uk) or at <http://www.rdforum.nhs.uk>.*

*Where a NHS organisation's role in the study is limited to identifying and referring potential participants to research sites ("participant identification centre"), guidance should be sought from the R&D office on the information it requires to give permission for this activity.*

*For non-NHS sites, site management permission should be obtained in accordance with the procedures of the relevant host organisation.*

*Sponsors are not required to notify the Committee of management permissions from host organisations*

#### Registration of Clinical Trials

All clinical trials (defined as the first four categories on the IRAS filter page) must be registered on a publically accessible database within 6 weeks of recruitment of the first participant (for medical device studies, within the timeline determined by the current registration and publication trees).

There is no requirement to separately notify the REC but you should do so at the earliest opportunity e.g. when submitting an amendment. We will audit the registration details as part of the annual progress reporting process.

To ensure transparency in research, we strongly recommend that all research is registered but for non-clinical trials this is not currently mandatory.

If a sponsor wishes to contest the need for registration they should contact Catherine Blewett ([catherineblewett@nhs.net](mailto:catherineblewett@nhs.net)), the HRA does not, however, expect exceptions to be made. Guidance on where to register is provided within IRAS.

**It is the responsibility of the sponsor to ensure that all the conditions are complied with before the start of the study or its initiation at a particular site (as applicable).**

## Ethical review of research sites

### NHS sites

The favourable opinion applies to all NHS sites taking part in the study, subject to management permission being obtained from the NHS/HSC R&D office prior to the start of the study (see "Conditions of the favourable opinion" below).

### Approved documents

The final list of documents reviewed and approved by the Committee is as follows:

| <i>Document</i>   | <i>Version</i> | <i>Date</i>       |
|---|----------------|-------------------|
| Evidence of Sponsor insurance or indemnity (non NHS Sponsors only) [Employers liability]      |                | 01 August 2015    |
| Letter from sponsor [Independent peer review approval feedback]                               |                | 07 February 2016  |
| Letters of invitation to participant [Recruitment email]                                      | 1.0            | 27 June 2016      |
| Non-validated questionnaire [SPSQ]  | 1.0            | 01 September 2015 |
| Other [Professional negligence ]  |                | 13 July 2015      |
| Other [Public product liability]  |                | 13 July 2015      |
| Other [Independent peer review approval feedback - minor change]                              | 1              | 03 May 2016       |
| Other [GCP certificate]   |                | 21 October 2015   |
| Other [debrief statement ]  | 3.0            | 23 August 2016    |
| Other [Clinician information sheet]   | 2.0            | 23 August 2016    |
| Other [vignette]  | 2.0            | 23 August 2016    |
| Other [debrief statement with highlighted changes]  | 3.0            | 23 August 2016    |
| Other [Vignette with highlighted changes]   | 2.0            | 23 August 2016    |
| Participant consent form [TBI Consent form]   | 3.0            | 28 June 2016      |
| Participant consent form [Non-clinical consent form]  | 3.0            | 28 June 2016      |
| Participant information sheet (PIS) [TBI Information sheet]                                   | 5.0            | 23 August 2016    |
| Participant information sheet (PIS) [Non-clinical information sheet]                          | 5.0            | 23 August 2016    |
| Participant information sheet (PIS) [TBI information sheet with highlighted changes]          | 5.0            | 23 August 2016    |
| Participant information sheet (PIS) [Non-clinical information sheet with highlighted changes] | 5.0            | 23 August 2016    |
| REC Application Form [REC_Form_13062016]  |                | 13 June 2016      |
| REC Application Form [REC_Form_01072016]  |                | 01 July 2016      |
| Research protocol or project proposal [Protocol]  | 3.0            | 27 June 2016      |
| Summary CV for Chief Investigator (CI) [Summary CV for CI]                                    |                | 03 June 2016      |
| Summary CV for supervisor (student research) [CV supervisor]                                  |                |                   |
| Validated questionnaire [HADS]  |                |                   |
| Validated questionnaire [List of Indiscriminate Psychopathology (LIPP)]                       |                |                   |
| Validated questionnaire [copyrighted measures]  |                | 03 June 2016      |
| Validated questionnaire [TOPF-UK]   |                |                   |
| Validated questionnaire [Word Memory Test]  |                |                   |
| Validated questionnaire [TOMM]  |                |                   |

### Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

### After ethical review

#### Reporting requirements

The attached document "*After ethical review – guidance for researchers*" gives detailed guidance on reporting requirements for studies with a favourable opinion, including:

- Notifying substantial amendments
- Adding new sites and investigators
- Notification of serious breaches of the protocol
- Progress and safety reports
- Notifying the end of the study

The HRA website also provides guidance on these topics, which is updated in the light of changes in reporting requirements or procedures.

### User Feedback

The Health Research Authority is continually striving to provide a high quality service to all applicants and sponsors. You are invited to give your view of the service you have received and the application procedure. If you wish to make your views known please use the feedback form available on the HRA website:

<http://www.hra.nhs.uk/about-the-hra/governance/quality-assurance/>

### HRA Training

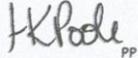
We are pleased to welcome researchers and R&D staff at our training days – see details at <http://www.hra.nhs.uk/hra-training/>

16/WM/0300

Please quote this number on all correspondence

With the Committee's best wishes for the success of this project.

Yours sincerely



**Mr Paul Hamilton**  
Chair

Email: NRESCommittee.WestMidlands-Edgbaston@nhs.net

Enclosures:  
Copy to:

"After ethical review – guidance for researchers"  
Dr Liz Boath

Ms Louise Alston, North Staffordshire Combined Healthcare NHS Trust

## Appendix M

### Health Research Authority Approval



Health Research Authority

Victoria Reece  
Trainee Clinical Psychologist  
School of Psychology, Sport and Exercise  
Clinical Psychology Department  
Science Centre, Staffordshire University,  
Leek Road, Stoke on Trent  
ST4 2DF

Email: [hra.approval@nhs.net](mailto:hra.approval@nhs.net)

5 December 2016

Dear Victoria,

#### Letter of HRA Approval

|                         |   |
|-------------------------|---|
| <b>Study title:</b>     | <b>Validation of the Symptoms of Post-Concussion Syndrome Questionnaire (SPSQ) as a self-report symptom validity test for individuals with an acquired head injury.</b> |
| <b>IRAS project ID:</b> | <b>200642</b>   |
| <b>REC reference:</b>   | <b>16/WM/0300</b>   |
| <b>Sponsor</b>          | <b>Staffordshire University</b>   |

I am pleased to confirm that HRA Approval has been given for the above referenced study, on the basis described in the application form, protocol, supporting documentation and any clarifications noted in this letter

#### Participation of NHS Organisations in England

The sponsor should now provide a copy of this letter to all participating NHS organisations in England.

