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The Relationship between Head Injury, Gender and Offending in Scottish Prisoners and a systematic review of the evidence for Third Wave Therapy Interventions for Traumatic Brain Injury

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Acknowledgements

Foreword

The original Major Research Project (MRP) could not proceed due to COVID-19 pandemic and ethics restrictions regarding participant research and administrative changes in services involved in the study. It was important for the research topic to be within the field of research of head injury in the criminal justice system. The brief report contains analysis of secondary data from previous studies supervised by Professor Tom McMillan. The research is in line with the National Prisoner Healthcare Network Report recommendations, considering head injury, offending and gender differences.

Chapter One: Systematic Review

The effectiveness of Third Wave Therapies in reducing psychological distress for survivors of Traumatic Brain Injury: A systematic review

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Abstract

Background

Traumatic Brain Injury (TBI) often causes significant psychological distress. Emerging research suggests that third wave psychological therapies (TWT) may be an effective transdiagnostic approach for ameliorating distress after TBI.

Aim

To examine the effectiveness of TWT for TBI and to investigate the quality of the evidence.

Method

Eight databases were systematically searched for TWT for TBI, including Acceptance and Commitment Therapy, Compassion Focused Therapy and Mindfulness-Based Cognitive Therapy. Thirteen papers were included. The Crowe Critical Appraisal Tool Version 1.4 (Crowe & Sheppard, 2011) was used to assess the quality of the articles. The systematic review is PRISMA compliant.

Results

The thirteen studies comprised five RCTs and eight pre-/post-intervention designs. Eleven papers reported significant improvements in psychological difficulties, including anxiety, depression, stress, emotional symptoms and self-criticism. Larger effect sizes were reported for ACT and CFT. The quality of the studies varied and there were several methodological weaknesses. Treatment improvements were maintained for CFT at three-month follow-up and one-year follow-up for Mindfulness based interventions. Treatment effects were not maintained for ACT at one-month follow-up.

Conclusions

Findings are promising for TWT as treatment for psychological difficulties, including depression, anxiety, stress, self-criticism and cognitive and emotional symptoms after TBI. However, further high quality research is required for recommending TWT due to poorly designed studies without a control and a lack of representativeness of TBI severity. Recommendations for future studies are discussed.

Keywords: *third wave modalities, traumatic brain injury, Acceptance and Commitment Therapy, Compassion Focused Therapy, Mindfulness Based Cognitive Therapy, systematic review.*

1. Introduction

Traumatic Brain Injury (TBI) is a worldwide public health concern (Dewan et al., 2018). In the United Kingdom, approximately 135,000 individuals suffer from a TBI every year (Department of Health, 2005). Psychological difficulties are common after TBI with many experiencing anxiety and depression (Gould et al., 2011; Osborn et al., 2016). Holistic neuro-rehabilitation is recommended for moderate-severe TBI and CBT or group mindfulness-based stress reduction for depression is recommended for mild-moderate TBI (SIGN, 2013; MATRIX, 2014). A recent review found CBT to be the preferred treatment for individuals with TBI experiencing behavioural and emotional difficulties (Gomez-de-Regil et al., 2019). Despite CBT being a recommended choice of treatment for TBI, there is some evidence for adverse outcomes in the treatment of PTSD (King, 2002). Third wave therapies (TWT) may be an alternative to traditional CBT as a treatment for survivors of TBI, as one treatment model does not suit everyone due to heterogeneity of difficulties resulting from TBI (Kangas & McDonald, 2011). TWT are an extension of CBT (Hayes, 2004), being a third development of psychotherapy with a focus on helping patients relate differently to psychological experiences, thoughts and beliefs, instead of merely modifying cognitions.

TWT's which have been used with a TBI population, include, Acceptance and Commitment Therapy (Hayes et al., 1999; Hayes, Strosahl & Wilson, 2012), Compassion Focused Therapy (Gilbert, 2009), and Mindfulness Based Cognitive Therapy (Kabat-Zinn, 1990; Segal, Williams & Teasdale, 2013). To date, no research has considered Dialectical Behaviour Therapy for a TBI population. Cochrane reviews also demonstrate that TWT is more effective than treatment as usual and as effective as other psychological therapies (Churchill et al., 2013).

This review focuses on the three TWT that have been used with a TBI population. Firstly, Acceptance and Commitment Therapy (Hayes et al., 2006), may be beneficial for supporting individuals recovering from mild to moderate TBI (Kangas & McDonald, 2011) who are experiencing psychological distress and complex adjustment related processes. Secondly, Compassion Focused Therapy (CFT) aims to develop compassionate attributes and skills, which influence affect regulation (Gilbert, 2009). Individuals with TBI are often self-critical and experience internal and external shame, which has been linked to distress (Freeman, Adams & Ashworth, 2015). Thirdly, there have been developments over the last 15 years on Mindfulness-Based Cognitive Therapy (MBCT) (Pierson & Hayes, 2007). There has been growing evidence of MBCT for improving the quality of life and wellbeing after TBI (Azulay, Smart, Mott & Cicerone, 2013; Bedard et al., 2003; 2005). The efficacy of TWT has been demonstrated for a range of health outcomes. To date, no systematic review has considered the effectiveness of third wave therapies for TBI.

1.5 Research Aim and Questions

The aim is to systematically review the effectiveness of TWT for individuals with TBI. The review focuses on the following questions:

1. Do TWT improve outcomes after TBI?

2. Are there model-specific outcomes of TWT which alleviate distress?

3. Are improvements following TWT maintained at follow-up?

4. Have TWT interventions been adapted for TBI?

2. Method

2.1. *Search Strategy*

Search and selection was carried out using the following electronic databases: Ebsco PsychINFO, Ebsco CINAHL, Ovid EMBASE, Ovid Medline, PubMed, Web of Science, Knowledge Network (NHS Education for Scotland) and Wiley Cochrane Library. This systematic review was conducted in accordance with a review protocol (Appendix 1.1) and adhered to the Preferred Reporting Items for Systematic Reviews (PRISMA; Moher, Liberati, Tetzlaff, Altman & PRISMA Group, 2009).

2.1.1. *Key Search Terms*

1. "Traumatic Brain Injury" OR "Brain Injury" OR "Head Injury" OR "TBI" OR "Head Injur*"

AND

2. "Third Wave" OR "Acceptance and Commitment Therapy" OR "ACT" OR "Acceptance-Based" OR "Accept commit* therap*" OR "Acceptance" OR "mindfulness" OR "compassion" OR "CFT" OR "Compassion focussed therapy" OR 'self-compassion' OR "compassionate mind" OR "DBT" OR "Dialectical Behaviour Therapy".

Search phrases were amalgamated using a Boolean operator "AND". In addition, truncations (*) were used to increase the accuracy of the searches. The database filter 'English language' was applied.

2.2. *Inclusion/Exclusion Criteria*

Inclusion criteria:

•Published in English

•Population: participants with TBI (aged 18 years or older)

•TBI participants who have received a third wave therapy intervention, whether individually or in a group, via single or multiple sessions (e.g. ACT, CFT, Mindfulness).

•Study design: Randomised Controlled Trial (RCT), clinical trial, pre-post design and follow-up.

•Studies with or without a control

•Comparators: standard clinical care and control group

•*Exclusion criteria:*

•Qualitative studies.

•Unpublished dissertations, book chapters, review articles, responses or letters replying to articles, conference abstracts.

•Studies where TWT was not the primary intervention.

2.3 Screening and selection

EndNote bibliographic software was used to store articles once searches were complete. All duplicates were removed.

2.4 Study selection and Data Extraction

A data extraction form was adapted from NICE guidance (2012)(see Appendix 1.2).

2.5 Study selection method

Initial searches yielded 1,570 results. After removing duplicates and screening titles and abstracts for relevance, the full text of 122 papers were read for assessment of eligibility. Fourteen papers remained, of which one RCT was excluded due to being an unpublished abstract (Sander et al., 2020). The reference lists of the selected studies and journals in which they were published were hand searched to ensure that relevant papers were not excluded (see Figure 1).

Identification

Records identified through database searching
(n =1,570)
PsychINFO (n=694)
CINAHL (n=483)
EMBASE (n=148)
MEDLINE (n=74)
PubMed (n=48)
Web of Science (n= 57)
Knowledge Network (n=43)
Cochrane Library (n= 23)

Additional records identified through other sources
(n = 1)

Screening

Records after duplicates removed
(n = 987)

Records screened by title
(n =987)

Records excluded
(n = 865)

Eligibility

Full-text articles assessed for eligibility
(n = 122)

Full-text articles excluded, with reasons
(n =109)
Non-TBI population
(n=79)
Paediatric acquired brain injury
(n=8)
No Intervention/Not Third Wave (n=16)
Case studies (n=2)
Qualitative review (3)
Systematic review (1)

Included

Studies included in quantitative synthesis
(n = 13)

Figure 1: PRISMA flow chart for Systematic Review

2.6 Quality Assessment

Studies were quality rated using the Crowe Critical Appraisal Tool (CCAT) (Crowe, 2013) (Appendix 1.3). The CCAT has established construct validity (Crowe & Sheppard, 2011), with reliability coefficients demonstrating a good level of agreement (consistency=0.83, absolute agreement=0.74) (Crowe, Sheppard & Campbell, 2012). The CCAT assesses study quality in line with the requirements of PRISMA guidance. Each of the 8 criteria are scored out of 5 and summed, giving a maximum total score of 40 (Appendix 1.4). The author and a second-rater scored a study not included in the current review with the CCAT in order to ensure accurate scoring. A random sample of six papers were rated by the author and an independent reviewer. Agreement between assessors was 87% and disagreements were resolved through discussion. Results using the CCAT are presented in Table 1. A quality rating of 0-50% was considered low; 50-74% moderate and over 75% is high quality. Although the CAAT does not yield qualitative categories, quality assessment was guided by other quality assessment tools (e.g. The Quality Assessment Tool, QATSDD; Sirriyeh et al., 2012).

2.7 Data Extraction

A data extraction tool was used (Appendix 1.2) to extract information for each heading in Table 2. The tool was designed by the author for the purpose of the review.

3. Results

3.1 Overview

Six of the thirteen studies were conducted in Canada, three in the UK, two in the USA, one in Australia and one in Sweden. The studies were published between 2002 and 2019 and comprised 652 participants. Methodological quality was highly variable, from 45% (Bedard et al., 2012) to 88% (Whiting et al., 2019) (see Table 1). Most of the studies had a moderate quality, with only one study having a score over 80%. There is no qualitative descriptions of CCAT scores available, however, higher percentages are associated with higher quality.

3.2 Design

There were five RCTs and eight employed a pre-/post-intervention design. The statistical analyses conducted across the studies appeared to be appropriate. Only three studies (Azulay et al., 2013; Bomyea et al., 2014; Whiting et al., 2019) used intent to treat analyses (ITT), to address any problems with missing data, minimising Type 1 errors and reducing bias.

3.3 Sample

The sample sizes ranged from 7 (Bedard et al., 2005) to 160 (Bomyea et al., 2017). Only five conducted a priori power analysis. The age of participants ranged from 18 to 65 years.

3.4 Intervention

Of the final studies, two used Acceptance and Commitment Therapy, two used Compassion Focused Therapy studies and nine were Mindfulness Based Stress Reduction or Mindfulness Based Cognitive Therapy studies. Nine studies delivered interventions in a group setting (70%), three on an individual basis and one in both individual and group format.

Table 1. Crowe Critical Appraisal Tool (CCAT) Quality Assessment Scores

Article	Preliminaries	Introduction	Design	Sampling	Data Collection	Ethical Matters	Results	Discussion	Total	Total %
Bomyea et al., 2017	5	5	4	3	2	2	4	4	29	73
Whiting et al., 2019	5	5	5	4	5	3	4	4	35	88
Ashworth et al., 2015	4	4	3	4	3	3	3	4	28	70
Campbell et al., 2019	4	4	4	4	3	4	4	4	31	78
Azulay et al., 2013	5	4	3	3	3	3	4	3	28	70
Bay & Chan 2019	4	4	3	4	3	3	3	3	27	68
Bedard et al., 2003	2	3	2	2	2	2	3	3	19	48
Bedard et al., 2005	4	4	3	4	2	2	3	2	24	60
Bedard et al., 2012	2	2	1	2	2	3	3	3	18	45
Bedard et al., 2014	4	4	3	3	3	2	3	4	26	65
Johansson et al., 2012	5	4	3	3	2	2	3	3	25	63
McMillan et al., 2002	5	5	4	3	4	2	4	3	30	75
Ozen et al., 2016	4	5	3	4	2	3	3	5	29	73

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***Table 2*. Characteristics of the reviewed studies**

Study	Title, Author/s, Year & Country	Study Aim & Sample Size (N)	Study Design	Third Wave Intervention, Treatment Components & Duration	Outcome Measures *	Statistical Analyses	Results	Key Findings Methodological Weaknesses
ACT								
1.	TBI and Treatment Response in a Randomized Trial of Acceptance and Commitment Therapy Bomyea, et al 2017 USA	Psychotherapy response in 129 veterans with and without mild TBI Participants with/without mild TBI met criteria for 1 anxiety or depressive disorder, including PTSD (DSM-IV).	Secondary Analysis 2-group RCT	ACT versus PCT 12 individual treatment sessions ACT treatment manual for use in a trans-diagnostic veteran population.	BSI-18 I-TBI MCA SF- 12 SFMCS-12 SFPCS-12 SDS RPQ	t-tests, χ^2 ITT	Treatment response in those with/without TBI did not differ for BSI, physical health-related SF-12 or SDS. Those with TBI improved less on mental health SF-12 mental health subscale. Scores improved over time on BSI-18 (p=.001, d=0.73), SDS (p<.01, d=0.60 & SFMCS-12 (p<.01, d=0.43). No statistically significant improvement on SFPCS-12. TBI group showed more improvement over time (p=.03, dTBI+=0.36, dTBI =-0.84). No improvement on RPQ.	Reduction in emotional symptoms with moderate effect size. Most outcomes improved post intervention. Not generalisable to severe TBI

Study	Title, Author/s, Year & Country	Study Aim & Sample Size (N)	Study Design	Third Wave Intervention, Treatment Components & Duration	Outcome Measures	Statistical Analyses	Results	Key Findings Methodological Weaknesses
2.	Can acceptance and commitment therapy facilitate psychological adjustment after a severe traumatic brain injury? A pilot randomised controlled trial Whiting et al 2019 Australia	ACT-Adjust for facilitating psychological adjustment and reducing psychological distress following severe TBI in 19 civilians with severe TBI (PTA>7 days).	Phase II Pilot RCT ACT adjust (N=10) or active control (befriending therapy (N=9) 2x2 repeated measures design	ACT-Adjust 7 weekly group sessions; focused on the ACT model.	AAQ-ABI DASS HADS MOT-Q PANAS RBANS SF-12 SLP SPRS-2	Retention of treatment gains one month – repeated measures ANOVA. ITT	ACT-adjust group had a greater reduction in DASS-depression, (F1,17=5.35, p=.03. Medium to Large ES partial, n2=.24 and for DASS stress (F1,17 =5.69, P=.03), large ES partial n2=.25. No significant differences for DASS depression (F1,17 =2.55, p=.13) and DASS stress (F1,17 = 2.37, p=.12) one month follow up.	Clinically significant reduction in stress post treatment. No support for the main hypothesis that ACT-Adjust was not more effective than Befriending in increasing psychological flexibility. Small sample size. No formal power analysis undertaken Short follow-up period.

Study	Title, Author/s, Year & Country	Study Aim & Sample Size (N)	Study Design	Third Wave Intervention, Treatment Components & Duration	Outcome Measures	Statistical Analyses	Results	Key Findings Methodological Weaknesses
CFT								
3.	An exploration of compassion focused therapy following acquired brain injury. Ashworth et al 2015 UK	CFT for 12 ABI patients (including N=7 TBI) with emotional difficulties including anxiety and depression, receiving neuropsychological rehabilitation.	Mixed Methods design. Pre-post design. 3m Follow-up analysis (*N*=9)	CFT group-or individual based during 18-week programme.	HADS FSCRS	Wilcoxon signed rank test.	Significant reduction in hated self and inadequate self pre- to post-intervention, and pre- to 3-month follow-up. Large effect size with a reduction in anxiety (r=.52), depression (r=.58, d=1.43) and self criticism (inadequate r=.67, d= 1.81; hated r=.60, d=1.5). Also, an increase in reassured self (r=-.56, d=-1.38).	CFT associated with significant reductions in self-criticism, anxiety and depression and an increase in ability to reassure the self. Further research required to determine specific intervention components which reduced difficulties. The study is limited due to being a naturalistic evaluation. Small sample size. Data may be prone to Type 1 and Type II errors. Baseline measures on the inadequate and hated subscale were not as high as other MH populations. A rater-blind, RCT is required.

Study	Title, Author/s, Year & Country	Study Aim & Sample Size (N)	Study Design	Third Wave Intervention, Treatment Components & Duration	Outcome Measures	Statistical Analyses	Results	Key Findings Methodological Weaknesses
4.	Brief compassion focused imagery for treatment of severe head injury Campbell et al 2019 UK	CFI intervention compared to individuals exposed to relaxation imagery. *N*=24 participants aged 18-64 with severe TBI (post traumatic amnesia >1 day) at least three months before. NHS community participants from TBI services	Pre-post design	CFI intervention	FOC MIS PANAS STAI EQ SCS RS SCS	t-test or Wilcoxon Signed-Rank tests. ANCOVA	Motivation for therapy increased pre-post preparatory video (T=149.0, z=3.44, p=0,001, r=.50). Changes on the FOC, STAI & PANAS were non-significant. ANOVA pre-to post- intervention changes were non significant. CFI and RI data was combined. RS scores increased (T=28.50, p<0.01, r=.41) Anxiety decreased on the STAI (T=40, p<0.05, r=.29).	Brief CFI did not produce a reliable change in people with severe HI. Small sample size Measures may not have been sufficiently sensitive to detect changes in a single session. Unclear if participants received CFI as a full treatment.

Study	Title, Author/s, Year & Country	Study Aim & Sample Size (N)	Study Design	Third Wave Intervention, Treatment Components & Duration	Outcome Measures	Statistical Analyses	Results	Key Findings Methodological Weaknesses
Mindfulness								
5.	A pilot study examining the effects of mindfulness-based stress reduction on symptoms of chronic mild traumatic brain injury/post-concussive syndrome Azulay et al 2013 Canada	MBSR tailored for 22 individuals with mild TBI and 3 months post-injury. Convenience sample *N*=11 men, *N*=11 women) ranging from 18-62 years of age. 80% of participants had post-injury of 12+ months.	Pre-post design ITT analysis	10-week group, 2 hour sessions, modelled after MBSR program of Kabat-Zinn, 5 groups run over 2 years.	CPT-A CVLT-II MAAS NSI PASAT PQOL PSES SPSI	t-tests	Improvements in perceived self-efficacy for management of cognitive (d=0.55) and emotional symptoms (d=0.56). Small to moderate ES on the NSI (d=0.32). Reduction in cognitive (d=0.36) and emotional symptoms (d=0.38). Small ES on CPT-A (d= 0.31) and PASAT (d=0.32). Clinically meaningful improvements on measure of quality of life (d=.43) and perceived self-efficacy (d=.50). No significant effect on verbal learning and memory.	MBSR can be adapted for participants with mTBI. All participants were receiving concurrent rehabilitation. Unable to isolate effects of MBSR. No adequate control group or randomisation. Small sample size. No specific measures of mental health and emotional regulation.

Study	Title, Author/s, Year & Country	Study Aim & Sample Size (N)	Study Design	Third Wave Intervention, Treatment Components & Duration	Outcome Measures	Statistical Analyses	Results	Key Findings Methodological Weaknesses
6.	Mindfulness-Based Versus Health Promotion Group Therapy After Traumatic Brain Injury Bay & Chan 2019 USA	PFM-GT versus health promotion active control group therapy (AC-GT) for 33 individuals randomised to PFM-GT (N=14) or AC-GT training (N=11). Participants aged 18 to 85 hospitalised for TBI. Not severe TBI.	Pre-post test design Repeated measures	8 week mindfulness-based group therapy PFM-GT compared to AC-GT. Six groups	CES-D PSS-10 PRQ	t-tests Regression analyses	Significant reductions in TBI depressive symptoms on the PFM-GT group, compared to AC-GT ($t(13)=3.27$, $p=0.006$, $d=0.37$). Significant mean reductions in chronic stress on the PFM-GT, compared to AC-GT ($t(13)=3.01$, $p=0.01$, $d=0.35$) Significant mean reduction in TBI symptom severity on the RPQ for the PFM-GT group in comparison to AC-GT ($t(13)=4.20$, $p=0.001$, $d=0.16$). ES in the small to moderate range.	Small sample size Data was self-reported and is subject to recall bias. No a priori sample size calculation

Study	Title, Author/s, Year & Country	Study Aim & Sample Size (N)	Study Design	Third Wave Intervention, Treatment Components & Duration	Outcome Measures	Statistical Analyses	Results	Key Findings Methodological Weaknesses
7.	Pilot evaluation of a mindfulness-based intervention to improve quality of life among individuals who sustained traumatic brain injuries Bedard et al 2003 Canada	MBSR for improving quality of life for 19 individuals with mild-moderate TBI. Convenience sample one year post-injury. Aged 18-65. *N*=10 completed treatment.	Pre-post design with drop-outs as controls.	12 week group intervention, based on Kabat-Zinn's MBSR & Kolb's experiential learning cycle.	BDI-II CGLC CIQ GSI IHLC PHLC PSDI PSS SCL-90 R SF-36	t-tests Two-way ANOVA	The SF-36 MH score of the intervention group improved by 15.40 at follow-up compared to the control group. Depression symptoms were almost halved in the intervention group. ES=0.312, in the medium-large range. GSI remained unchanged after the intervention. PSDI approached statistical significance $(F_{(1,11)}=4.63, P = 0.054)$ with a moderate to large ES. No changes on the CIQ post intervention.	Small sample size due to recruitment and retention difficulties. No follow-up. Low statistical power Medication use and number of years post-injury not taken into account. The sample was 3-10 years post-injury. 50% started the programme and less completed it.

Study	Title, Author/s, Year & Country	Study Aim & Sample Size (N)	Study Design	Third Wave Intervention, Treatment Components & Duration	Outcome Measures	Statistical Analyses	Results	Key Findings Methodological Weaknesses
8.	A Mindfulness-Based Intervention to Improve Quality of Life Among Individuals Who Sustained Traumatic Brain Injuries: One-Year Follow-Up Bedard, et al 2005 Canada	7 out 10 completed follow-up interview, 1 year post intervention. 5 women and 2 men. Aged 18-65. Brain injury suffered more than one year prior to study initiation	Pre-post Follow-up study	12 Weekly groups. Intervention based on Kabat-Zinn's MBSR and Kolb's experiential learning cycle.	BDI CIQ HLC SCL90 SF-36 VAS	Repeated measures (ANOVA) Fisher's (LSD) t-test with Bonferroni correction.	Improvements post intervention maintained at follow-up. SF-36 mental health component remained higher than baseline and comparable to normative data. The cognitive affective scale of the BDI-II indicated a continued reduction in depression. Continued improvement of energy level.	Small sample size. Lack of control group. Passage of time alone may have explained improvement True prospective design not utilised.

Study	Title, Author/s, Year & Country	Study Aim & Sample Size (N)	Study Design	Third Wave Intervention, Treatment Components & Duration	Outcome Measures	Statistical Analyses	Results	Key Findings Methodological Weaknesses
9.	Mindfulness-based cognitive therapy: benefits in reducing depression following traumatic brain injury Bedard et al. 2012 Canada	MBCT treatment for psychological distress and depression in TBI population. *N*=20 completed the study. TBI suffered more than 1 year earlier & evidence of clinical depression (DSM-IV) Average age 47.1. Ages ranged from 20-77.	Pre-post design	8 week MBCT intervention. 90-minute session weekly. Combination of Kabat-Zinn manualised MBSR program and Segal and colleagues manual for MBCT.	BDI-II HADS PCRS-R PHQ-9 SCL-90-R SF-36 MPAI-4	t-test and McNemar χ^2	MBCT significantly reduced depression symptoms on all scales for BDI-II, PHQ-9 and HADS. BDI-II obtained values of 0.71, 0.49, and 0.74 for total, cognitive and somatic totals. Medium ES of 0.64 for HADS depression subscale and 0.96 for PHQ-9. Medium ES for all (0.39), pain related (0.41), anxiety-related (0.23) medications and a small ES for depression related medications (0.12). Reduced pain intensity and increased energy levels.	Small sample size No control group. No follow-up

Study	Title, Author/s, Year & Country	Study Aim & Sample Size (N)	Study Design	Third Wave Intervention, Treatment Components & Duration	Outcome Measures	Statistical Analyses	Results	Key Findings Methodological Weaknesses
10.	Mindfulness-based cognitive therapy reduces depression in people with a traumatic brain injury: Results from a randomized controlled trial Bedard et al. 2014 Canada	MBCT for depression in 100 individuals with TBI, randomised to treatment (*N*=52) or control arms (N=48). Randomisation (1:1) at 3 sites. For analysis, *N*=38 in treatment arm, *N*=38 in control arm.	RCT	10- week MBCT or wait-list control arm. MBCT based on Segal and colleagues manual. The intervention was adapted for TBI population.	BDI-II PHLMS PHQ-9 SCL-90 TMS	Repeated ANOVA ANCOVA	Reduction in BDI-II scores greater for intervention group (6.63, n=38), compared to control group (2.13, n=38, p=.029). Medium ES for BDI-II (d=0.56). No improvement on the PHQ-9 and SCL-90R Depression scales. Improvement in BDI-II maintained at 3-month follow-up. Small ES for PHLMS-Acceptance and TMS-subscales. 84% and 73% of participants randomised to treatment completed follow-up. Reductions maintained at follow-up.	MBCT reduced symptoms of depression. Increase in mindfulness not demonstrated. High drop out rate. Unclear how many sessions attended. Participants were not blind to intervention, however, research assistants were blind to group. Control group was a wait list control.

Study	Title, Author/s, Year & Country	Study Aim & Sample Size (N)	Study Design	Third Wave Intervention, Treatment Components & Duration	Outcome Measures	Statistical Analyses	Results	Key Findings Methodological Weaknesses
11.	Mindfulness-based stress reduction (MBSR) improves long-term mental fatigue after stroke or traumatic brain injury Johansson et al. 2012 Sweden	MBSR for 29 patients with mental fatigue after stroke or TBI. *N*=15 randomised to MBSR and N=14 controls – no active treatment. Aged 30-65.	RCT	8 weekly 2.5 hour groups based on Kabat-Zinn's MBSR program	CPRS FAS MSF TMT	ANCOVA t-tests Mann Whitney U-test Pearson's correlation	Significant difference between the two groups after 8 weeks (F=8.47, p=0.008). Decline in MFS (p=.004) for MBSR. Significant improvement for MBSR depression (p=0.006) for MBSR group 1 and group 2 (p=0.002) and anxiety (p=0.004) for group 1 and group 2 (p=0.02). MBSR group 1 performed TMT B faster than controls (F=7.39, p=0.013) and for TMT C (F=4.84, p-0.039). Improvement in mental fatigue and information processing speed for MBSR (r=-0.48, p=0.023).	MBSR promising for individuals suffering from fatigue after stroke or TBI. Small sample size Relatively short intervention No ES detailed. Insufficient information to calculate ES.

Study	Title, Author/s, Year & Country	Study Aim & Sample Size (N)	Study Design	Third Wave Intervention, Treatment Components & Duration	Outcome Measures	Statistical Analyses	Results	Key Findings Methodological Weaknesses
12.	Brief Mindfulness training for attentional problems after traumatic brain injury: A randomised control treatment trial McMillan et al. 2002 UK	Attentional Control Training (ACT) compared to no-treatment group. N=145 TBI patients recruited from Neurosurgical unit. Aged 16-65. 3-12 months post-injury. ACT (N=44) PE (N=38) Control (N=48)	RCT Pre, post and 12-month follow-up Random allocation to ACT, PE or Control	ACT group - five sessions over 4 weeks using ACT audiotape obtained from Dr Kabat-Zinn PE group (therapist contact and autiotape-based training based on physical exercise). Control group received no therapist contact.	AMIPB CFQ GHQ HADS PASAT RPCSQ SMQ TMT	ANOVA	No statistically significant differences pre-post treatment or at 6 or 12-month follow-up. Pre-treatment groups had higher scores on the CFQ compared to the control group. At 12-month follow-up, ACT group and PE groups had a greater reduction in self-reported cognitive failures compared to control group.	The sample included a range of TBI severity. Therapist contact was limited. More intensive intervention may be required.

Study	Title, Author/s, Year & Country	Study Aim & Sample Size (N)	Study Design	Third Wave Intervention, Treatment Components & Duration	Outcome Measures	Statistical Analyses	Results	Key Findings Methodological Weaknesses
13.	Mindfulness Interventions improve Depression Symptoms After Traumatic Brain Injury: Are Individual Changes Clinically Significant? Ozen et al. 2016 Canada	MBI for 90 participants pre-post treatment Study 1. Pilot (*N*=10), Study 2. Pilot (*N*=20), Study 3, RCT (*N*=60)	Pre-post design	Study 1. 12-week Mindfulness group based on Kabat-Zinn MBSR and Kolb's experiential learning cycle. Study 2&3 8-week and 10-week interventions combined MBSR and MBCT.	BDI-II	Three criteria to measure clinical significance of BDI-II DATA. Reliable Change (RC) scores.	45/90 BDI-II scores clinically improved (50%). In study 3, more participants in the treatment group (20/38) had improved scores compared to controls (13/38).	Half of participants had pre to post treatment BDI-II scores that met the standard for clinically important difference The MBIs were not identical across the three studies. The studies included had different aims. Depression symptom change was based on the BDI-II and no other outcome measure.