*Appendix B* provides important information for sponsors and participating NHS organisations in England for arranging and confirming capacity and capability. **Please read *Appendix B* carefully**, in particular the following sections:

- *Participating NHS organisations in England* – this clarifies the types of participating organisations in the study and whether or not all organisations will be undertaking the same activities
- *Confirmation of capacity and capability* - this confirms whether or not each type of participating NHS organisation in England is expected to give formal confirmation of capacity and capability. Where formal confirmation is not expected, the section also provides details on the time limit given to participating organisations to opt out of the study, or request additional time, before their participation is assumed.
- *Allocation of responsibilities and rights are agreed and documented (4.1 of HRA assessment criteria)* - this provides detail on the form of agreement to be used in the study to confirm capacity and capability, where applicable.

Further information on funding, HR processes, and compliance with HRA criteria and standards is also provided.

Page 1 of 7

It is critical that you involve both the research management function (e.g. R&D office) supporting each organisation and the local research team (where there is one) in setting up your study. Contact details and further information about working with the research management function for each organisation can be accessed from [www.hra.nhs.uk/hra-approval](http://www.hra.nhs.uk/hra-approval).

### Appendices

The HRA Approval letter contains the following appendices:

- A – List of documents reviewed during HRA assessment
- B – Summary of HRA assessment

### After HRA Approval

The document "*After Ethical Review – guidance for sponsors and investigators*", issued with your REC favourable opinion, gives detailed guidance on reporting expectations for studies, including:

- Registration of research
- Notifying amendments
- Notifying the end of the study

The HRA website also provides guidance on these topics, and is updated in the light of changes in reporting expectations or procedures.

In addition to the guidance in the above, please note the following:

- HRA Approval applies for the duration of your REC favourable opinion, unless otherwise notified in writing by the HRA.
- Substantial amendments should be submitted directly to the Research Ethics Committee, as detailed in the *After Ethical Review* document. Non-substantial amendments should be submitted for review by the HRA using the form provided on the [HRA website](#), and emailed to [hra.amendments@nhs.net](mailto:hra.amendments@nhs.net).
- The HRA will categorise amendments (substantial and non-substantial) and issue confirmation of continued HRA Approval. Further details can be found on the [HRA website](#).

### Scope

HRA Approval provides an approval for research involving patients or staff in NHS organisations in England.

If your study involves NHS organisations in other countries in the UK, please contact the relevant national coordinating functions for support and advice. Further information can be found at <http://www.hra.nhs.uk/resources/applying-for-reviews/nhs-hsc-rd-review/>.

If there are participating non-NHS organisations, local agreement should be obtained in accordance with the procedures of the local participating non-NHS organisation.

|                 |        |
|-----------------|--------|
| IRAS project ID | 200642 |
|-----------------|--------|

#### **User Feedback**

The Health Research Authority is continually striving to provide a high quality service to all applicants and sponsors. You are invited to give your view of the service you have received and the application procedure. If you wish to make your views known please email the HRA at [hra.approval@nhs.net](mailto:hra.approval@nhs.net). Additionally, one of our staff would be happy to call and discuss your experience of HRA Approval.

#### **HRA Training**

We are pleased to welcome researchers and research management staff at our training days – see details at <http://www.hra.nhs.uk/hra-training/>

Your IRAS project ID is **200642**. Please quote this on all correspondence.

Yours sincerely

Simon Connolly  
Senior Assessor

Email: [hra.approval@nhs.net](mailto:hra.approval@nhs.net)

Copy to: *Dr Liz Boath, Staffordshire University*  
*Ms Louise Alston, North Staffordshire Combined Healthcare NHS Trust*

## Appendix A - List of Documents

The final document set assessed and approved by HRA Approval is listed below.

| <i>Document</i>   | <i>Version</i> | <i>Date</i>       |
|---|----------------|-------------------|
| Evidence of Sponsor insurance or indemnity (non NHS Sponsors only)      |                |                   |
| Letter from sponsor [Independent peer review approval feedback]         |                | 07 February 2016  |
| Letters of invitation to participant [Recruitment email]                | 1.0            | 27 June 2016      |
| Non-validated questionnaire [SPSQ]                                      | 1.0            | 01 September 2015 |
| Other [Independent peer review approval feedback - minor change]        | 1              | 03 May 2016       |
| Other [debrief statement ]  | 3.0            | 23 August 2016    |
| Other [Clinician information sheet]                                     | 2.0            | 23 August 2016    |
| Other [vignette]  | 2.0            | 23 August 2016    |
| Other [Statement of activities]   |                |                   |
| Other [Schedule of events]  |                |                   |
| Participant consent form [TBI Consent form]                             | 3.0            | 28 June 2016      |
| Participant consent form [Non-clinical consent form]                    | 3.0            | 28 June 2016      |
| Participant information sheet (PIS) [TBI Information sheet]             | 5.0            | 23 August 2016    |
| Participant information sheet (PIS) [Non-clinical information sheet]    | 5.0            | 23 August 2016    |
| REC Application Form [REC_Form_01072016]                                |                | 01 July 2016      |
| Research protocol or project proposal [Protocol]                        | 3.0            | 27 June 2016      |
| Summary CV for Chief Investigator (CI) [Summary CV for CI]              |                | 03 June 2016      |
| Summary CV for supervisor (student research) [CV supervisor]            |                |                   |
| Validated questionnaire [HADS]  |                |                   |
| Validated questionnaire [List of Indiscriminate Psychopathology (LIPP)] |                |                   |
| Validated questionnaire [copyrighted measures]                          |                | 03 June 2016      |
| Validated questionnaire [TOPF-UK]                                       |                |                   |
| Validated questionnaire [Word Memory Test]                              |                |                   |
| Validated questionnaire [TOMM]  |                |                   |

## Appendix B - Summary of HRA Assessment

This appendix provides assurance to you, the sponsor and the NHS in England that the study, as reviewed for HRA Approval, is compliant with relevant standards. It also provides information and clarification, where appropriate, to participating NHS organisations in England to assist in assessing and arranging capacity and capability.

**For information on how the sponsor should be working with participating NHS organisations in England, please refer to the, *participating NHS organisations, capacity and capability and Allocation of responsibilities and rights are agreed and documented (4.1 of HRA assessment criteria) sections in this appendix.***

The following person is the sponsor contact for the purpose of addressing participating organisation questions relating to the study:

Name: Victoria Reece  
 Tel: 01782 294007  
 Email: [victoria.reece@sssft.nhs.uk](mailto:victoria.reece@sssft.nhs.uk)