Key to abbreviations in Appendix 1.5

1. *Are TWT effective in improving outcomes after TBI?*

Eleven of the thirteen TWT studies [1,2,3,5,6,7,8,9,10,11,13] reported significant outcome improvements, supporting the effectiveness of TWT for a range of mental health difficulties following TBI. Effect sizes (ES) were reported in nine studies [1,2,3,4,5,6,7,9,10], with moderate-large ES's for both ACT [1,2], and one CFT study[3] and small-moderate ES's for MBSR [5,6,7,9,10]. Small sample sizes may have contributed to the smaller ES's. There was insufficient information to calculate ES in three studies [11,12,13]. The lack of a control group in all pre-post designs, makes it difficult to conclude whether symptom improvements were due to the intervention. The study quality varied, with three of high quality (75%+) [2,4,12,], eight of moderate quality (50%-74%) [1,3,5,6,8,10,11,13] and two of poor quality (below 50%) [7,9.] Two studies on CFI and Mindfulness training reported no change [4&12]. Bomyea et al., 2017 randomised trial of ACT reported modest improvements on the BSI (d=.74), SDS (d=.74), and SFMCS (d=.43). However, there was less improvement on the mental health SF-12 subscale and there was no significant improvement on the RPQ-13. However, the study is not generalisable to severe TBI. Whiting et al., 2019 pilot RCT found a significant reduction in anxiety and depression following ACT with a medium to large effect size for depression ($\eta2$=.25) and a large effect for DASS stress scores ($\eta2$=.25). For the ACT studies[1,2], there was inadequate power with no formal power analysis.

For CFT, Ashworth et al., 2015 found significant pre-post intervention improvements in anxiety (r =.52), depression (r=.58, d=1.43), reassure-self (r=.56,d=-1.38) and self-criticism (inadequate r =.67, d=1.81; hated r =.60, d=1.5), with large ES. However, generalisability was limited as the baseline scores were lower than in the control group. Campbell et al., 2019 found that CFI did not improve empathy, self-

compassion, relaxation or anxiety after severe HI; the sample size was modest and it is unclear whether the measures were sufficiently sensitive to detect change. As a limitation, participants had severe HI and it is not clear whether CFI would be suitable for a range of HI severity.

Azulay et al., 2013 reported significant improvements for quality of life (d=.43) and perceived quality of life (d=.50) after MBSR with a small-moderate ES on the Neurobehavioural Symptom Inventory (d=.32), a reduction in cognitive (d=.36) and emotional symptoms (d=.38). There were small but significant effects for working memory and attention. The study only included mild TBI, limiting generalisability. Significant reductions in depressive symptoms (d=.37) and chronic stress were found post MBSR Group Therapy (d=.35) for mild to moderate TBI (Bay et al., 2019). As a limitation, the study is unable to generalise because participants were from a university setting. Bedard et al., 2003; 2012) reported a medium-large ES for improvement in BDI depression (d=.312) and large ES for PHQ-9 (d=.64) after MBCT in mild-moderate TBI participants. There was no improvement in anxiety, pain or level of functioning. They used a convenience sample, limiting generalisability of findings. In a later study, a medium ES was found for improvement on the BDI-II after MBCT (d=.56) and no effect on the PHQ-9 and SCL-90R (Bedard et al., 2014). The results are not generalisable due to participants self-selecting. Significant improvements were found for depression and anxiety and mental fatigue and information processing after MBSR (Johansson et al., 2012). However, the sample size was small and participants had stroke and TBI. One RCT found no improvement in cognitive function, mood or symptoms after a brief exposure to mindfulness training (McMillan et al., 2002). The study included participants with a

30

range of TBI severity. Ozen et al., 2016 found a reduction in depression. However, there was no defining information regarding participants. Study findings of effectiveness are summarised in Table 2.

2. *Are there model-specific outcomes of TWT's which alleviate distress?*

Overall, it is difficult to interpret results due to a lack of controlled designs, as change may be attributable to factors outside of the intervention. The designs of the studies included did not ascertain if specific treatment components contributed to the effectiveness. Ashworth, 2015 found improvements in self-compassion/self-criticism. However, concepts specific to CFT, such as shame/self-criticism, were not explored. Whiting et al., 2019 considered model-specific outcomes, such as psychological flexibility, increased participation in meaningful activities (committed action) and decreased levels of psychological distress. Whiting et al., 2019 found a large ES for improvements in depression and stress. Despite improvements in psychological flexibility, no specific component of ACT was found to be more effective than the control group. Azulay et al., 2013 found that perceived self-efficacy resulted in improvements for cognitive and emotional difficulties. Overall, the studies lacked investigation of successful treatment components.

3. *Are improvements following Third Wave Therapies maintained at follow-up?*

Five studies considered whether treatment gains were retained post-intervention (Ashworth et al., 2015; Bedard et al., 2005; Bedard et al., 2014; McMillan et al., 2002; Whiting et al., 2019) and overall improvements appeared to be maintained for CFT and Mindfulness-based interventions. There was no evidence of treatment effects being maintained for ACT. Whiting et al. (2019) found ACT-Adjust interaction effect

at post intervention was not maintained after a brief one-month post-intervention. The researcher postulated there may have been a delayed benefit, as in some CBT studies (Hsieh et al., 2012). CFT intervention gains were maintained at three-month follow-up (Ashworth et al., 2015) and improvements were maintained at one-year follow-up after a Mindfulness-Based Intervention (Bedard et al., 2005) with the mental health component of the SF-36 remaining comparable to normative data. In addition, the cognitive affective scale of the BDI-II demonstrated a reduction in depression symptoms and improved self-report of energy level. Statistical significance was achieved; however, the sample size was small (n=7) and three participants could not be contacted. The researchers emphasised that results should be interpreted cautiously due to the lack of control group and the possibility that maturation could explain the findings (Bedard et al., 2005). Improvements on the BDI-II were maintained for MBCT at three-month follow-up (Bedard et al., 2014). McMillan et al., 2002 found no significant differences at pre, post, six or twelve-month follow-up. There was a greater reduction in self-reported cognitive failures at 12-month follow-up, however, due to no other differences being reported, the researchers indicated these could be chance findings.

4. Have TWT interventions made adaptations for a TBI population?

Whiting et al., 2019 accommodated potential cognitive impairment, repeating information and utilising a variety of formats (verbal and visual). Bedard et al., 2012 adapted the MBCT intervention to the needs of a TBI population, by shortening meditation sessions and incorporating memory aids and repeating concepts. Bedard et al., 2014 also adapted MBCT for a TBI population, taking into account difficulties with attention, concentration, memory and fatigue and the intervention duration was

increased. Azulay et al. (2013) MBSR intervention was modelled on MBSR designed by Kabat-Zinn, with modifications for cognitive difficulties that the population may face. The treatment sessions were extended; however, the intervention components were not sufficiently detailed. Ozen et al., 2016 adapted MBSR to address potential difficulties associated with TBI, including problems with attention, concentration, fatigue and memory. Sessions were reduced in length from 2-2.5 hours to 1.5 hours and homework was shortened. In addition, memory aids, simplified language, repetition and visual aids were utilised to help reinforce concepts. Attrition and drop out rates were not clearly detailed in the majority of the studies. In one study, 28% did not complete the study (Bedard et al., 2014). Although reasons were provided, this is a high drop out rate and questions whether the interventions require further adaptations for a TBI population. No studies detailed evidence to the adaptations made.

Discussion

TWT Interventions demonstrated improvements in psychological difficulties such as depression, anxiety, stress and emotional and cognitive functions after TBI. Treatment gains were maintained for CFT and Mindfulness but not for ACT. There are relatively few published studies on TWT and TBI and this systematic review indicates weaknesses in study methodology. There has been more research into the effectiveness of mindfulness, however, study quality varied with small ES's. Four of the mindfulness studies were published by the same author[7,8,9,10,] which may introduce bias. Risk of bias was not assessed. Two ACT studies found improvements, but these dissipated over time in Whiting et al., 2019 study, which had the highest quality. Only one CFT study found significant improvements that were maintained at follow up.

Most studies reported improvements in mental health. However, there were significant methodological weaknesses, including a lack of robust randomised designs with active controls and samples were predominantly participants with mild TBI; therefore it is unclear whether findings generalise to severe TBI. There was a relatively small sample size in some of the studies, with high variability in effect size estimates ($d=0.12$[9]-$d=1.81$[3]). Treatment gains were maintained for 3-12 months in three studies (Ashworth et al., 2014; Bedard et al., 2005; Bedard et al., 2014). However, these studies were of poor-moderate quality with significant methodological weaknesses. There were five RCT's, with only three utilising an active control (Bay et al., 2019; McMillan et al., 2002; Whiting et al., 2019). However, randomisation did not occur as planned in Bay et al., 2019 study. The RCT's considered potential for bias by including random sequence allocation to intervention or control conditions, blinding of assessors and ITT analysis methods to account for missing data and for repeated measures of outcomes. Attrition and drop out rates were not clearly detailed in the majority of the studies, and were high in one (Bedard et al., 2014). Without detailed fidelity checks, it is difficult to determine if interventions were delivered as prescribed. Another limitation is sampling and representation of the TBI population. The majority of the participants had experienced mild-moderate HI, with only two studies, including severe HI. One study self-selected participants and one study included a range of severities. Overall, the evidence base for TWT is inconclusive and more high-quality research is required to inform clinical practice.

Limitations

One limitation is that the review restricted inclusion to studies written in English. The CCAT (Crowe & Sheppard, 2011) was used to assess the quality of research and a

limitation of a generic tool is that it may not be sufficiently sensitive to the specific research question and the CCAT does not assess risk of bias. A design-specific tool may provide a more rigorous framework for quality appraisal. The study had assistance of a second reviewer in the process of evaluating the quality of the studies included. It is hoped this improved inter-rater reliability of this review.

Conclusion

This is the first systematic review of the potential benefit of TWT for TBI. Intervention effectiveness seemed promising for ACT, CFT and Mindfulness Interventions, demonstrating improvements in psychological difficulties such as depression, anxiety, stress and emotional and cognitive functions after TBI. Treatment gains were maintained for CFT and Mindfulness, but not ACT. However, the majority of studies were uncontrolled designs of moderate quality with methodological weaknesses. The RCT with the highest quality rating found treatment effects were not maintained over time. Future studies with rigorous study designs, including randomised clinical trials with larger sample sizes are required. Due to the limitations detailed above, further research is warranted.

Recommendations for Future Research

Treatments for individuals with TBI remain under-researched, despite high rates of psychological distress. Further large-scale research on TWT is required. Utilising active controls would allow more reliable conclusions to be made about the effectiveness of interventions. It is important that study quality is enhanced and it may be beneficial to compare TWT with CBT outcomes. Further research on model-specific outcomes and mechanisms of change is required.

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Chapter Two:

Understanding of Head Injury (HI) in Secure Forensic Mental Health Service Provision: A Service Need Evaluation

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Abstract

Background & Aims
The Scottish Government has placed importance on enhancing awareness of head injury (HI) in the Criminal Justice System to ensure the needs of individuals with HI are met and assessing knowledge about HI in service providers (NPHN, 2016). The first aim of the study was to investigate the prevalence and characteristics of HI and service need in forensic mental health service provision, across medium and low secure hospitals in Glasgow and whether there is a need for history of HI being considered in formulation, treatment and care plans. The second part of the study was to assess staff knowledge of HI.

Methods

A cross-sectional design was planned. Participants would have been male inpatients from forensic low and medium secure services in NHS GG&C. For these participants, all data was planned to be collected retrospectively from clinical case notes, including risk assessments and medical records. Information would have been collated on history of HI, psychiatric diagnoses, index offence, length of stay, details of risk assessments, and whether HI is considered in formulation and treatment plans. For the second part of the study, staff knowledge of HI would have been assessed by HI measures, including CM-TBI questionnaire, a knowledge of concussion measure and vignettes.

Applications

This would have been the first study to examine service need and understanding of HI in forensic mental health service provision in Glasgow. The study might have identified potential unmet service needs, with recommendations for changes in practice.

1. Introduction

Head Injury (HI) is considered to be one of the most significant public health problems (McCrea, 2008). Meta-analyses estimate the prevalence of HI among adult criminal offenders to be 51%-60% in adults (Shiroma, Ferguson & Pickelsimer, 2010; Farrer & Hedges, 2011). The prevalence of HI in the offending population is estimated to be seven times that of the general population estimate of 8.5% (Shiroma, Ferguson & Pickelsimer, 2010). Despite the high prevalence of HI and a significant service need for offenders, it is often not identified or assessed, and there is little evidence about knowledge about HI in service providers (NPHN, 2016). Emphasis has been placed on increasing public awareness and improving both public and professional knowledge of HI, particularly due to the prevalence of HI and its implications in the offending population (Glaze & Bonczar, 2008). Recently, the Scottish Government placed emphasised a need for service development for HI in the Criminal Justice System (NPHN, 2016). Emotional changes and cognitive impairment that are common after HI such as emotional dysregulation, impulsivity, and difficulties in problem-solving, may increase offending behaviour (NPHN, 2016; Williams et al. 2018) and may be associated with the higher number of disciplinary incidents reported in prisons (Merbitz et al., 1995). These long-term effects of mild HI can often be 'hidden' because they are often not associated with physical disability (NPHN, 2016).

Little research on HI in mental health patients has been carried out (Hawley & Maden, 2003). The prevalence of severe HI in a random sample of 50 maximum-security forensic psychiatric patients in the US was reported as 22% (Martell, 1992). Hawley & Maden (2003) reported the prevalence of HI involving loss of

consciousness to be 24% in 113 mentally disordered offenders in five medium secure units in England; including four NHS units and one independent unit. However, clinical case notes may not have information on history of HI and could under-report the prevalence. They also found that patients with a history of HI were more difficult to discharge than patients without. For 43 (96%) patients in the HI group, discharge to the community was either delayed or problematic, in comparison to 52 (83%) in the non-HI group. Moreover, a previous study reported that health professionals in a prison setting had misconceptions about HI (Yuhasz, 2013). This indicates a need for increasing the awareness of HI in forensic populations.

Colantonio et al. (2007) reported a history of HI in 23% of health records for 394 forensic mental health patients in Canada. This study indicates a need for further research on the prevalence of HI and of its severity and persisting sequelae in mentally disordered offenders in forensic mental health services, as there may be implications for formulation and treatment. There has also been an emphasis on ensuring staff training on HI and appropriate behaviour management (Morrell, 1998; NPHN, 2016). For example, offenders with a history of HI may have difficulty following rules (Merbitz et al., 1995). It has been recommended that there is routine screening for HI at admission due to implications for forensic treatment outcomes (Williams et al., 2010). Therefore, the present study will assess service needs in a Forensic Mental Health population, including the prevalence of HI, history of multiple or severe HI, relevance to formulation and intervention and whether there is evidence of HI being considered in the formulation, treatment and care plans. Case note review is highly likely to underestimate the true prevalence of HI. Therefore, the focus of this study was on the extent to which HI is incorporated in assessment and

treatment. This study planned to investigate the relationship between HI and offending characteristics. In addition, staff knowledge of HI was to be assessed to identify potential training needs. This is in line with the NHPN 2016 report and SIGN 130, which emphasises a need to heighten awareness and knowledge about HI.

2. Aims and Hypotheses

2.1. Aims:

1. To investigate the prevalence of HI in a forensic medium and low secure hospital sample, including history of multiple or severe HI, cause, type of HI, and effects on functioning, index offence, the relevance of HI to formulation and intervention and evidence of HI being considered in the assessment, treatment and rehabilitation plans.

2. To investigate whether there are differences in offending characteristics (e.g. violent offending) in the HI and No-Significant HI group.

3. To assess staff knowledge about HI and whether HI is considered in formulation and treatment plans (e.g. the effects on daily functioning will not be detailed).

4. To assess whether staff knowledge and whether there are misconceptions about the cause, prevalence and persisting impact of HI on patients.

2.2. Hypotheses

1. There will be significantly higher rates of HI in forensic service provision than in the general population.

2. HI will be significantly associated with violent offending and greater difficulty with discharge compared to non-HI.

3. Staff will have misconceptions about HI and limited knowledge about the cause, prevalence and persisting impact of HI on patients.

3. Method

3.1. Participants

The research was to be carried out in Forensic Mental Health Secure Provision in Glasgow. This comprises a medium secure specialist mental health hospital and forensic low secure mental health in-patient services in NHS GGC, including both admission and rehabilitation wards. For the first aim of the research, the sample would have represented all eligible male inpatients age 18 and above in the male with mental illness wards, (n=56) in medium secure and (n=30) in low secure. Current case files, historical medical records including Scottish Care Information (SCI Store), Admission Reports, Care Programme Approach and Risk Assessments for all patients would have be reviewed retrospectively using a checklist/data capture form devised for the study.

The study variables included: socio-demographic variables such as age, ethnicity, and level of education. History of previous head injury/brain injury, previous forensic psychiatric history, index offence, current psychiatric diagnoses, alcohol and substance abuse, length of stay in low/medium secure services, details of risk assessments, and whether HI is considered in formulation and treatment plans represents the clinical variables that would have been examined. If a history of head/brain injury is ascertained, further review would have considered relevant factors, including cause of HI (i.e. road traffic accident, falls, assault), severity of HI, evidence of loss of consciousness (LOC) and duration of LOC, impact on daily functioning if known, hospitalisations for HI in clinical records and how the history of head/brain injury had been determined (i.e. medical/hospital records, relative reports or self-reports, or a combination of reports). All patients in forensic secure provision

in Glasgow were eligible to be included, including new admissions. In addition, patients discharged within the last 3 months would have been included.

For the third aim of the research, participants would have been NHS staff at medium and low secure services over the age of 18 who had direct clinical contact and involvement in patient formulation, including: clinical psychologists, psychiatrists, occupational therapists and a representative sample of staff nurses. Approximately 50 staff would have been included. There was no employment duration requirement. Participants who do not understand written information in English would have been excluded from the study.

3.2. Recruitment

Data was to be obtained from patient medical records to determine if there is a history of HI. Approval from the Medical Director of Mental Health and Learning Disabilities (Consultant Forensic Psychiatrist) was obtained. An information leaflet was to be sent to NHS staff working at Rowanbank and Leverndale by e-mail from the consultant of the Males with Mental Illness (MMI) service. All staff were eligible to participate, including psychologists, psychiatrists, occupational therapists and staff nurses. A list of staff interested in taking part was to be collated by the Consultant Clinical Psychologist of the Males with Mental Illness Service at multi-disciplinary team meetings and ward rounds after distributing the information sheet (Appendix 2.1). The researcher planned to then liaise with interested NHS staff and provide measures to be completed. Written informed consent (Appendix 2.2) was to be obtained from staff prior to conducting any study activity, such as providing the measures.

3.3. Measures

Data collection instrument for case file review

The data collection instrument was designed for the purposes of the study to gather information on previous forensic psychiatric history, socio-demographic details, history of alcohol and substance use, history of HI and whether HI is considered in risk assessment and formulation and treatment plans. Please see (Appendix 2.3).

NHS Staff Demographic and Background Questionnaire

Demographic details which were planned to be included: language, education, qualifications, number of years working in the NHS and any previous training/experience of working with HI (Appendix 2.4).

Primary Outcome Measure

Common Misconceptions about Traumatic Brain Injury Questionnaire (CM-TBI)

The CM-TBI (Appendix 2.5) assesses knowledge about HI. This study planned to administer the 20-item short version (Linden at el., 2013) to staff participants, which utilises a 5-point Likert scale, giving a total score between 20 and 100. The CM-TBI is psychometrically valid, categorising questions into recovery, sequelae, insight and hidden injury subdomains: It has been used successfully with probation officers and has good internal consistency (.84) and test-retest reliability (.82); Good internal consistency has been found on the subscales of recovery (.73) and sequelae (.81), (O'Rourke et al., 2018). There is no formal cut off point for the CM-TBI. Higher scores are associated with greater knowledge. A previous study with a nursing student population found a mean score of 22.73 (Gurusamy et al., 2019).

Secondary Measures

Knowledge of Concussion

The 20-item knowledge about concussion questionnaire (Appendix 2.6) was adapted for use with professionals in a study assessing knowledge of concussion in the general population (McKinlay et al., 2011). The question responses are 'True' or 'False' and in this study. 'Don't Know' will be an additional option. Incorrect responses or 'Don't Know' will score zero and correct responses 1.

Knowledge about Head Injury and HI Services questionnaire

A measure of staff knowledge about HI specifically relevant to the Criminal Justice System was devised (Appendix 2.7). It assesses knowledge of HI and why information about HI is relevant to forensic staff. It also assesses whether staff recognise symptoms and behaviours that can be a consequence of HI. Questions will be developed from key reviews: Shiroma et al, 2010; Williams et al., 2018 & McMillan, 2019.

Vignettes

Vignettes have been utilised in HI research to determine knowledge and understanding of the effects of HI, injury management, including symptoms that are expected to occur after a HI (Davies & McMillan, 2005). There are no standardised vignettes suitable for this study (Sullivan & Edmed, 2016). These were developed with relevance to forensic mental health patients by the researcher (see Appendix 2.8). The scoring guide can be found in Appendix 2.8.

4. Design

This study is a quantitative cross-sectional design. For aim 1 and 2, it was planned that variables between patients with HI and patients without HI would have been compared to investigate prevalence of HI in forensic service provision and differences in offending. For aim 3, data would have been collected at one point to determine if HI is considered in formulation and treatment plans. For aim 4, measures of assessing staff understanding of HI would have been collected at one time point to determine staff knowledge and whether there are misconceptions about HI.

Definition of HI

Participants would have been grouped into 'significant' HI, which is likely to have persisting effects on daily life (HI group) or no HI/no 'significant HI', which would have included participants with no HI or mild HI. The HI group would have included those with moderate or severe HI and/or one or more periods of multiple-HI (Bogner & Corrigan, 2009).

4.1. Procedure

Aim 1 & 2

All data were to be collected retrospectively from historical records, current case files, medical records and relevant documents such as CPA and Risk Assessments. Data would have been reviewed at Rowanbank Clinic, Forensic Medium Secure Hospital and Low Secure services at Leverndale Hospital. A data collection instrument was to be utilised to record retrospective anonymised patient data from case notes, such as demographics, reason for admission, index offence, length of admission, legal status, clinical diagnosis, forensic history, and psychiatric history. When reviewing clinical

case notes, the researcher would have identified any details of previous HI. Admissions and discharge reports were to be extracted and current case files would have been reviewed to determine if HI is acknowledged and whether any action had been taken. Data on whether patients in HI group are most difficult to be discharged compared to patients without HI would have been analysed due to previous findings (e.g. Hawley & Maden, 2003). For the analysis, retrospective data would have been divided into two groups to compare characteristics, for individuals who have sustained significant HI and those who have no record of having suffered significant HI (HI v no significant HI).

Aim 3

For the third aim of the research, participants (NHS staff) were be informed of the purpose of the research through an information sheet (Appendix 2.1) distributed by the Consultant Clinical Psychologist of the Males with Mental Illness Service. Interested participants would have been provided with the researchers contact details. Participants would have completed an informed consent form (Appendix 2.2) prior to completing the measures and vignettes. Participants would have been informed that their involvement would be voluntary, being free to withdraw at any time. If a participant was to drop out during data capture in the study, data would have been destroyed. Participants were to be provided with information on anonymity of responses and right of withdrawal. Data would have been kept confidential and anonymity of staff would have been maintained by storing staff responses electronically with an ID number. Staff names would have been kept separately in a confidential and password protected Excel sheet with their name and ID number. Pseudonymised forms and measures were to be kept in a locked cabinet. It was planned that a summary of study findings would have been made available to the

MMI consultant to feedback to staff. Data was to be pseudonymised with a code number linking to identifiable data, which was to be held separately. The data was going to be stored and backed up on the secure server at the University of Glasgow and on a University of Glasgow encrypted laptop with access available only to the researcher, University supervisor and representatives of NHS GG&C for auditing the study. Personal information would have been destroyed after the follow-up was complete.

4.2. Data Analysis

Data would have been analysed using IBM Statistical Package for Social Sciences (SPSS) version 26 (IBM, 2019).

Aim 1: To investigate the prevalence of HI in a forensic medium and low secure hospital, a data summary (frequency distributions for categorical data; mean, SD, and range for continuous data) would have been presented by HI group for demographic variables. This would have included history of multiple or severe HI, cause of HI, type of HI, effect on functioning and whether HI was detailed in patient formulation and intervention plans.

Aim 2: A data summary (frequency distributions for categorical data; mean, SD, range for continuous data) would have been presented by HI group. Univariate analysis was planned to investigate the relationship between HI v no HI group and offending characteristics. Groups would have been compared using Fisher's Exact test for categorical variables and Wilcoxon or Mann-Whitney U tests would have been used for ordinal or continuous variables. Comparisons would have be made between patients with HI and without a known history of HI for clinical factors, such as violent

offending, index offence, length of admission, delay in discharge, number of violent incidences and forensic history. Significant results would have been interpreted further with multivariate analysis. A logistic regression would have been conduced with violent offending as the outcome variable and binary variables (e.g. HI v no HI) and a poisson regression or a negative binomial regression would have been carried out with the length of admission as the outcome variable.

Aim 3: Descriptive statistics would have been presented on demographic information, total scores and scores for each subdomain on the CM-TBI measure (recovery, sequelae, insight and hidden injury). Total score of the concussion questionnaire and total score of the vignettes would also have been presented. There would have been a qualitative summary of the HI services questionnaire. It was planned that Kruskal-Wallis tests/ One-Way ANOVA would have been conducted to determine if there were differences in responses between staff groups, defined by, professional role, qualifications, knowledge of someone with HI, experience working with someone with HI and receiving training on HI on total scores and subdomain scores. Comparisons would also have been made between NHS staff working at low secure and medium secure services.

4.3. Justification of Sample Size

A previous study identifying the prevalence of HI amongst patients in UK medium secure units (n=113; Hawley & Maden, 2003) was used to estimate sample size using G*Power (Version 3.1; Faul, Erdfelder, Lang & Buchner, 2007). With power of 0.80 to detect an effect, probability of 0.05, and a medium effect size (0.5), for a Fishers Exact Test, the sample size required is n=64 for aim 1, comparing HI and non-HI

group variables: offending characteristics, diagnosis and length of stay. The current study aimed for n=86 for aims 1 and 2 and n=50 for aim 3.

4.4.Setting and Equipment

For the first and second aim, a data extraction form was to be completed for every patient retrospectively and for the third aim, staff would have completed the measures on site at the medium and low secure units.

5. Health and Safety Issues

The research would have been conducted in line with NHS health and safety guidelines. Any possible risks relating to conducting research was to be assessed by NHS ethics and the Ethics department at Rowanbank Clinic. Risk was considered to be low as the researcher would only have been interacting with professional staff. The researcher had undergone all safety training, such as breakaway training required by NHS prior to commencing.

6. Ethical issues

Ethical approval was pending approval from NHS Research Ethics and NHS R&D approval. Caldicott Guardian Approval was to be obtained for accessing retrospective NHS data. For the first aim of the research, patients would not have been approached for consent due to data being collected retrospectively from case notes, which was going to be anonymised once collected. Consent was obtained from an internal ethics committee for Rowanbank Clinic/Leverndale Hospital. The researcher would have passed on information to the ward manager and ward clinical psychologist if a history of HI was identified for patients in the MMI wards, which was not already included in patient care/treatment and management plans.

7. Financial Issues

Costs were mostly for travel and photocopying questionnaires. It was estimated that costs will not exceed £200 and are available from the University.

8. Practical Applications

Establishing an understanding of HI in this population may guide formulation and the development of a pathway for appropriate care and treatment. The results of the study were to be disseminated in a peer reviewed scientific journal and in conference presentations. An internal report of the findings was going to be provided to Forensic Mental Health Service Provision in GG&C. Staff participants would have been able to request study findings.

9. Brief Critical Appraisal of Planned Methods

The main limitation of the first part of this study is the retrospective design. Data would have been collected via medical records and case-notes. The limitations of self-report are well documented and it is possible HI would have been under-reported and individuals may not have been asked about HI. Retrospective studies can be criticised due to the potential for methodological problems, such as selection bias and the difficulty in controlling for accurate HI. Moreover, the design would preclude being able to determine the causal relationship with risk factors and the outcome (e.g. length of admission). However, it is imperative to understand HI in this population further to provide support for further research.

This study would have been the first known study to assess staff knowledge of HI in forensic service provision in Glasgow, Scotland. As a limitation of assessing staff

knowledge, the sample size would have been small. There may have been difficulties with recruitment due to staff shortages and staff sickness. Research with a large number of staff participants would be beneficial to determine understanding of HI and misconceptions, providing insight to gaps in knowledge and understanding which could have provided support for providing staff training on HI.

One limitation of the research is a lack of validated measures assessing HI knowledge and misconceptions of HI. Although the CM-TBI demonstrates strong internal consistency for two subscales (recovery and sequelae), weaker reliability has been reported for two subscales (hidden injury and insight). The representativeness of the sample may have been a limitation, with staff participants self-selecting into the study.

Staff participants who had an interest in HI due to working with an individual with HI may have been more likely to participate due to an interest in the area. Although some of the outcome measures were validated, the researcher developed and designed one measure and three training vignettes. The limitation of this includes lack of blinding as the researcher designed and would have been the sole assessor of the outcome measures and vignettes. However, there is a lack of appropriate measures and vignettes in HI research. Furthermore, the influence of social desirability in self-reporting may have been problematic when assessing HI misconceptions. Nonetheless, the research would have possibly highlighted gaps in training.

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Chapter Three: MRP Brief Report

Gender Differences in Offending in Prisoners with Head Injury in Scotland

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Plain English Summary
Background
Head Injury (HI) is more prevalent in prisoners than the general population (McMillan et al., 2019). HI can cause behavioural, cognitive and emotional changes, including aggression, and these effects have been linked with offending (Williams et al., 2018). The Scottish Government has placed importance on considering prisoners' needs with HI (National Prisoner Healthcare Network, 2016). However, there is currently very little research on gender differences and offending in prisoners with HI. Further research is required to identify differences in male and female prisoners with HI.

Aims

This study investigated gender differences in offending in male and female prisoners with HI, including the number of convictions and violent offences. The study also investigated whether a younger age of first sustaining HI was associated with a risk in offending and gender differences in depression, anxiety, and alcohol and substance use in prisoners with HI.

Method
The study is a secondary data analysis of 200 prisoners (101 females and 99 males) recruited to a health and wellbeing study, from five Scottish Prisons (HMPs Low Moss, Shotts, Cornton Vale, Edinburgh and Greenock). Participants were included if they were aged over 16 and serving a prison sentence. Participants completed questionnaires about demographics, HI, mental health and offending history. Participants were grouped by having a history of a significant HI, which is likely to have a persisting effect on daily life compared to no significant HI.