### HRA assessment criteria

| Section | HRA Assessment Criteria   | Compliant with Standards | Comments   |
|---------|---|--------------------------|--|
| 1.1     | IRAS application completed correctly                                | Yes                      | No comments  |
| 2.1     | Participant information/consent documents and consent process       | Yes                      | No comments  |
| 3.1     | Protocol assessment   | Yes                      | No comments  |
| 4.1     | Allocation of responsibilities and rights are agreed and documented | Yes                      | Statement of activities will form agreement between sponsor and participating NHS organisations.   |
| 4.2     | Insurance/indemnity arrangements assessed                           | Yes                      | Where applicable, independent contractors (e.g. General Practitioners) should ensure that the professional indemnity provided by their medical defence organisation covers the activities expected of them for this research study |

| Section | HRA Assessment Criteria  | Compliant with Standards | Comments  |
|---------|--|--------------------------|---|
| 4.3     | Financial arrangements assessed  | Yes                      | Study forms part of a doctorate. No funding will be provided by the sponsor to participating NHS organisations. Schedule of events provided without cost attribution. |
| 5.1     | Compliance with the Data Protection Act and data security issues assessed          | Yes                      | No comments   |
| 5.2     | CTIMPS – Arrangements for compliance with the Clinical Trials Regulations assessed | Not Applicable           |   |
| 5.3     | Compliance with any applicable laws or regulations                                 | Yes                      | No comments   |
| 6.1     | NHS Research Ethics Committee favourable opinion received for applicable studies   | Yes                      | No comments   |
| 6.2     | CTIMPS – Clinical Trials Authorisation (CTA) letter received                       | Not Applicable           |   |
| 6.3     | Devices – MHRA notice of no objection received                                     | Not Applicable           |   |
| 6.4     | Other regulatory approvals and authorisations received                             | Not Applicable           |   |

#### Participating NHS Organisations in England

*This provides detail on the types of participating NHS organisations in the study and a statement as to whether the activities at all organisations are the same or different.*

At participating NHS organisations participants will be recruited and research activities may take place.

The Chief Investigator or sponsor should share relevant study documents with participating NHS organisations in England in order to put arrangements in place to deliver the study. The documents should be sent to both the local study team, where applicable, and the office providing the research management function at the participating organisation. For NIHR CRN Portfolio studies, the Local LCRN contact should also be copied into this correspondence. For further guidance on working with participating NHS organisations please see the HRA website.

If chief investigators, sponsors or principal investigators are asked to complete site level forms for participating NHS organisations in England which are not provided in IRAS or on the HRA website, the chief investigator, sponsor or principal investigator should notify the HRA immediately at [hra.approval@nhs.net](mailto:hra.approval@nhs.net). The HRA will work with these organisations to achieve a consistent approach to information provision.

### Confirmation of Capacity and Capability

*This describes whether formal confirmation of capacity and capability is expected from participating NHS organisations in England.*

Participating NHS organisations in England **will be expected to formally confirm their capacity and capability to host this research.**

- Following issue of this letter, participating NHS organisations in England may now confirm to the sponsor their capacity and capability to host this research, when ready to do so. How capacity and capability will be confirmed is detailed in the *Allocation of responsibilities and rights are agreed and documented (4.1 of HRA assessment criteria)* section of this appendix.
- The [Assessing, Arranging, and Confirming](#) document on the HRA website provides further information for the sponsor and NHS organisations on assessing, arranging and confirming capacity and capability.

### Principal Investigator Suitability

*This confirms whether the sponsor position on whether a PI, LC or neither should be in place is correct for each type of participating NHS organisation in England and the minimum expectations for education, training and experience that PIs should meet (where applicable).*

A local collaborator will be in place at each participating NHS organisation to facilitate the student completing research activities at sites.

GCP training is not a generic training expectation, in line with the [HRA statement on training expectations](#).

### HR Good Practice Resource Pack Expectations

*This confirms the HR Good Practice Resource Pack expectations for the study and the pre-engagement checks that should and should not be undertaken*

Where access arrangements are not in place researchers will require a letter of access to complete research activities in NHS organisations. It will need to be confirmed that appropriate DBS and occupational health checks have taken place.

### Other Information to Aid Study Set-up

*This details any other information that may be helpful to sponsors and participating NHS organisations in England to aid study set-up.*

- The applicant has indicated that they do not intend to apply for inclusion on the NIHR CRN Portfolio.

## Appendix N

### NHS Research and Development approval

**RESEARCH AND DEVELOPMENT DEPARTMENT**  
Harplands Hospital, Management Suite  
Hilton Road, Stoke-on-Trent, ST4 6TH  
Telephone: 01782 441687 : Fax: 01782 441637  
Email: r&d@northstaffs.nhs.uk : Twitter: @nschtresearch

09 February 2017

**Researcher:**  
Victoria Reece  
Trainee Clinical Psychologist  
South Staffordshire & Shropshire Healthcare NHSFT  
Horizon Care & Education Group (Child LAC)  
Venture House  
12 Prospect Park  
Longford Road  
Cannock WS11 0LG

Dear Victoria

#### Letter of Access for NHS Researchers

This *Letter of Access for NHS Researchers* has been issued by North Staffordshire Combined Healthcare NHS Trust, Research and Development Department, and we can confirm that we have undertaken the relevant pre-engagement checks in accordance with the NIHR "Research Passport and Streamlined Human Resources Arrangements" (September 2012)<sup>1</sup> enabling you to undertake research related activity at this NHS organisation.

|                                |   |                  |
|--------------------------------|---|------------------|
| Research Reference Numbers:    | R&D Ref.:   | CHC0135/RS       |
|                                | IRAS ID.:   | 200642           |
|                                | UKCRN ID.:  | N/A              |
|                                | REC Ref.:   | 16/WM/0300       |
|                                | Protocol Version.:  | 3.0 (27/06/2016) |
| Research Title:                | Determining the SPSQ as a symptom validity test   |                  |
| Date Research Ends:            | 30/07/2017  |                  |
| Date Letter of Access Expires: | 30/07/2017  |                  |
| Local Research Manager:        | Sue Wood  |                  |
| Research Activity:             | Consenting participants, Conducting study interview including facilitating battery of study assessments |                  |

This letter should be presented before you commence your research at this organisation.

Chairman: Mr David Rogers

Chief Executive: Mrs Caroline Donovan

*Working to improve the mental health and wellbeing of local communities*



<sup>1</sup> <http://www.nihr.ac.uk/policy-and-standards/research-passports.htm>

<sup>2</sup> **Victoria Reece's current NHS Proforma will expire on 22/09/2017.** The issue of this Letter of Access is therefore conditional on the validation of a new NHS Proforma if the researcher's contract end date has expired.

<sup>3</sup> HRA Approval Letter dated 05/12/2016 / NHS Confirmation of Capacity and Capability dated 09/02/2017

<sup>4</sup> [www.hra.nhs.uk/resources/research-legislation-and-governance/research-governance-frameworks/](http://www.hra.nhs.uk/resources/research-legislation-and-governance/research-governance-frameworks/)

In accepting this letter, this confirms your right of access to conduct research through our organisation for the purpose and on the terms and conditions set out below. This right of access commences from the date of this letter and ends on **30/07/2017**<sup>2</sup> unless terminated earlier in accordance with the clauses below:

1. As an existing NHS employee you do not require an additional honorary research contract with North Staffordshire Combined Healthcare NHS Trust. This organisation is satisfied that the research activities you will undertake in this organisation are commensurate with the activities you undertake for your employer. Your employer is fully responsible for ensuring such checks as necessary have been carried out. Your employer has confirmed in writing to this organisation that the necessary pre-engagement checks are in place in accordance with the role you plan to carry out in the organisation.
2. You have a right of access to conduct such research as confirmed by North Staffordshire Combined Healthcare NHS Trust, Research and Development Department.