Findings
Seventy percent of participants had a significant HI. Overall, Males had more involvement with the criminal justice system, with a higher number of convictions

and were arrested and charged at an earlier age than females. Violent offending was the most common cause of offending, with males being 2.45 times more likely to have a violent offence. HI predicted the number of convictions, and was 70% higher compared to no significant HI. Findings suggest that 54% of participants had anxiety and 25.5% had depression. Females had a higher proportion of anxiety and depression compared to males; however, males with depression or anxiety had double the number of convictions compared to females.

Conclusions and implications

Prison services need to be aware of high rates of HI for male and female prisoners, since HI was found to be associated with offending. Depression and anxiety were associated with number of convictions, in particular for males. Prison interventions for males and females with HI may help address the long-term impacts of HI. Interventions may improve mental health needs of prisoners and reduce re-offending rates.

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Abstract

Background: Head Injury (HI) is twice as high in prisoners, compared to the general population (McMillan et al., 2019) and is considered a risk factor for offending (Colantonio et al., 2014), violent offending and an earlier age of offending (Williams et al., 2018). There is currently very little research considering HI and gender differences and the impact on offending.

Aims: To investigate gender differences in offending, including number of convictions and violent offending in prisoners with HI. Secondary aims include investigating whether age at first HI is associated with risk of offending and differences in mental health, including depression, anxiety and substance use.

Method: Secondary data analysis of a study with a retrospective, cross-sectional design; 200 prisoners (101 females and 99 males) were recruited from five Scottish prisons. Participants completed self-report measures, such as the OSU-TBI ID and a measure to gather information on offending history and mental health.

Results: Seventy percent of the sample had a significant HI. There was no significant association between gender and HI or gender and the age of first HI with LoC. Males had more convictions (U=3295.0, z = -3.903, p= .001). HI predicted the number of convictions, (OR: 1.70, 95% CI 1.16, 2.46, p= .006), with males having more convictions and being 2.45 times more likely to report a violent offence compared to females (OR: 2.45, 95% CI 1.03, 5.81, p= .042). An interaction was present between depression, anxiety and number of convictions for males.

Conclusions: HI was associated with offending and males had more involvement with the CJS. Males with depression had double the number of convictions and this was similar for anxiety. Interventions may be paramount in improving mental health needs in prisoners with HI, ultimately reducing re-offending rates.

Keywords: *gender differences, prisoners, convictions and head injury*

1. Introduction

Meta-analyses report the prevalence of Head Injury (HI) in prisoners to be 51%-60%, which is significantly higher than in the general population (Farrer & Hedges, 2011; Shiroma et al., 2010). The recent national prison population study in Scotland found a lifetime prevalence of Hospitalised Head Injury (HHI) in prisoners to be twice as high as in a matched general population sample, with 25% of prisoners under the age of 35 reporting HHI (McMillan et al., 2019). The presence of HI was high for both male (25.1%) and female prisoners (18.5%) (McMillan et al., 2019) compared with an estimate of 12% of the general population having HHI (Frost et al., 2013). In Scotland, 95% of the prison population are male and 5% are female (SCCJR, 2015). Research has indicated that there is a higher proportion of offending in the younger age group (15-19) (Richards, 2011). HI can result in neuropsychological effects, such as emotional regulation deficits, including impulsivity, irritability and poor social judgement (McAllister, 2008;) and cognitive difficulties, including emotional dysregulation, problem-solving difficulties, impulsiveness and aggression and it is thought that these effects are associated with increased risk of criminality, including violent offending (Williams et al. 2019). Individuals with HI and a history of offending are at increased risk of re-offending (Fazel et al., 2011), with poorer treatment outcomes (Shiroma et al., 2010).

There is very little research on gender differences and HI in prisoners. Studies have typically focused on male prisoners, possibly due to female prisoners comprising a small proportion of the prison population. There is a lack of research on characteristics of female prisoners. High rates of anxiety, depression and substance use have been reported following HI (Whelan-Goodinson et al., 2009). Moreover,

depression has been associated with aggression (Baguley et al., 2006) and females with HI are at increased risk of anxiety and depression, with males having higher offending rates (McKinlay & Albicini et al., 2016). HI early in life can be associated with abnormal neurodevelopment and potentially with crime (Williams et al., 2018). Significant HI includes moderate-severe HI, with loss of conscious (LoC) of >30 minutes and one or more episodes of multiple HI. Significant HI is likely to cause persisting effects on daily life (Bogner & Corrigan, 2009). There may be differences between males and females and the relationship between HI and offending. Understanding gender differences could have significant implications for assessment, management and rehabilitation implications for individuals with HI in the criminal justice system (CJS). Indeed, the Scottish Government and the NHS have prioritised individuals with HI in the CJS, including gender differences (National Prisoner Healthcare Network, 2016). The present study investigates whether there are gender differences in outcomes following HI and offending.

Aims

This study's primary aim is to investigate whether there are gender differences in offending in prisoners who report HI, particularly, the prevalence of HI, the number of convictions and violent offences. The study's secondary aims include investigating whether a younger age at first HI is associated with an increased risk in offending among male and female prisoners and whether there are gender differences in depression and anxiety, and problematic alcohol and substance use in prisoners with HI.

Method

Design

This study uses a quantitative, cross-sectional retrospective design comparing males and females in Scottish prisons with and without significant HI. Secondary data were used from two recently completed studies. The existing data was collected from March 2018 to December 2019. Data was extracted from an SPSS database. Comparisons between number and severity of HI, with loss of consciousness (LoC) will be compared by gender. The statistical design is a mix of correlational and experimental design.

Participants

The data accessed was from two hundred participants (101 females and 99 males) recruited to a health and wellbeing study carried out by previous DClinPsy trainees and a research worker.

Procedure

The projects had NHS Research Ethics, NHS Research and Development and Scottish Prison Service approvals. Participants were recruited from five Scottish prisons (HMPs Low Moss, Shotts, Cornton Vale, Edinburgh and Greenock). Participants were included in the original studies if aged over 16 and serving a custodial sentence. Written informed consent had been obtained prior to a semi-structured interview and assessment. Approval for access to the existing data was obtained from the relevant NHS R&D departments and authorised by the sponsor (Appendix 3.1).

Measures:

The Ohio State University Traumatic Brain Injury Identification Method (OSU TBI-ID, Corrigan & Bogner, 2007).

The OSU-TBI was used to assess cause and severity of single and multiple HI and the likelihood of persisting effects. It has a good inter-rater reliability (r >0.6) and large effect sizes for comparing OSU TBI-ID with behavioural, cognitive and psychiatric outcomes (Bogner & Corrigan, 2009). Multiple head injury is defined as periods of "multiple repeated impacts to the head" (Bogner & Corrigan, 2009). The OSU-TBI-ID also assesses at first TBI with LoC, and whether TBI with LoC occurred prior to the age of 15.

The Hospital Anxiety and Depression Scale (HADS)

The HADS has good reliability and validity for assessing anxiety and depression in a HI population (Whelan-Goodinson et al., 2009). It comprises 14 items and responses are rated on a 4-point Likert scale. Scores >10 are indicative of moderate-severe anxiety or depression (Zigmond & Snaith, 1983). The HADS internal consistency is good. Cronbach's alpha is .84 for the depression scale and is .85 for anxiety scale (Gough et al., 2009). The HADS is a screening tool for anxiety and depression and is not a diagnostic tool.

Demographic and Offending History

A proforma was utilised to gather information on HI and prisoners in Scotland (Walker, 2017). Demographic information was gathered for age, gender, education, alcohol and substance use, offence history, age of first offence and duration of time in prison.

Data Analysis

Data were analysed using IBM Statistical Package for Social Sciences version 26 (IBM, 2019). Demographic data are presented as measures of central tendency for continuous variables and frequencies (%). Inferential tests are two-tailed. Data was assessed for normality and violated assumptions; therefore non-parametric tests were adopted. Mann-Whitney U tests were used to compare continuous variables (e.g., differences in gender and the number of convictions). Chi-square/Fishers exact tests examined gender differences for categorical variables. Significant results were further analysed using regression. Negative Binomial Regression was carried out to assess whether offending (measured by number of convictions) was predicted by gender or HI severity. A Negative Binomial Regression is appropriate for count variables where data does not follow a Poisson distribution. Negative binomial regression derives from a Poisson distribution, which is suitable for count data analysis and considers the issue of over-dispersion in the data. A logistic regression was conducted with violent offences as the outcome/dependent variable due to the variable being categorical to explore risk factors for violent offending.

Definition of groups

OSU-TBI classifications were used to define groups. Participants were grouped based on whether they had a history of 'significant' HI that is likely to have persisting effects on daily life (HI group) or no HI/no 'significant HI (NoS-HI Group). The NoS-HI included participants with no self-report of HI or mild HI without LoC and no periods of multiple HI. The HI group included those with moderate or severe HI (LoC> 30 minutes) and/or one or more periods of multiple-HI (Bogner & Corrigan, 2009).

Results

Demographic Data

The median age of the 200 participants was 35, (IQR 29,42; range 20-73 years). In total, 97% of participants were white. Just over half (52%) reported previous problematic alcohol use and 77% previous problematic drug use. Age did not differ between males (M=36.26, SD= 10.16) and females (M= 35.97, SD= 9.83; t (198)= .207, p= .84). The median number of years in education was 11 (IQR 10,12; range 0-20 years); 47% went to mainstream school, 14% received 1:1 support at mainstream school, and 40% attended a special school for behaviour or learning difficulties. Truanting was common, with 85% of participants frequently missing school due to truancy and 69% because of suspension. 67% were employed before being sentenced and 33% were unemployed.

Univariate Analysis

Head Injury Epidemiology

In total, 70% (N=142) of participants met the criteria for significant HI (Table 1). There were 72.2% (72) of males with significant HI and 69.3% (70) of females with significant HI. There was no statistically significant association between gender and HI group (Fishers Exact Test, F(1) =.243, p=.534, Cramer's V=.46; Table 1), the occurrence of significant HI did not differ by gender (F(2) =1.063, p=.770, Cramer's V=-.75) or the occurrence of a first HI, before/after age 15, (F(1) = 7.075, p=.007.

Table 1. Head Injury by Gender; median and range or % (n)

	Male	Female	Total
Age first Head Injury	10 (3-24)	12 (0-33)	10 (0-34)
Age first TBI with LoC	14 (0-42)	15 (3-37)	14 (0-42)
HI Group	72.7% (72)	69.3% (70)	70% (142)
No Significant HI	26.3% (26.3)	30.7% (31)	28.1% (57)
Multiple/Repeated	61.6% (61)	64.3% (65)	63% (126)
First HI with LoC before age 15	79.8% (79)	54.5% (55)	67% (134)

Gender differences in Offending (table 2)

In the overall sample including HI and non-HI, the results of the Mann Whitney U Test found a significant difference in conviction rates, with males having more convictions than females (U=3295.0, z=-3.903, p=.001; r=.03). There was no significant gender difference in the total time in prison (U=3451.5, z=-1.692, p=.091) or in the longest sentence (U=3967.0, z=-.722, p=.472). First arrest was at a younger age in males (U = 2721.5, z =-4.830, p =.001; r =.35). Males were charged at a younger age (U=1453.5, z =-2.695, r =.22). Violence was the most common offence type. Differences in violent offending by gender were non-significant (F(1)= 2.616, p=.091), as were differences for other offences, sexual offences (F(1)= .000, p=.650) or property offences (F (1)=.498, p=.480).

Table 2. *Offending Characteristics* of Males and Females (Median, Range & IQR)

Variable	*Male*	*Female*	*Total*
Number of convictions	10.5 (1-100) IQR=4,39	5 (0-100) IQR=1,14	7 (0-100), IQR=2,20
Total time in prison all sentences (months)	13.75 (.40-300) IQR=5,36	9 (.20-252) IQR=3,31.4	12 (.20-300) IQR=4,35
Longest sentence (months)	21.5 (.75-240) IQR=9,54	22 (0-330) IQR=10.5,61.5	21.75 (0-330) IQR=10,54
Age first arrest	14 (7-55) IQR=13,16	17 (7-69) IQR=14.75,25.25	15 (7-69) IQR=14,20
Age first charged	16 (7-55) IQR=14,17	16.5 (10-59) IQR=15,21	16 (7-59) IQR=14,19
Offending types (N, %)			
Violent	82 (83%)	73 (72%)	155 (77.5%)
Sexual	3 (3%)	3 (3%)	6 (3%)
Property	47 (47.5%)	54 (54%)	101 (50.5%)
Other	83 (84%)	77 (76%)	160 (80%)

Head Injury and Offending

The HI group had significantly more convictions compared to the NoS-HI group (U=2906.5, z = -2.835, p= .004, r = .20) and the effect size small. The results of a Mann Whitney U test found a significant difference between HI group and age at first arrest, with the HI group being found to be significantly more likely to be arrested at a younger age (U=2995, z =-2.199, p=.028, r =.16), with a small effect size. Individuals in the HI group were significantly more likely to have committed violent offences, ($F_{(1)}$ =8.903, p= .002, Cramer's V = .22). There was no significant difference between the HI group and the NoS-HI group in length of sentence (U=3062, z = -1.395, p=.164) or total time in prison for all sentences (U=3157.5, z =-790, p=.431).

There was no significant difference with HI and number of convictions (U=3727, z = -1.868, p=.062) (Table 3).

Table 3. Head Injury and Offending (Median or %)

	No. Convictions	No. Arrests	Total time in prison all sentences Months	Longest Sentence Months	Age Arrest	First Violent Offences
HI	10	20	12	18	15	N=119 (84%)
Non S-HI	4	8	10	27	16	N=36 (63%)
OSU Repeated	10	20	10	18	15	N=107 (85%)
OSU No Repeated	6	15	13.7	36	16	N=48 (66%)
First HI with LoC Before 15	9	20	12.5	21.2	15	N=107 (80%)
First HI with LoC After 15	6	13	10	10	17	N=38 (76%)

Mental Health and Substance Misuse

HADS anxiety scores were above the cut-off in 54% (*N*=108) and HADS depression in 25.5% (*N*=51) of the overall sample (Table 4). A Fishers Exact Test found a higher proportion of females compared to males reported clinical depression (F(1) =10.56, p =.000, Cramer's V =.24) and anxiety (F(1)= 22.18, p=.000, Cramer's V =.34). There was no significant difference in proportions in the HI and NoS-HI groups with clinical depression (F(1)=.203, p= .330, Cramer's V= .04) or anxiety (F(1)=1.20, p=.270, Cramer's V=.09). There was no significant gender difference in problematic alcohol use (F(1)=.177, p=.671, Cramer's V=.04) or problematic substance use (F(1)=.006, p= .868, Cramer's V=.02). The HI group reported more problematic alcohol use (F(1)=9.85, p=.002, Cramer's V=.23) and substance use (F(1)=7.42, p=.005, Cramer's V=.21).

Table 4. Mental Health and Substance use by Gender and HI (N, %)

	HADS Anxiety	**HADS Depression**	**Alcohol Use**	*Substance Use*
Male	37 (37)	36 (36)	49 (49)	75 (76)
Female	71 (72)	15 (15)	54 (53)	78 (77)
Total	108 (54)	51 (26)	103 (51)	153 (76)
HI	80 (57)	38 (27)	84 (59)	117 (82)
NoS-HI	27 (47)	13 (23)	19 (33)	36 (63)
Total HI/NoS-HI	108 (54)	51 (26)	103 (51)	153 (76)

Regression Modelling for Convictions (*Negative binomial regression)*

Predictor variables were included where group differences were found in univariate analysis. Number of convictions was entered as the dependent variable and gender, HI grouping (HI v NoS-HI), HADS Depression, HADS Anxiety, first HI under 15 as predictor variables. The independent variables were coded as binary. Age was also entered to adjust for as a continuous linear covariate. The HI category was a two category dummy variable, to incorporate the nominal variable consisting of 'NoS-HI' and 'HI' into the model. The likelihood ratio chi-square test indicated that the full model was a significant improvement in fit over a null (no predictors) model (p< .001).

Main effects

HI group was a significant predictor of the number of convictions (OR: 1.70, 95% CI 1.16, 2.46, p= .006) (Table 5). On average, individuals with HI had 1.70 times the number of convictions compared to the NoS-HI group. The number of convictions was 1.70 [(1.70)*100%] = 70%, i.e. the mean number of convictions is 70% higher in those with a history of HI, with males having a higher number of convictions than females. The mean number of convictions for females was 0.60 times that of males, i.e. 40% lower [(.60-1)*100%]=-40%. Age at first HI with LoC Under 15 was not associated with a higher number of convictions. A significant main effect was found for problematic alcohol use 0.61, adjusting for gender and other covariates; for males the effect was 0.78 and for females 0.37, with a hint of an interaction (p=0.058). Overall, adjusting for covariates in the model, individuals reporting alcohol use had 39% fewer convictions. A significant effect was found for substance use 0.30, indicating that individuals with substance use had 70% fewer convictions.

Interactions with gender

The associations between number of convictions and HADS Depression and Anxiety were different for males and females (interaction p-values <0.001 and 0.013). Males with clinical depression had twice as many convictions (OR=2.08, 95%, CI 95% 1.06, 2.76, p= .028) (Figure 1). This was similar for HADS anxiety, showing males with anxiety to have a higher number of convictions, and females with anxiety having a lower number of convictions, though neither association was statistically significant (Figure 2).

Table 5. *Negative Binomial Regression*: Number of convictions in relation to gender and head injury (HI) group.

Outcome: No. Convictions	Males			Females			Total			Gender Interaction p-value
	Ratio	95% CI	p	Ratio	95% CI	p	Ratio	95% CI	p	
Gender	-	-	-	-	-	-	0.60	0.43, 0.84	.003	-
HI Grouping	1.71	1.06, 2.76	.028	2.36	1.28 4.36	.006	1.70	1.16, 2.46	.006	.787
HADS Depression	2.08	1.14, 3.30	.017	0.53	0.30, 0.93	.028	1.08	0.74, 1.60	.681	.000
HADS Anxiety	1.23	0.78, 1.93	.374	0.82	0.43, 1.57	.558	1.07	0.75, 1.52	.692	.013
First HI with LoC, Under 15	0.65	0.37, 1.15	.144	1.70	0.97, 2.94	.062	0.93	0.62, 1.40	.735	.163
Alcohol Use	0.78	0.50, 1.20	.257	0.37	0.21, 0.64	.000	0.61	0.44, 0.84	.003	.058
Substance Use	0.31	0.18, 0.53	.000	0.43	0.27, 0.84	.013	0.30	0.20, 0.44	.000	.295
Age	1.01	0.10, 1.04	.254	0.98	0.95, 1.02	.357	1.00	0.98, 1.03	.394	.491

Figure 1. *Interaction for Gender x Depression x Number of Convictions*
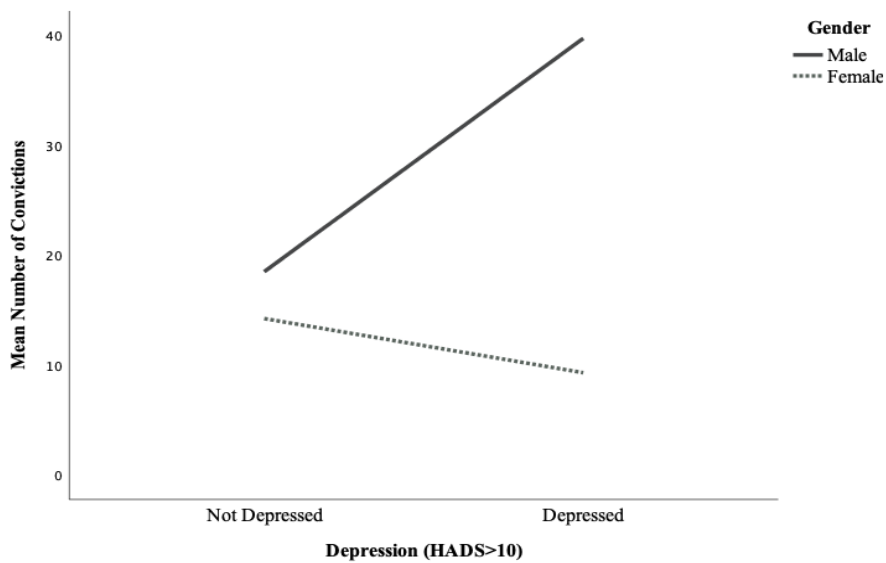

Figure 2. *Interaction for Gender x Anxiety x Number of Convictions*
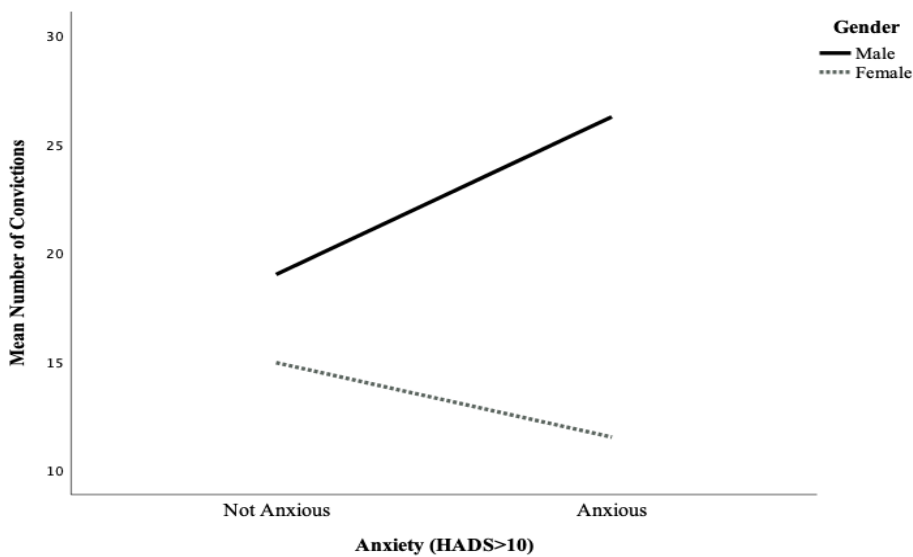
Regression Modelling for Violent Offences *(Binary Logistic Regression)*

Possible risk factors for violent offences (gender, age, first HI with LoC before/after

age 15, HADS Depression and HADS Anxiety) were modelled using logistic

regression (Table 5). The logistic regression was significant, χ^2 (8, N=180) = 27.35,

p= .001 and explained 22.3% (Nagelkerke R^2) of variance and correctly classified

81% of cases. As shown in table 6, gender and HI were risk factors, with a statistically significant contribution to the model, after controlling for all other factors. Males were more likely to report a violent offence compared to females, (OR: 2.45, 95% CI 1.03, 5.81, p=.042). Males with a HI were more likely to have committed a violent offence compared to females (OR: 0.27, 95% CI 0.83, 0.86, p=.027). The odds ratio of 0.34, indicated that females with HI were 66% less likely than males to have a violent offence (OR: .34, CI 0.15, 0.80, p=.011), controlling for other factors in the model. No interactions were present between gender and other predictors.

Table 6. Logistic Regression: Violent offences in relation to gender and head injury (HI) group

Outcome: Violent Offences	Males ($R^2 = .017$)			Females ($R^2 = .014$)			Total ($R^2 = .013$)			Gender Interaction p-value
	Ratio	95% CI	p	Ratio	95% CI	p	Ratio	95% CI	p	
Gender	-	-	-	-	-	-	2.45	1.03, 5.81	.042	-
HI Grouping	0.27	0.83, 0.86	.027	0.43	0.12, 1.50	.184	0.34	0.15, 0.80	.011	.160
HADS Depression	0.41	0.44, 3.76	.430	1.58	0.50, 4.98	.434	1.13	0.44, 2.91	.801	.241
HADS Anxiety	0.38	0.91, 1.57	.181	0.63	0.17, 2.30	.486	0.49	0.20, 1.20	.118	.835
First HI with LoC, Under 15	1.05	0.26, 4.21	.946	0.61	0.19, 1.94	.404	0.75	0.31, 1.84	.536	.122
Alcohol Use	3.82	0.93, 15.80	.064	3.23	0.98, 10.49	.051	3.19	1.34, 7.64	.009	.529
Substance Use	3.27	0.87, 12.35	.080	1.08	0.27, 4.30	.941	2.03	0.80, 5.08	.133	.150
Age	0.96	0.91, 1.02	.961	0.95	0.89, 1.01	.112	0.05	0.92, 1.00	.052	.197

Discussion

This is the first study to investigate gender differences in offending in prisoners who report HI in Scotland. Overall, 'significant' HI was found in 70% of the overall sample of male and female prisoners. As a comparison to the prison population, this is significantly more than approximately 12% of the general adult population who have a history of HI with LoC (Frost et al., 2013). HI was found to be a predictor for a higher number of convictions. Prevalence rates of significant HI were similar for males and females. There were significant gender differences, with males having more involvement with the CJS, being arrested and charged at a younger age. Violent offending was associated with the HI group and males were more likely to report violent offending, compared to females. These effects were found while controlling for all other factors. The HI group had more difficulties with problematic alcohol use and substance use. Research in the general population has reported prevalence of HI being twice as high in males (16.7%) than in females (8.5%) (Frost et al., 2013). There is substantial evidence that HI is highly prevalent in female prisoners (NPHN, 2016), with an prevalence of 21% being found in one study (Durand et al., 2017). However, this study found HI is highly prevalent in both male (72.7%) and female prisoners (69.3%).

Gender differences in Offending

HI predicted higher numbers of convictions and violent offences. This is consistent with other studies (Shiroma et al., 2010; Williams et al., 2019). HI was found to be associated with violent offending, with a greater risk in males than female prisoners. Males were twice as likely to report violent offences compared to females. The literature supports this finding, with males having proportionally higher rates of

offending compared to females, in particular violent offences (Bennett, Farrington & Huesmann, 2004). In the analyses, potential confounding variables were controlled for, indicating that HI is an important predictor as findings are not explained by other common problems prisoners may experience such as anxiety, depression or substance use.

Gender differences in occurrence of Age of first HI and Offending

Previous studies indicate that sustaining a HI at a young age is associated with a greater risk of offending (Richards, 2011) There is little evidence with regard to gender differences in general or specifically the impact of early HI and none were found in the present study.

Gender differences in Mental Health, Substance Abuse and Offending

Previous research suggests that female prisoners with HI often experience anxiety and depression (Ferguson et al., 2012) and may have worse clinical outcomes compared to men (Farace & Alves, 2000). This study found the same gender effect, with females reporting higher prevalence of mental health difficulties than men. Males may be less likely to self-report anxiety and depression. In addition, anxiety and depression were associated with more convictions particularly in males. One possible explanation could be a variation in emotion regulation and coping styles. The findings suggest mental health treatment and support would be beneficial to males and females with HI in the CJS. Alcohol and substance were not associated with a higher number of convictions for males or females.

Strengths and Limitations

There may be biases in recall associated with self-report of HI, although the OSU TBI-ID is designed to minimise limitations of self-report (Bogner & Corrigan, 2009) and it is validated with a prison population, with good test-retest reliability). The

study also relied on self-report for the number of convictions. However, the number of convictions may be the best outcome measure for offending, as it is likely to be recalled accurately. This study did not detail the frequency or severity of violent offences, this could have been explored further. As a limitation, the HADS is a screening measure, rather than a diagnostic tool for anxiety and depression. Future studies could utilise clinical interview and assess diagnostic criteria, e.g. utilising the Structured Clinical Interview for DSM-5. The study strength is a large sample size, which can be considered as a reliable representative of the prison population. The majority of research is disproportionate with male prisoners however, this study had an equal representation of both male and female prisoners.

Further research

There is a need to further examine the interaction between mental health difficulties, HI and offending to establish areas for intervention to reduce re-offending.

Conclusions

Overall, this study found high rates of HI in both male and female prisoners. Males were found to have a higher number of convictions and violent offences. Depression and anxiety were associated with number of convictions, in particular for males. Both males and females with HI had a higher number of convictions. Findings indicate the need for further research on gender differences in HI and offending to provide insight into causal mechanisms, which increase risk of offending. HI staff training and prison interventions for may improve mental health needs of prisoners and ultimately reduce re-offending rates by meeting the needs of individuals with HI.

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Appendices

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Appendix 1.2. Data Extraction for Analysis

Domain

Citation Reference	Authors, title, date and country
Method for selecting participants & participant characteristics	Inclusion and exclusion criteria Setting recruited from, Referral, TBI severity, Age, Gender, Education
Design	Non-Randomised designs Randomised Controlled Trial (RCT), Clinical Trial, non-controlled study
Intervention Characteristics	Third Wave Therapy intervention, specific elements of the Third Wave Therapy, delivery of intervention, format of intervention delivery and No. of sessions and duration
Effectiveness of Intervention	Primary and secondary outcome measures, effect sizes, attrition rate and follow-up if available.

Appendix 1.3. CCAT Quality Rating Tool

Crowe Critical Appraisal Tool (CCAT) Form (v1.4) Reference _____ Reviewer _____

This form must be used in conjunction with the CCAT User Guide (v1.4); otherwise validity and reliability may be severely compromised.