**Please note** that you cannot start the research until the Chief Investigator has received a letter of HRA approval from the Health Research Authority and the Principal Investigator has received NHS Confirmation of Capacity and Capability from North Staffordshire Combined Healthcare NHS Trust, Research and Development Department confirming the conduct<sup>3</sup> of the research study identified above.

3. You are considered to be a legal visitor to the organisations premises. You are not entitled to any form of payment or access to other benefits provided by this organisation or this organisation to employees and this letter does not give rise to any other relationship between you and this organisation, in particular that of an employee.
4. While undertaking research through this organisation you will remain accountable to your substantive employer, but you are required to follow the reasonable instructions of this organisation or those instructions given on their behalf in relation to the terms of this right of access.
  - 4.1. To clarify any specific governance requirements at this organisation you must contact the Local Research Manager named above directly.
5. Where any third party claim is made, whether or not legal proceedings are issued, arising out of or in connection with your right of access, you are required to co-operate fully with any investigation by this organisation in connection with any such claim and to give all such assistance as may reasonably be required regarding the conduct of any legal proceedings.
6. You must act in accordance with this organisations policies and procedures, which are available to you upon request, and the Research Governance Framework<sup>4</sup>.

Chairman: Mr David Rogers

Chief Executive: Mrs Caroline Donovan

*Working to improve the mental health and wellbeing of local communities*



@nscht1



www.combined.nhs.uk



<sup>1</sup> <http://www.nihr.ac.uk/policy-and-standards/research-passports.htm>

<sup>2</sup> Victoria Reece's current NHS Proforma will expire on **22/09/2017**. The issue of this Letter of Access is therefore conditional on the validation of a new NHS Proforma if the researcher's contract end date has expired.

<sup>3</sup> HRA Approval Letter dated 05/12/2016 / NHS Confirmation of Capacity and Capability dated 09/02/2017

<sup>4</sup> [www.hra.nhs.uk/resources/research-legislation-and-governance/research-governance-frameworks/](http://www.hra.nhs.uk/resources/research-legislation-and-governance/research-governance-frameworks/)

7. You are required to co-operate with this organisation in discharging its duties under the Health and Safety at Work Act 1974, and other health and safety legislation and to take reasonable care for the health and safety of yourself and others while on this organisations premises. You must observe the same standards of care and propriety in dealing with patients, staff, visitors, equipment and premises as is expected of any other contract holder and you must act appropriately, responsibly and professionally at all times.
8. If you have a physical or mental health condition or disability which may affect your research role and which might require special adjustments to your role, if you have not already done so, you must notify your employer, and this organisation prior to commencing your research role.
9. You are required to ensure that all information regarding patients or staff remains secure and strictly confidential at all times. You must ensure that you understand and comply with the requirements of the NHS Confidentiality Code of Practice and the Data Protection Act 1998. Furthermore you should be aware that under the Act, unauthorised disclosure of information is an offence and such disclosures may lead to prosecution.

*Please note researchers are not permitted any access to personal identifiable information without the prior informed consent of patients/research participants.*

10. You should ensure that, where you are issued with an identity or security card, a bleep number, email or library account, keys or protective clothing, these are returned upon termination of this arrangement. Please note that this organisation does not accept responsibility for damage to or loss of personal property.
11. This organisation may revoke this letter and/or terminate your right to attend at any time either by giving seven days' written notice to you or immediately without any notice if you are in breach of any of the terms or conditions described in this letter or if you commit any act that we reasonably consider to amount to serious misconduct or to be disruptive and/or prejudicial to the interests and/or business of this organisation or if you are convicted of any criminal offence. You must not undertake regulated activity if you are barred from such work. If you are barred from working with adults or children this letter of access is immediately terminated. Your employer will immediately withdraw you from undertaking this or any other regulated activity and you MUST stop undertaking any regulated activity immediately.
12. Your substantive employer is responsible for your conduct during this research project and may in the circumstances described above instigate disciplinary action against you.
13. No organisation will indemnify you against any liability incurred as a result of any breach of confidentiality or breach of the Data Protection Act 1998. Any breach of the Data Protection Act 1998 may result in legal action against you and/or your substantive employer.

Chairman: Mr David Rogers

Chief Executive: Mrs Caroline Donovan

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www.combined.nhs.uk



<sup>1</sup><http://www.nihr.ac.uk/policy-and-standards/research-passports.htm>

<sup>2</sup>Victoria Reece's current NHS Proforma will expire on 22/09/2017. The issue of this Letter of Access is therefore conditional on the validation of a new NHS Proforma if the researcher's contract end date has expired.

<sup>3</sup>HRA Approval Letter dated 05/12/2016 / NHS Confirmation of Capacity and Capability dated 09/02/2017

<sup>4</sup>[www.hra.nhs.uk/resources/research-legislation-and-governance/research-governance-frameworks/](http://www.hra.nhs.uk/resources/research-legislation-and-governance/research-governance-frameworks/)

14. If your circumstances change in relation to your health, criminal record, professional registration or suitability to work with adults or children, or any other aspect that may impact on your suitability to conduct research, or your role in research changes, you must inform the organisation that employs you through its normal procedures. You must also inform your nominated Local Research Manager as named above directly.

Yours sincerely



**Sue Wood**  
R&D Manager

**Copies:**

*North Staffordshire Combined Healthcare NHS Trust, HR Directorate:*  
Alexa Lloyd, HR Advisor, Trust HQ, Bellringer Road, Trentham, Stoke-on-Trent, ST4 8HH

*HR Department of Substantive Employer:*  
Audrey Bright, R&D Department, South Staffordshire & Shropshire Healthcare NHSFT

Chairman: Mr David Rogers

Chief Executive: Mrs Caroline Donovan

*Working to improve the mental health and wellbeing of local communities*



<sup>1</sup> <http://www.nihr.ac.uk/policy-and-standards/research-passports.htm>

<sup>2</sup> Victoria Reece's current NHS Proforma will expire on 22/09/2017. The issue of this Letter of Access is therefore conditional on the validation of a new NHS Proforma if the researcher's contract end date has expired.

<sup>3</sup> HRA Approval Letter dated 05/12/2016 / NHS Confirmation of Capacity and Capability dated 09/02/2017

<sup>4</sup> [www.hra.nhs.uk/resources/research-legislation-and-governance/research-governance-frameworks/](http://www.hra.nhs.uk/resources/research-legislation-and-governance/research-governance-frameworks/)

## Appendix O

### SPSS Output: Demographic group differences

#### Report

| Group   |                | Age    | Years of education |
|---------|----------------|--------|--------------------|
| Control | Mean           | 31.53  | 16.83              |
|         | N              | 30     | 30                 |
|         | Std. Deviation | 11.539 | 2.574              |
| Malinge | Mean           | 29.80  | 18.07              |
|         | N              | 30     | 30                 |
|         | Std. Deviation | 10.121 | 2.888              |
| Total   | Mean           | 30.67  | 17.45              |
|         | N              | 60     | 60                 |
|         | Std. Deviation | 10.797 | 2.783              |

#### Hypothesis Test Summary

|   | Null Hypothesis  | Test                                    | Sig. | Decision                    |
|---|--|---|------|-----------------------------|
| 1 | The distribution of Sex is the same across categories of Group.                | Independent-Samples Mann-Whitney U Test | .776 | Retain the null hypothesis. |
| 2 | The distribution of Age is the same across categories of Group.                | Independent-Samples Mann-Whitney U Test | .374 | Retain the null hypothesis. |
| 3 | The distribution of Years of education is the same across categories of Group. | Independent-Samples Mann-Whitney U Test | .093 | Retain the null hypothesis. |

Asymptotic significances are displayed. The significance level is .05.