Citation

	Year

Research design (add if not listed)

❏ Not research	Article	Editorial	Report	Opinion	Guideline	Pamphlet	…
❏ Historical	…
❏ Qualitative	Narrative	Phenomenology	Ethnography	Grounded theory	Narrative case study	…
❏ Descriptive, Exploratory, Observational	A. Cross-sectional	Longitudinal	Retrospective	Prospective	Correlational	Predictive	…
	B. Cohort	Case-control	Survey	Developmental	Normative	Case study	…

Experimental

	❏ True experiment	Pre-test/post-test control group	Solomon four-group	Post-test only control group	Randomised two-factor	Placebo controlled trial	…
	❏ Quasi-experiment	Post-test only	Non-equivalent control group	Counter balanced *(cross-over)*	Multiple time series	Separate sample pre-test post-test [no Control] [Control]	…
	❏ Single system	One-shot experimental *(case study)*	Simple time series	One group pre-test/post-test	Interactive	Multiple baseline	Within subjects *(Equivalent time, repeated measures, multiple treatment)*	…

❏ Mixed Methods	Action research	Sequential	Concurrent	Transformative	…
❏ Synthesis	Systematic review	Critical review	Thematic synthesis	Meta-ethnography	Narrative synthesis	…
❏ Other	…

Variables and analysis

Intervention(s), Treatment(s), Exposure(s)	Outcome(s), Output(s), Predictor(s), Measure(s)	Data analysis method(s)

Sampling

		Group 1		Group 2		Group 3		Group 4		Control
Total size										
Population, sample, setting										

Data collection (add if not listed)

Audit/Review	a) Primary	Secondary	… b) Authoritative	Partisan	Antagonist	… c) Literature	Systematic	…	Interview	a) Formal	Informal	… b) Structured	Semi-structured	Unstructured	… c) One-on-one	Group	Multiple	Self-administered	…
Observation	a) Participant	Non-participant	… b) Structured	Semi-structured	Unstructured	… c) Covert	Candid	…	Testing	a) Standardised	Norm-ref	Criterion-ref	Ipsative	… b) Objective	Subjective	… c) One-on-one	Group	Self-administered	…

Scores

Preliminaries		Design		Data Collection		Results		Total [/40]	
Introduction		Sampling		Ethical Matters		Discussion		Total [%]	

General notes

Appraise research on the merits of the research design used, not against other research designs.

Category Item	Item descriptors [☑ Present; ☒ Absent; ■ Not applicable]	Description [Important information for each item]	Score [0–5]
1. Preliminaries			
Title	1. Includes study aims ❏ and design ❏		
Abstract (assess last)	1. Key information ❏ 2. Balanced ❏ and informative ❏		
Text (assess last)	1. Sufficient detail others could reproduce ❏ 2. Clear/concise writing ❏, table(s) ❏, diagram(s) ❏, figure(s) ❏		
		Preliminaries [/5]	
2. Introduction			
Background	1. Summary of current knowledge ❏ 2. Specific problem(s) addressed ❏ and reason(s) for addressing ❏		
Objective	1. Primary objective(s), hypothesis(es), or aim(s) ❏ 2. Secondary question(s) ❏		
	Is it worth continuing?	**Introduction [/5]**	
3. Design			
Research design	1. Research design(s) chosen ❏ and why ❏ 2. Suitability of research design(s) ❏		
Intervention, Treatment, Exposure	1. Intervention(s)/treatment(s)/exposure(s) chosen ❏ and why ❏ 2. Precise details of the intervention(s)/treatment(s)/exposure(s) ❏ for each group ❏ 3. Intervention(s)/treatment(s)/exposure(s) valid ❏ and reliable ❏		
Outcome, Output, Predictor, Measure	1. Outcome(s)/output(s)/predictor(s)/measure(s) chosen ❏ and why ❏ 2. Clearly define outcome(s)/output(s)/predictor(s)/measure(s) ❏ 3. Outcome(s)/output(s)/predictor(s)/measure(s) valid ❏ and reliable ❏		
Bias, etc	1. Potential bias ❏, confounding variables ❏, effect modifiers ❏, interactions ❏ 2. Sequence generation ❏, group allocation ❏, group balance ❏, and by whom ❏ 3. Equivalent treatment of participants/cases/groups ❏		
	Is it worth continuing?	**Design [/5]**	
4. Sampling			
Sampling method	1. Sampling method(s) chosen ❏ and why ❏ 2. Suitability of sampling method ❏		
Sample size	1. Sample size ❏, how chosen ❏, and why ❏ 2. Suitability of sample size ❏		
Sampling protocol	1. Target/actual/sample population(s): description ❏ and suitability ❏ 2. Participants/cases/groups: inclusion ❏ and exclusion ❏ criteria 3. Recruitment of participants/cases/groups ❏		
	Is it worth continuing?	**Sampling [/5]**	
5. Data collection			
Collection method	1. Collection method(s) chosen ❏ and why ❏ 2. Suitability of collection method(s) ❏		
Collection protocol	1. Include date(s) ❏, location(s) ❏, setting(s) ❏, personnel ❏, materials ❏, processes ❏ 2. Method(s) to ensure/enhance quality of measurement/instrumentation ❏ 3. Manage non-participation ❏, withdrawal ❏, incomplete/lost data ❏		
	Is it worth continuing?	**Data collection [/5]**	
6. Ethical matters			
Participant ethics	1. Informed consent ❏, equity ❏ 2. Privacy ❏, confidentiality/anonymity ❏		
Researcher ethics	1. Ethical approval ❏, funding ❏, conflict(s) of interest ❏ 2. Subjectivities ❏, relationship(s) with participants/cases ❏		
	Is it worth continuing?	**Ethical matters [/5]**	
7. Results			
Analysis, Integration, Interpretation method	1. A.I.I. method(s) for primary outcome(s)/output(s)/predictor(s) chosen ❏ and why ❏ 2. Additional A.I.I. methods (e.g. subgroup analysis) chosen ❏ and why ❏ 3. Suitability of analysis/integration/interpretation method(s) ❏		
Essential analysis	1. Flow of participants/cases/groups through each stage of research ❏ 2. Demographic and other characteristics of participants/cases/groups ❏ 3. Analyse raw data ❏, response rate ❏, non-participation/withdrawal/incomplete/lost data ❏		
Outcome, Output, Predictor analysis	1. Summary of results ❏ and precision ❏ for each outcome/output/predictor/measure 2. Consideration of benefits/harms ❏, unexpected results ❏, problems/failures ❏ 3. Description of outlying data (e.g. diverse cases, adverse effects, minor themes) ❏		
		Results [/5]	
8. Discussion			
Interpretation	1. Interpretation of results in the context of current evidence ❏ and objectives ❏ 2. Draw inferences consistent with the strength of the data ❏ 3. Consideration of alternative explanations for observed results ❏ 4. Account for bias ❏, confounding/effect modifiers/interactions/imprecision ❏		
Generalisation	1. Consideration of overall practical usefulness of the study ❏ 2. Description of generalisability (external validity) of the study ❏		
Concluding remarks	1. Highlight study's particular strengths ❏ 2. Suggest steps that may improve future results (e.g. limitations) ❏ 3. Suggest further studies ❏		
		Discussion [/5]	
9. Total			
Total score	1. Add all scores for categories 1–8		
		Total [/40]	

Appendix 1.4. CCAT Scoring Guidelines

Overview of scoring a paper

The Form is divided into eight categories and 22 items. Each item has multiple item descriptors that make it easier to appraise and score a category. Each category receives its own score on a 6 point scale from 0–5. The lowest score a category can achieve is 0, and 5 is the highest score. Categories can only be scored as a whole number or integer, i.e. 0, 1, 2, 3, 4, or 5, that is half marks are not allowed.

There are tick boxes (❑) beside item descriptors. The tick box is useful to indicate if the item descriptor is

- Present (☑) – For an item descriptor to be marked as present, there should be evidence of it being present rather than an assumption of presence.
- Absent (☒) – For an item descriptor to be marked as absent, it is implied that it should be present in the first place.
- Not applicable (■) – For an item descriptor to be marked as not applicable, the descriptor must not be relevant given the characteristics of the paper being appraised and is, therefore, not considered when assigning a score to a category.

Whether an item descriptor is present, absent, or not applicable is further explored in the section *Guidelines for scoring categories and items*. All categories must be scored because all categories are applicable in all research designs. Only item descriptors may be marked 'not applicable'.

While it may be tempting to add up all the present marks (☑) and all the absent marks (☒) in each category and to use the proportion of one to the other to calculate the score for the category, this is not appropriate. It is incorrect because not all item descriptors in a category have equal importance. For example, in the *Introduction* category there are two items (*Background* and *Objective*) and a total of five tick boxes. If a paper being appraised has all boxes marked as present (☑) except for *Primary objective(s), hypothesis(es), or aim(s),* which is marked as absent (☒), should the paper be scored 4/5 for that category? It could be argued that a research paper without a primary objective, hypothesis, or aim is fundamentally flawed and, as a result, should be scored 0/5 even though the other four tick boxes were marked as present.

Therefore, the tick marks for present, absent, or not applicable are to be used as a guide to scoring a category and not as a simple check list. It is up to you as the appraiser to take into consideration all aspects of each category and based on both the tick marks and judgement assign a score to a category.

Similarly, the research design used in each paper should be appraised on its own merits and not relative to some preconceived notion of a hierarchy of research designs or 'gold standard'. What is most important is that the paper used an appropriate research design based on the research question being addressed, rather than what research design was used.

The total score given to a paper can be expressed as a percentage by dividing the *Total* by 40 (that is, eight categories multiplied by the maximum score of five) and writing the result on the first page of the Form. The *Total %* should be written to the nearest full percent (Table 1). There is no need for decimal places because they do not add anything to the accuracy of the score obtained.

Finally, the *Total* or *Total %* score a paper obtains is not the sole criterion on which an overall assessment of a paper is based. The *Total* or *Total %* score is a useful summary but may not be applicable in all cases. When reporting an appraisal using the CCAT, the score obtained in

3

every category must be stated along with the *Total* or *Total %* score. This prevents papers that score high overall but very poor in one or more categories being hidden amongst papers which scored high throughout all categories. Based on the reasons for the appraisal, some papers which have a low score in certain category but which have a high total score may be ranked lower than those with a lower total score but a high score in that particular category. These processes are up to you, as the appraiser, to detail before you begin appraising papers.

Table 1 *Total* and corresponding *Total %*

Total	Total %	Total	Total %	Total	Total %	Total	Total %
0	0	10	25	20	50	30	75
1	3	11	28	21	53	31	78
2	5	12	30	22	55	32	80
3	8	13	33	23	58	33	83
4	10	14	35	24	60	34	85
5	13	15	38	25	63	35	88
6	15	16	40	26	65	36	90
7	18	17	43	27	68	37	93
8	20	18	45	28	70	38	95
9	23	19	48	29	73	39	98

4

Appendix 1.5. Key to Abbreviations

[1] Key to abbreviations
Population: ABI = Acquired Brain Injury; MBI = Mild Brain Injury; PCS = Postconcussive symptoms; SHI = Severe Head Injury; TBI = Traumatic Brain Injury.
Design: RCT= Randomised Controlled Trial; ITT- Intention To Treat Analysis.
Treatment abbreviations: AC-GT = Active Control Group Therapy; ACT = Acceptance and Commitment Therapy; CBT = Cognitive Behavioural Therapy; CFT = Compassion Focused Therapy, MBCT = Mindfulness Based Cognitive Therapy, MBSR = Mindfulness Based Stress Reduction; PCT = Present Centered Therapy; RI = Relaxation Imagery.
Assessment measures abbreviations: AAQ-ABI = The Acceptance and Action Questionnaire – Acquired Brain Injury; AMIPB = Adult Memory and Information Processing Battery; BDI-II = Beck Depression Inventory; BSI-18 = Brief Symptom Inventory-18; CES = The Center for Epidemiologic Studies – Depression; CFQ = Cognitive Failures Questionnaire; CIQ = Community Integration Questionnaire; CPRS = The Comprehensive Psychopathological Rating Scale; CPT-A = Continuous Performance Test of Attention; CVLT-II = California Verbal Learning Test; DASS = Depression Anxiety Stress Scales-21; EQ = Empathy Quotient; FOC = Fears of Compassion Scale; FSCRS=Forms of Self-Criticism/Self-Attacking and Self-Reassurance Scale; GHQ-12 = The General Health Questionnaire; GOS = Glasgow Outcome Scale; GSI = Global Severity Index; HADS = The Hospital Anxiety and Depression Scale; I-TBI = Injury and Traumatic Stress clinical consortium TBI screen; MAAS = Mindful Attention & Awareness Scale; MCA = Montreal Cognitive Assessment; MFS = Mental Fatigue Scale; MHLC = Multidimensional Health Locus of Control Scale; MIS = Motivation for Intervention Scale; MOT-Q = The Motivation for Traumatic Brain Injury Rehabilitation Questionnaire; MPAI-5 = Mayo Portland Adaptability Inventory-4; NSI = Neurobehavioural Symptom Inventory; PANAS = The Positive and Negative Affect Scales; PASAT = Paced Auditory Serial Addition Test; PCRS-R = Patient Competency Rating Scale-Relative; PFM-GT = Positive Focused Mindfulness Group Therapy; PHLMS = Philadelphia Mindfulness Scale; PHQ-9= Patient Health Questionnaire-9; PQOL = Perceived Quality of Life Scale; PSDI = The Positive Symptom Distress Index; PSES = Perceived Self-Efficacy Scale; PSS-10 = Perceived Stress Scale; RBANS = The Repeatable Battery for the Assessment of Neuropsychological Status; RPQ = Rivermead Post-Concussion Symptoms Questionnaire; RS = Relaxation Scale; SCL-90 R= Symptom Checklist 90 – Revised; SCS = Self Compassion Scale; SDS = Sheenan Disability Scale; SF-12 = Short Form 12 Health Survey; SF-36 = Short Form Health Survey 36; SFMCS-12 = Mental Health Composite Score; SFPCS-12 = Physical Health Composite Score; SLP = The Survey of Life Principles Version 2.2- Card Sorting Task; SMQ = Sunderland Memory Questionnaire; SPRS-2 = The Sydney Psychosocial Reintegration Scale-2; SPSI = Social Problem-Solving Inventory-Revised, Short-Form; TEA = Test of Everyday Attention; TMS = Toronto Mindfulness Scale; TMT = Trail Making Test; TPF = The Test of Premorbid Functioning.

Appendix 2.1. Participant Information Sheet

PARTICIPANT INFORMATION SHEET

Understanding of Head Injury (HI) in Secure Forensic Mental Health Service Provision: A Service Need Evaluation

We would like to invite you to take part in a research study on head injury and its impact on patients in secure forensic mental health provision. Before you decide if you would like to take part in the research study, it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully. If you would like any further information or to ask any questions about the study, please don't hesitate to contact us.

What is the purpose of the study?
We are carrying out this study to explore the needs of individuals who have sustained head injuries and to look at existing staff knowledge of working with patients with head injury. This may identify training needs. The study will contribute towards the researcher's qualifications, and will fulfil a component on their Doctorate in Clinical Psychology and is also part of a larger programme of work designed to improve services for individuals brain injury.

Why have I been invited?
You have been invited as you have direct clinical contact with patients in forensic mental health provision at Leverndale Hospital or Rowanbank Clinic.

Do I have to take part?
No, it is up to you to decide whether or not to take part. There will be no consequences for you either way. If you wish to partake, you will be given this information sheet to keep and you will be asked to sign a consent form. If you decide to take part, you are still free to withdraw at any time and without giving a reason. If you withdraw, any data collected will be destroyed.

What will happen if I take part?
You will meet the researcher and be asked to complete a brief demographic questionnaire about your education, qualifications, number of years working in the NHS and previous training/experience of working with an individual with head injury and three questionnaires about your knowledge of head injury. You will then read three vignettes and answer some open-ended questions on the vignettes.

Where will the study take place?
The study will take place within the area you work in, either at Leverndale Hospital or Rowanbank Clinic.

What will I be asked to do?

You will be asked to complete four questionnaires, which will take approximately 20 minutes to complete. You will then be asked to read three vignettes and answer some open-ended questions about the vignettes.