## Appendix P

SPSS Output: Premorbid functioning, anxiety, and depression comparisons

|             |                | Report |              |                 |
|-------------|----------------|--------|--------------|-----------------|
| Group       |                | TOPF   | HADS anxiety | HADS depression |
| Control     | Mean           | 53.07  | 5.37         | 1.30            |
|             | N              | 30     | 30           | 30              |
|             | Std. Deviation | 9.505  | 2.834        | 1.579           |
| Malingering | Mean           | 45.77  | 13.27        | 10.30           |
|             | N              | 30     | 30           | 30              |
|             | Std. Deviation | 11.936 | 4.675        | 5.428           |
| Total       | Mean           | 49.42  | 9.32         | 5.80            |
|             | N              | 60     | 60           | 60              |
|             | Std. Deviation | 11.313 | 5.528        | 6.025           |

### Hypothesis Test Summary

|   | Null Hypothesis   | Test                                    | Sig. | Decision                    |
|---|---|---|------|-----------------------------|
| 1 | The distribution of TOPF is the same across categories of Group.            | Independent-Samples Mann-Whitney U Test | .024 | Reject the null hypothesis. |
| 2 | The distribution of HADS anxiety is the same across categories of Group.    | Independent-Samples Mann-Whitney U Test | .000 | Reject the null hypothesis. |
| 3 | The distribution of HADS depression is the same across categories of Group. | Independent-Samples Mann-Whitney U Test | .000 | Reject the null hypothesis. |

Asymptotic significances are displayed. The significance level is .05.

## Appendix Q

SPSS Output: Within group premorbid functioning, anxiety, and depression correlations (malingering group)

|                 |            |                         | topf  | anxiety | depression | spsq   |
|-----------------|------------|-------------------------|-------|---------|------------|--------|
| Kendall's tau_b | topf       | Correlation Coefficient | 1.000 | -.163   | -.160      | -.212  |
|                 |            | Sig. (2-tailed)         | .     | .221    | .229       | .107   |
|                 |            | N                       | 30    | 30      | 30         | 30     |
|                 | anxiety    | Correlation Coefficient | -.163 | 1.000   | .599**     | .496** |
|                 |            | Sig. (2-tailed)         | .221  | .       | .000       | .000   |
|                 |            | N                       | 30    | 30      | 30         | 30     |
|                 | depression | Correlation Coefficient | -.160 | .599**  | 1.000      | .504** |
|                 |            | Sig. (2-tailed)         | .229  | .000    | .          | .000   |
|                 |            | N                       | 30    | 30      | 30         | 30     |
|                 | spsq       | Correlation Coefficient | -.212 | .496**  | .504**     | 1.000  |
|                 |            | Sig. (2-tailed)         | .107  | .000    | .000       | .      |
|                 |            | N                       | 30    | 30      | 30         | 30     |

\*\* . Correlation is significant at the 0.01 level (2-tailed).

## Appendix R

SPSS Output: Within group premorbid functioning, anxiety, and depression correlations (control group)

### Correlations

|                 |            |                         | topf  | anxiety | depression | spsq   |
|-----------------|------------|-------------------------|-------|---------|------------|--------|
| Kendall's tau_b | topf       | Correlation Coefficient | 1.000 | -.061   | -.232      | -.226  |
|                 |            | Sig. (2-tailed)         | .     | .661    | .115       | .096   |
|                 |            | N                       | 29    | 29      | 29         | 29     |
|                 | anxiety    | Correlation Coefficient | -.061 | 1.000   | .487**     | .505** |
|                 |            | Sig. (2-tailed)         | .661  | .       | .001       | .000   |
|                 |            | N                       | 29    | 29      | 29         | 29     |
|                 | depression | Correlation Coefficient | -.232 | .487**  | 1.000      | .567** |
|                 |            | Sig. (2-tailed)         | .115  | .001    | .          | .000   |
|                 |            | N                       | 29    | 29      | 29         | 29     |
|                 | spsq       | Correlation Coefficient | -.226 | .505**  | .567**     | 1.000  |
|                 |            | Sig. (2-tailed)         | .096  | .000    | .000       | .      |
|                 |            | N                       | 29    | 29      | 29         | 29     |

\*\* . Correlation is significant at the 0.01 level (2-tailed).

## Appendix S

SPSS Output: Kruskal-Wallis H test and contingency tables for TOMM, SRSI, and WMT

### TOMM

|       |                | Group          |         | Total  |       |
|-------|----------------|----------------|---------|--------|-------|
|       |                | Control        | Malinge |        |       |
| TOMM  | Pass           | Count          | 30      | 8      | 38    |
|       |                | % within Group | 100.0%  | 26.7%  | 63.3% |
|       | Fail           | Count          | 0       | 22     | 22    |
|       |                | % within Group | 0.0%    | 73.3%  | 36.7% |
| Total | Count          | 30             | 30      | 60     |       |
|       | % within Group | 100.0%         | 100.0%  | 100.0% |       |

### SRSI

|       |                | Group          |         | Total  |       |
|-------|----------------|----------------|---------|--------|-------|
|       |                | Control        | Malinge |        |       |
| SRSI  | Pass           | Count          | 30      | 6      | 36    |
|       |                | % within Group | 100.0%  | 20.0%  | 60.0% |
|       | Fail           | Count          | 0       | 24     | 24    |
|       |                | % within Group | 0.0%    | 80.0%  | 40.0% |
| Total | Count          | 30             | 30      | 60     |       |
|       | % within Group | 100.0%         | 100.0%  | 100.0% |       |

### WMT

|       |                | Group          |         | Total  |       |
|-------|----------------|----------------|---------|--------|-------|
|       |                | Control        | Malinge |        |       |
| WMT   | Pass           | Count          | 30      | 6      | 36    |
|       |                | % within Group | 100.0%  | 20.0%  | 60.0% |
|       | Fail           | Count          | 0       | 24     | 24    |
|       |                | % within Group | 0.0%    | 80.0%  | 40.0% |
| Total | Count          | 30             | 30      | 60     |       |
|       | % within Group | 100.0%         | 100.0%  | 100.0% |       |

### Test Statistics<sup>a,b</sup>

|             | TOMM   | SRSI   | WMT    |
|-------------|--------|--------|--------|
| Chi-Square  | 34.158 | 39.333 | 39.333 |
| df          | 1      | 1      | 1      |
| Asymp. Sig. | .000   | .000   | .000   |

a. Kruskal Wallis Test

b. Grouping Variable: Group

## Appendix T

### SPSS Output: Kruskal-Wallis H for SPCS

|             |                | Report     |              |                  |
|-------------|----------------|------------|--------------|------------------|
| Group       |                | total SPCS | Pseudo total | Pseudo frequency |
| Control     | Mean           | 9.57       | 1.87         | 1.57             |
|             | N              | 30         | 30           | 30               |
|             | Std. Deviation | 6.317      | 2.556        | 2.046            |
| Malingering | Mean           | 51.87      | 15.17        | 9.13             |
|             | N              | 30         | 30           | 30               |
|             | Std. Deviation | 21.654     | 10.403       | 4.890            |
| Total       | Mean           | 30.72      | 8.52         | 5.35             |
|             | N              | 60         | 60           | 60               |
|             | Std. Deviation | 26.552     | 10.068       | 5.326            |

| Test Statistics <sup>a,b</sup> |            |              |                  |
|--------------------------------|------------|--------------|------------------|
|                                | total SPCS | Pseudo total | Pseudo frequency |
| Chi-Square                     | 42.358     | 30.870       | 29.684           |
| df                             | 1          | 1            | 1                |
| Asymp. Sig.                    | .000       | .000         | .000             |

a. Kruskal Wallis Test

b. Grouping Variable: Group

## Appendix U

SPSS Output: Kruskal-Wallis H of pseudo items

| Test Statistics <sup>a,b</sup> |        |       |        |        |        |        |        |        |       |        |        |        |        |        |        |        |        |
|--------------------------------|--------|-------|--------|--------|--------|--------|--------|--------|-------|--------|--------|--------|--------|--------|--------|--------|--------|
|                                | f1     | f2    | f3     | f4     | f5     | f6     | f7     | f8     | f9    | f10    | f11    | f12    | f13    | f14    | f15    | totalF | freqF  |
| Chi-Square                     | 33.621 | 1.896 | 20.248 | 10.316 | 15.674 | 15.698 | 17.695 | 15.243 | 5.789 | 12.786 | 19.259 | 25.052 | 18.201 | 31.046 | 29.545 | 30.870 | 29.684 |
| df                             | 1      | 1     | 1      | 1      | 1      | 1      | 1      | 1      | 1     | 1      | 1      | 1      | 1      | 1      | 1      | 1      | 1      |
| Asymp. Sig.                    | .000   | .169  | .000   | .001   | .000   | .000   | .000   | .000   | .016  | .000   | .000   | .000   | .000   | .000   | .000   | .000   | .000   |

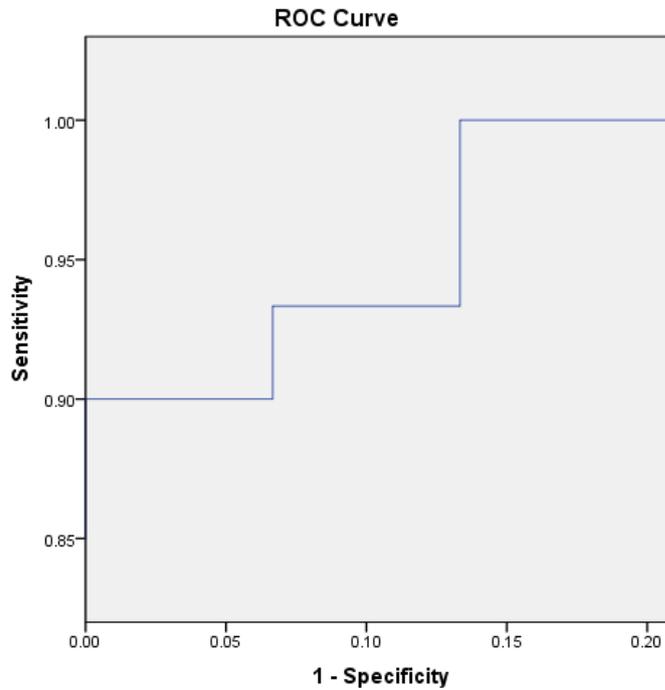
a. Kruskal Wallis Test

b. Grouping Variable: group

## Appendix V

SPSS Output: ROC curves and classification statistics

SPCS Total Score:



### Area Under the Curve

Test Result Variable(s): SPCS

| Area | Std. Error <sup>a</sup> | Asymptotic Sig. <sup>b</sup> | Asymptotic 95% Confidence Interval |             |
|------|-------------------------|------------------------------|------------------------------------|-------------|
|      |                         |                              | Lower Bound                        | Upper Bound |
| .989 | .009                    | .000                         | .972                               | 1.000       |

a. Under the nonparametric assumption

b. Null hypothesis: true area = 0.5

### Coordinates of the Curve

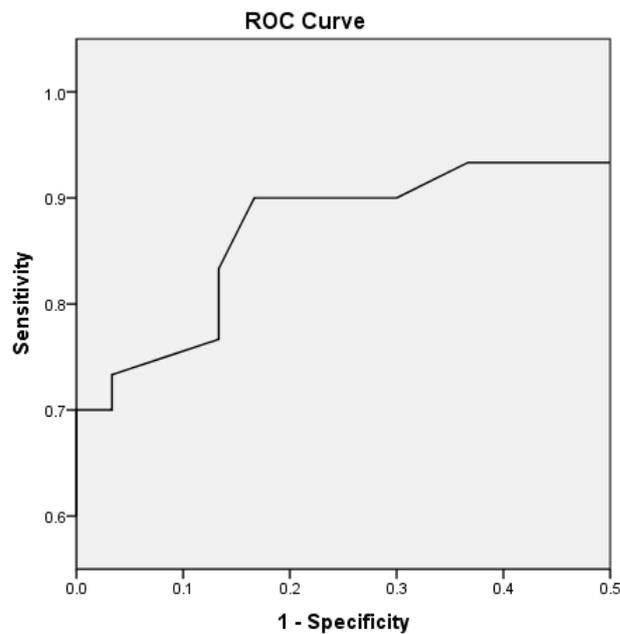
Test Result Variable(s): SPCS

| Positive if Greater<br>Than or Equal<br>To <sup>a</sup> | Sensitivity | 1 - Specificity |
|---|-------------|-----------------|
| -1.00   | 1.000       | 1.000           |
| 1.00  | 1.000       | .967            |
| 2.50  | 1.000       | .900            |
| 3.50  | 1.000       | .867            |
| 4.50  | 1.000       | .833            |
| 5.50  | 1.000       | .733            |
| 6.50  | 1.000       | .700            |
| 7.50  | 1.000       | .567            |
| 8.50  | 1.000       | .467            |
| 9.50  | 1.000       | .400            |
| 10.50   | 1.000       | .300            |
| 12.00   | 1.000       | .233            |
| 13.50   | 1.000       | .200            |
| 14.50   | 1.000       | .167            |
| 16.00   | 1.000       | .133            |
| 17.50   | .967        | .133            |
| 19.50   | .933        | .133            |
| 21.50   | .933        | .100            |
| 22.50   | .933        | .067            |
| 23.50   | .900        | .067            |
| 25.50   | .900        | .000            |
| 28.00   | .867        | .000            |
| 29.50   | .833        | .000            |
| 32.50   | .800        | .000            |
| 36.50   | .767        | .000            |
| 38.50   | .667        | .000            |
| 41.50   | .633        | .000            |
| 45.00   | .600        | .000            |
| 46.50   | .567        | .000            |
| 48.00   | .533        | .000            |
| 51.50   | .467        | .000            |
| 56.00   | .400        | .000            |
| 59.50   | .333        | .000            |
| 63.00   | .267        | .000            |
| 67.50   | .233        | .000            |

|       |      |      |
|-------|------|------|
| 70.50 | .200 | .000 |
| 73.50 | .167 | .000 |
| 81.50 | .133 | .000 |
| 88.50 | .100 | .000 |
| 92.00 | .033 | .000 |
| 95.00 | .000 | .000 |

a. The smallest cutoff value is the minimum observed test value minus 1, and the largest cutoff value is the maximum observed test value plus 1. All the other cutoff values are the averages of two consecutive ordered observed test values.

Pseudo Symptoms Total Score:



Diagonal segments are produced by ties.

### Area Under the Curve

Test Result Variable(s): total pseudo

| Area | Std. Error <sup>a</sup> | Asymptotic Sig. <sup>b</sup> | Asymptotic 95% Confidence Interval |             |
|------|-------------------------|------------------------------|------------------------------------|-------------|
|      |                         |                              | Lower Bound                        | Upper Bound |
| .914 | .040                    | .000                         | .835                               | .992        |

The test result variable(s): totalF has at least one tie between the positive actual state group and the negative actual state group. Statistics may be biased.

a. Under the nonparametric assumption

b. Null hypothesis: true area = 0.5

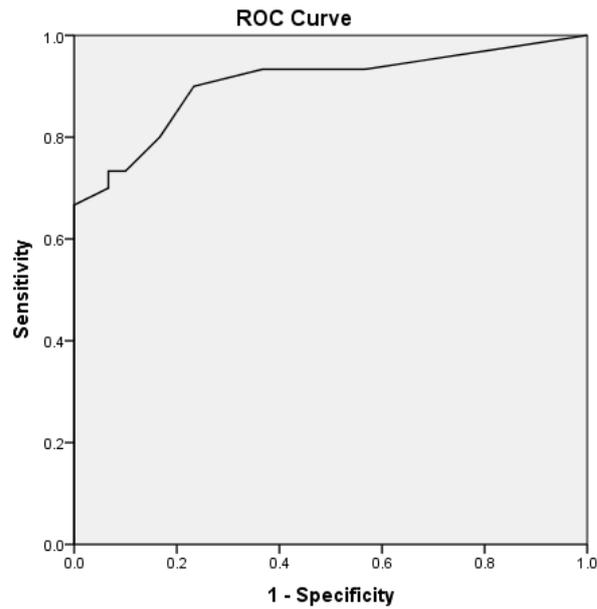
### Coordinates of the Curve

Test Result Variable(s): total pseudo

| Positive if Greater Than or Equal To <sup>a</sup> | Sensitivity | 1 - Specificity |
|---|-------------|-----------------|
| -1.00   | 1.000       | 1.000           |
| .50   | .933        | .567            |
| 1.50  | .933        | .367            |
| 2.50  | .900        | .300            |
| 3.50  | .900        | .167            |
| 4.50  | .833        | .133            |
| 6.00  | .767        | .133            |
| 7.50  | .733        | .033            |
| 8.50  | .700        | .033            |
| 9.50  | .700        | .000            |
| 10.50   | .667        | .000            |
| 11.50   | .633        | .000            |
| 12.50   | .567        | .000            |
| 14.00   | .533        | .000            |
| 15.50   | .467        | .000            |
| 16.50   | .400        | .000            |
| 17.50   | .367        | .000            |
| 18.50   | .333        | .000            |
| 19.50   | .300        | .000            |
| 21.00   | .200        | .000            |
| 22.50   | .167        | .000            |
| 27.00   | .133        | .000            |
| 32.50   | .100        | .000            |
| 35.00   | .067        | .000            |
| 38.00   | .033        | .000            |
| 41.00   | .000        | .000            |

a. The smallest cutoff value is the minimum observed test value minus 1, and the largest cutoff value is the maximum observed test value plus 1. All the other cutoff values are the averages of two consecutive ordered observed test values.

## Frequency of Pseudo Symptoms:



Diagonal segments are produced by ties.

### Area Under the Curve

Test Result Variable(s): freqF

| Area | Std. Error <sup>a</sup> | Asymptotic Sig. <sup>b</sup> | Asymptotic 95% Confidence Interval |             |
|------|-------------------------|------------------------------|------------------------------------|-------------|
|      |                         |                              | Lower Bound                        | Upper Bound |
| .906 | .041                    | .000                         | .825                               | .986        |

The test result variable(s): freqF has at least one tie between the positive actual state group and the negative actual state group. Statistics may be biased.

a. Under the nonparametric assumption

b. Null hypothesis: true area = 0.5

### Coordinates of the Curve

Test Result Variable(s): freqF

| To <sup>a</sup> | Positive if Greater Than or Equal |                 |
|-----------------|-----------------------------------|-----------------|
|                 | Sensitivity                       | 1 - Specificity |
| -1.00           | 1.000                             | 1.000           |
| .50             | .933                              | .567            |
| 1.50            | .933                              | .367            |
| 2.50            | .900                              | .233            |
| 3.50            | .800                              | .167            |
| 4.50            | .733                              | .100            |
| 5.50            | .733                              | .067            |
| 6.50            | .700                              | .067            |
| 7.50            | .667                              | .000            |

|       |      |      |
|-------|------|------|
| 8.50  | .567 | .000 |
| 9.50  | .533 | .000 |
| 10.50 | .500 | .000 |
| 11.50 | .400 | .000 |
| 12.50 | .333 | .000 |
| 13.50 | .233 | .000 |
| 14.50 | .167 | .000 |
| 16.00 | .000 | .000 |

a. The smallest cutoff value is the minimum observed test value minus 1, and the largest cutoff value is the maximum observed test value plus 1. All the other cutoff values are the averages of two consecutive ordered observed test values.

## **Appendix W**

Author guidelines for the Journal of Clinical and Experimental Neuropsychology

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- **Results:** Outline the important and relevant results of the analyses.
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## **Paper Three: Reflective Account**

Reflections on the research journey

## **ABSTRACT**

The final part of this thesis is a review and commentary on the process of undertaking the project starting with the selection of a topic through to writing up ready for submission. The researcher kept a journal throughout the project to document and record various experiences and supervisory discussions, and using Schon's (1983) model of reflection, these 'reflections *in action*' were used to develop 'reflections *on action*'. Difficulties encountered by the researcher are discussed and considered within the context of the current challenges faced by clinicians working in the NHS. The overall experience of completing this thesis was concluded to be a positive learning opportunity.

Abstract word count: 105

Paper 3 word count: 1,659

## Reflective Account

### **Introduction**

Schon's (1983) model of reflection states that there are two types of reflective practice. The first is termed 'reflection *in* action', and the second 'reflection *on* action'. Reflection in action involves experiencing reflection in the moment and making adjustments whilst practicing. Reflection on action is completed at a later point and involves processing something that has already happened and considering if anything would be done differently next time. This reflective account will aim to reflect *on* action, by making use of a research journal that was kept throughout the thesis journey and could be said to contain some *in* action reflections. I will now consider and discuss the process of undertaking this thesis and reflect upon some of the challenges that I encountered.

### **Selecting a research topic and developing ideas**

I was initially interested in a thesis topic that concerned neuropsychology as my undergraduate degree was dual honours in Psychology and Neuroscience. Up until the point of starting on clinical training I had not had the opportunity to apply the neuroscience side of my degree. Prior to starting clinical training, as an Assistant Psychologist working in forensic services, I had always had an interest in psychometric testing and had experience of administering a range of measures. In the first year the Assessing Psychological Processes module involved developing an understanding of neuroanatomy and psychological processes with regards to neuropsychological assessment. I took the opportunity to discuss research projects with visiting clinicians delivering teaching sessions, one of whom became the clinical research supervisor for the project. I explored the topic of

assessing malingering and symptom validity in traumatic brain injury (TBI), and more specifically in patients with a diagnosis of post concussion syndrome (PCS). I initially looked into validating an existing self-report measure of symptom severity, The Post Concussive Symptom Questionnaire (PCSQ; Lees-Haley, 1992). However, following an exploration of the literature a need was identified for a new measure to be developed that had included both genuine and pseudo symptoms of PCS.

### **Literature review**

When developing a research question for the literature review paper into the use of validity measures in mild TBI, I initially found that searches were generating thousands of research papers. I decided to narrow the research question to specifically investigate the use of symptom validity tests (SVTs) when assessing for PCS. I acknowledged that there are SVT measures that may have been validated in mTBI populations that could be applied to assessing validity in PCS, however, I decided to concentrate the review on papers that had focussed specifically on the use of SVTs in PCS. In the same way that a literature review may focus specifically on interventions in stroke as opposed to all non-traumatic acquired brain injury.

With no prior experience of writing a full literature review paper I was somewhat surprised by the amount of time and effort required to identify, consider and critically appraise relevant papers. This led to a deviation from my original research gantt chart, and on reflection, when planning future projects I will allocate more time to reviewing the existing literature.

## **Empirical paper**

### *The approval process*

Following gaining approval from the peer review panel at Staffordshire University, ethical approval was sought from an NHS Research Ethics Committee (NHS REC) through the submission of an Integrated Research Application System (IRAS) application. At the time of submission to the NHS REC, changes were being made to the process of gaining ethical approval. The changes mainly concerned the Health Research Authority (HRA) having more of a role in the application process, and were designed to speed up the process of applying for ethical approval by removing duplicate application routes through multiple research and development teams. However, when the IRAS application for this research project was first submitted the system was mid-change and a backlog of applications built up causing delays in getting ethical approval and commencing with the research. Data collection with non-clinical participants was able to be commenced after NHS REC approval was given on 08/09/16. In order to approach potential clinical participants however, HRA approval was required. Apologies were sent from the HRA as there were significant delays obtaining this approval; the approval letter was not received until the 05/12/16. As the original IRAS application had stated that local Research and Development (R&D) approval was required, this then had to be completed following receipt of the HRA approval letter. R&D approval for the identified research site that responded positively to my enquiries about supporting with recruitment of clinical participants was finally granted on 09/02/17. This left very little time to attempt to collect a clinical sample, which is discussed in more detail below.

### *Difficulties with recruitment*

The main challenge that was encountered in the completion of this thesis was recruiting a clinical sample. In order to avoid potential ethical dilemmas, the inclusion and exclusion criteria was agreed with the NHS REC whereby patients involved in litigation or receiving benefits as a result of their head injury were excluded from participating in the research. This significantly reduced the number of potential participants. A number of clinicians and services were contacted to support with recruitment to the research study. Of those who responded, just one service suggested that they may have been able to support recruitment of mTBI patients. Other clinicians stated a number of reasons as to why recruitment from their service was not possible which included service reorganisation, meaning mTBI patients were not generally picked up by the service. Time was another factor, whereby as more demands were placed on clinicians in NHS services, they were less able to provide support in research projects. One specialist Accident & Emergency Neuropsychology partnership service for individuals with mTBI was identified, however, my repeated attempts to get in touch with the Neuropsychology team there were unsuccessful. This may be reflective of a changing NHS. Services are pressured to see more patients with smaller teams, meaning that the more severe patients are prioritised, and the mild TBI patients fall through the rehab net. Clinicians also have less time to engage with research. A survey carried out by ComRes (Association of Medical Research Charities, 2013) with 392 GPs, hospital doctors and nurses in the NHS, identified similar barriers to taking part in research – including lack of time (62%), funding (30%), practical support (27%) and difficulties navigating regulation (24%). Despite universal

agreement that research in the NHS is important in developing and improving treatments for patients; financial pressures on time and a drive to cut waiting lists means that research has become less of a priority for clinicians. This may be problematic if the NHS is to compete with private providers to become an innovative research organisation focused on driving improvements in patient care.

During a supervision meeting to review the raw data, I had a discussion with my clinical research supervisor about the possibility of being less specific with the recruitment of clinical participants and opening up the criteria to moderate-severe TBI patients. There were a couple of issues with this however. Firstly this would have involved making changes to the research protocol and submitting changes to ethics, and re-contacting neuropsychology services to seek support with recruitment, which given the late stage of the research and the need to start writing up, may not have been achievable. Secondly, as identified in the appraisal of Tsandis et al. (2008) in part 1 of this thesis, it is possible that moderate-severe TBI patients have deficits in self-awareness, and so their participation as a clinical sample could be considered problematic as symptom reporting requires self-awareness as well as self-report.

If the project were to be run again, and the inclusion and exclusion criteria were altered to allow those seeking compensation and disability benefit to participate, recruitment may be an easier task. A lot of research that is carried out with mTBI patients and performance/symptom validity testing takes place in the United States, and a large percentage is with military populations and in private clinics. It could be argued that the ethical procedures for independent clinical

practices are not as stringent as in the NHS. Many research papers investigating symptom validity testing make use of archival data of groups of individuals involved in litigation. However, the extent to which participants have given consent to their responses being used for research purposes is unknown.

### **Closing reflections**

In summary, the process of developing and writing this thesis has been frustrating at times, and I frequently felt that I had very little control over the project (with regards to relying on ethical bodies, clinical services, and clinicians) yet I also held all of the responsibility. Looking back however, it is important to also recognise what was achieved in completing this thesis. I successfully recruited 60 participants, a number that seemed slightly daunting at the beginning given that meeting with each participant involved completing a battery of psychometric measures, plus time to score and interpret their responses. I found some exciting initial results for the new measure, and although its validation with a clinical sample is still required, it compared favourably to established measures currently used in clinical services.

To conclude, the completion of this thesis was experienced overall as a positive learning opportunity, despite some of the difficulties that were met along the journey to submission.

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