What are the possible disadvantages and risks of taking part?

There are no identified disadvantages or risks to taking part other than the time needed for your involvement. Your participation will have no impact on your work.

What are the possible benefits to taking part?

Although there is no direct benefit from taking part, you may increase your knowledge about the causes and effects of a head injury on patients. The information collected in the study will give us an indication of whether there is a service training need, which may allow service improvements.

Will my taking part in this study be kept confidential?

You will be provided with an identification number to ensure that all information is anonymised. All data will be collected, stored and processed in accordance with the General Data Protection Regulation (2018). Information collected will be kept within the University of Glasgow university department in a locked cabinet for 10 years in order to meet record keeping guidelines and for future research. Scientific publications arising from the research will not identify you or anyone taking part in the study. All information will be kept strictly confidential, being accessible to only the researcher and their supervisor at the University of Glasgow, and by NHS Greater Glasgow & Clyde who will ensure the study is being conducted correctly.

What happens to the results of the research study?

When the project is completed, the findings will be submitted for publication in a peer reviewed international journal. The results may be used in conference presentations and will be detailed within theses to fulfil the requirements of the Doctorate in Clinical Psychology. A summary of the results may be provided to Forensic Mental Health Service Provision in GGC if requested.

Who is organising and funding this research?

The University of Glasgow is organising the research. The research is funded by the University of Glasgow. The research follows from a recommendation by the National Prison Healthcare Network.

Who has reviewed the study?

The study has been reviewed by the University of Glasgow College of Medical Veterinary and Life Sciences, the NHS Research Ethics Service and the NHS GG&C Research and Development department.

Contact details for Further Information

If you have any questions or concerns about any aspect of this study, please contact Amy Foreman or Professor Tom McMillan (0141 211 0354), who are organising the research.

Contact for Independent Information or Complaints

You have the right to obtain independent information or to complain about your involvement in this study if you are not happy with it.

If you have concerns and wish to complain formally, you can do this through the NHS Complaints Procedure:

Complaints
Glasgow City HSCP
Commonwealth House
32 Albion Street
Glasgow
G1 1LH
Phone: 0141 287 0130
Email: **GCHPComplaints@ggc.scot.nhs.uk**

Research Team

Principal Investigator:
Amy Foreman
Trainee Clinical Psychologist
Tel: 0141 232 6529
Email:
Amy.Foreman@ggc.scot.nhs.uk

Project Supervisor
Professor Tom McMillan
Professor of Clinical Neuropsychology
Institute of Health and Wellbeing
University of Glasgow
Tel: 0141 211 0354
Email:Thomas.McMillan@glasgow.ac.uk

Thank you for considering this request to take part in the

University *of* Glasgow

Institute of Health & Wellbeing

NHS Greater Glasgow and Clyde
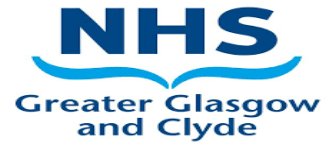
Participant ID: _____   **Date:** _____

CONSENT FORM

Understanding of Head Injury (HI) in Secure Forensic Mental Health Service

Provision: A Service Need Evaluation

Please initial the boxes below to consent

1. I confirm I have read and understood the Information Sheet (V2) Dated 20.02.20 for the above study and have had the opportunity to ask questions.

2. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason.

3. I understand that data collected during the study will be looked at by individuals from University of Glasgow (1 researcher and university supervisor), NHS Greater Glasgow and Clyde for audit purposes, by regulatory authorities or by the NHS Board, where it is relevant to my taking part in this research.

4. I agree to my data being retained for a period of 10 years. I understand this is for purpose of future research and that data will be destroyed confidentially after this period.

5. I agree to taking part in the above study.

_____   _____   _____
Name of participant   **Date**   **Signature**

_____   _____   _____

Appendix 2.3. Case file review data collection instrument

Low/Medium Secure Data Collection Instrument

Socio demographic Details	
Age	
Ethnicity	
Level of Education	
Previous forensic psychiatric history	
Index offence – if any	
Length of admission in low or medium secure services	
Any known delays in discharge	
Previous prison sentence	
Current psychiatric diagnoses	
History of alcohol/substance use	
Alcohol Use (Y/N)	
Substance Use (Y/N)	
History of Head Injury	
Y/N	
Cause of HI	
Severity of HI	
Loss of Consciousness (Y/N)	
Duration of LoC	
Any detail on impact of daily functioning	
Hospitalisations for HI	
Risk assessment	
Detail of HI (Y/N)	
Formulation and treatment plan	
Detail of HI taken into account (Y/N)	

Appendix 2.4. Demographic and Background Questionnaire

University *of* Glasgow

Institute of Health
& Wellbeing

NHS
Greater Glasgow
and Clyde
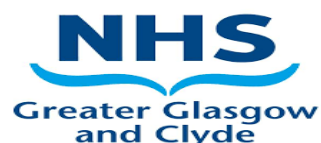
<u>Demographic and Background Questionnaire</u>

Participant ID:._____   Date:_____

Question	Response
1. What is your gender?	
2. What is your first language?	
3. What is your job title?	
4. What is the highest level of education you completed?	□School □Certificate/Diploma A-level or equivalent □University Degree □University Masters □University Doctorate
5. How long have you worked in forensic mental health services for?	
6. Have you received any training in working with individuals with Head Injury?	□Yes □No
6a. If yes, what type of training? E.g. Workshop	
7. Have you previously worked with an individual with a Head Injury?	□Yes □No
8. Do you have training needs regarding HI assessment or management?	□Yes □No
8a. If yes, briefly indicate what training you would like to receive	

Appendix 2.5. Common Misconceptions about Traumatic Brain Injury Questionnaire (CM-TBI)

Participant ID: _____   **Date:** _____

<u>**Common Misconceptions about Traumatic Brain Injury Questionnaire (CM-TBI) (Linden et al., 2013)**</u>

Please indicate your response below by placing a tick (✓) in the box you agree with most for each statement

	Strongly Agree	Agree	Don't Know	Disagree	Strongly Disagree
1. A head injury can cause brain damage even if the individual is not knocked unconscious					
2. Whiplash injuries to the neck can cause brain damage even if there is no direct blow to the head					
3. It is common for people with brain injuries to be easily angered					
4. It is common for a person's personality to change after a brain injury					
5. Problems with speech, coordination, and walking can be caused by brain damage					
6. Problems with irritability and difficulties control- ling anger are common in people who had a brain injury					

	Strongly Agree	Agree	Don't Know	Disagree	Strongly Disagree
7. Most people with brain damage are not fully aware of its effect on their behaviour					
8. People who have survived a brain injury usually show a good understanding of their problems because they experience them every day					
9. Brain injuries often cause a person to feel depressed, sad, and hopeless					
10. It is common for people to experience changes in behaviour after a brain injury					
11. Sometimes a second blow to the head can help a person remember things that were forgotten					
12. Recovery from a brain injury usually is complete in about 5 months					
13. Once a person is able to walk again, his/her brain is almost fully recovered					

	Strongly Agree	Agree	Don't Know	Disagree	Strongly Disagree
14. Once a person with a brain injury realizes their degree of impairment they will always be aware of this					
15. A person who has a brain injury will be "just like new" in several months					
16. Asking people who were brain injured about their progress is the most accurate, informative way to find out how they have progressed					
17. It is good advice to remain completely inactive during recovery from a brain injury					
18. Once a person recovering from a brain injury feels "back to normal," the recovery process is complete					
19. How quickly a person recovers depends mainly on how hard they work at recovering					
20. The primary goal of brain injury rehabilitation is to increase physical abilities such as walking					

Appendix 2.6. Knowledge of Concussion Questionnaire

University of Glasgow
Institute of Health & Wellbeing

Participant ID:_____   **Date:_____**

Knowledge of Concussion Questionnaire (McKinlay & Buck, 2018)

*Please circle either **True** or **False** to each statement*

Question	Answer	
1. Sometimes symptoms can take hours to show up	True	False
2. A concussion is harmless and never results in long-term problems or brain damage	True	False
3. A head injury can cause brain damage even if the person is not knocked out	True	False
4. Symptoms of concussion are apparent at the time of injury	True	False
5. A concussion requires the individual to stop what they are doing e.g. if playing sports	True	False
6. An individual who displays any signs or symptoms of concussion should not be allowed to immediately resume their usual activities	True	False
7. It is safe to return to sports etc as soon as the concussion clears	True	False
8. An injury is concussion only when there is a loss of consciousness	True	False
9. There are no long term effects of concussion	True	False
10. A concussion only occurs when an individual loses consciousness (blacks out)	True	False

Question	Answer	
11. Sometimes a second blow to the head can help a person remember things that were forgotten	True	False
12. It is easy to tell if a person has brain damage from a head injury by the way they act	True	False
13. Temporary confusion is not concussion if it clears within 5 min	True	False
14. A person who has recovered from one concussion is less able to cope with the effects of a second blow to the head	True	False
15. Young children recover better from concussion than adults	True	False
16. A concussion occurs only as a result of a blow directly to the head	True	False
17. An individual who reports having a headache after a concussion will likely demonstrate other signs	True	False
18. Being knocked out is not the same as a concussion	True	False
19. People who have had one head injury are more likely to have another	True	False
20. Someone with a concussion should be kept awake	True	False

Appendix 2.7. Knowledge about Head Injury Questionnaire

University of Glasgow
Institute of Health & Wellbeing

NHS Greater Glasgow and Clyde

Participant ID: _____   **Date:** _____

Knowledge about Head Injury (HI) Questionnaire (14 item)

Question

1. A Mild head injury is associated with:
 	
   a) Loss of consciousness for less than 30 minutes
   b) A period of confusion and disorientation
   c) Impairment of memory for new information for a period of less than 24 hours
   d) All of the above
   e) Unsure

2. What is the most common cause of head injury in offenders? a) Intimate partner violence b) Falls c) Assault d) Road traffic accidents e) All of the above f) Unsure
3. The prevalence of head injury in a forensic secure settings is: a) Similar to the general population b) Half that of the than the general population c) Twice the prevalence of the general population c) Three times the prevalence of the general population d) Unsure
4. Approximately what percentage of forensic mental health patients in medium secure units report having sustained a HI? a) 10% b) 20-25%

c) 40-50%
d) 60-70%
e) 80-90%
f) Unsure

5. Please identify some cognitive changes commonly reported after a HI?

_____

_____

_____

6. Please identify some behavioural changes which are a common consequence of a HI?

_____

_____

_____

7. Brain injury is not associated with an increased risk of violent offending and involvement with the criminal justice system?

a) True
b) False
c) Unsure

8. Are any of the following neuropsychological deficits associated with head injury? Please circle as many or as few you feel are appropriate

a) Cognitive difficulties with thinking
b) Difficulty solving problems
c) Emotional regulation
d) Learning difficulties
e) Language problems
f) Unsure

9. Please name some of the possible ongoing symptoms associated with HI?

_____

_____

_____

10. If you suspect a patient may have long-lasting symptoms of HI, what would you do?

_____

_____

11. There is not an increased risk of mental illness with coexisting offending in adult males.

a) True
b) False
c) Unsure

12. Individuals with HI may have specific needs and can require adaptations in forensic settings.

a) True
b) False
c) Unsure

13. What percentage of patients with a history of head injury have behavioural problems, including anger management, irritability and aggression?

a) 16.5%
b) 48.5%
c) 75.5%
d) Unsure

14. Forensic mental health patients in secure settings with a history of head injury:

a) Have no more difficulties with discharge compared to patients without a history of HI
b) Are more difficult to discharge than patients without a history of HI
c) Are discharged quicker than patients without HI
d) Unsure

Participant ID: _____   **Date:** _____

Understanding of Head Injury (HI) in Secure Forensic Mental Health Service Provision: A Service Need Evaluation
Please read the following vignettes and answer the questions below

Vignette 1.

Jamie was angry he had lost money on a bet he had with his friends at the pub one evening. He got into a fight and was hit on the head, causing him to fall to the ground. Jamie lost consciousness for about 15 minutes. He woke spontaneously with a sore head and could not remember what had happened. He has sustained injuries to his head in the past as he had a career in boxing and presented at A&E several times in the past due to sustaining blows to the head from boxing.

Police were called to his girlfriend's address and he was arrested for assault and possession of an offensive weapon. He had threatened his girlfriend and her brother with a knife. He had been behaving out of character, being irritable, anxious and having aggressive outbursts. He reported feeling 'threatened' by his girlfriend's brother and was under the influence of drugs. Jamie had no previous contact with the criminal justice system. His index offence was assault and being in possession of an offensive weapon. When the police arrived at the scene, Jamie behaved in a threatening manner towards them, brandishing the knife.

Since entering prison, Jamie behaved aggressively towards prisoners and prison officers and seemed to find it difficult to control his feelings. This resulted in several disciplinary incidents and he exhibited great difficulty in adapting to prison life and in complying with prison rules and regimes. Staff described Jamie as "unwell" and "challenging". He seems low in mood, agitated and reported delusional beliefs. He was referred to a medium secure unit for assessment under a compulsory treatment order (CTO).

Vignette 1. Questions

1. Does this vignette fit the definition for a traumatic brain injury?

    YES/NO

  1a. If yes, is it mild, moderate or severe?

    _____

2. Please list any behaviours exhibited by Jamie which you think could be a consequence of his previous head injuries.

    _____
    _____
    _____
    _____
    _____
    _____

3. You are concerned by Jamie's presentation on admission to the medium secure unit. What steps do you think would be appropriate to ensure effective management and care?

    _____
    _____
    _____
    _____
    _____
    _____
    _____
    _____
    _____

    Any   other   comments/observations   about   the   vignette?
    _____
    _____
    _____

Vignette 2.

At the age of four, David fell through the banisters in the stairwell of the block of flats his family lived in. He lost consciousness for an hour and was taken to A&E. His father was physically violent towards him throughout his childhood, and he often sustained blows to his head. He found primary school and secondary school very difficult. He was unable to pay attention in class and concentrate on work. He was teased and bullied because of his poor work in class, and he compensated for this by adopting a role as the class clown.

David dropped out of secondary school at the age of 12 and his family moved around a lot so he did not enrol in another school. He became involved in a gang as he thought this would make him feel protected and safe. He is often described as 'impulsive' and is known to the police for shoplifting/kleptomania (a recurrent failure to resist the urge to steal).

David was sentenced at the high court for assault and robbery. He has a history of gang violence. He was acquitted on account on insanity at the high court due to lacking criminal responsibility by reason of his mental disorder at time of the offence.

A decision was made to refer him to medium secure for care and treatment. Since his admission, he has been irritable towards others and often complains of dizziness and headaches. Sometimes you find it difficult to hear what he is saying. He struggles to get a good night sleep. He also states that he is unable to concentrate during your admission assessment interviews.

Vignette 2. Questions

1. Does this vignette fit the criteria for traumatic brain injury?
   YES/NO

   1a. If yes, is it mild, moderate or severe?

   _____

2. Does David present with any potential symptoms of traumatic brain injury? If so, please list any symptoms.

   _____
   _____
   _____
   _____
   _____
   _____
   _____
   _____
   _____
   _____

3. What adjustments could you make when gathering information for the admission assessment?

   _____
   _____
   _____
   _____
   _____
   _____
   _____
   _____
   _____
   _____

   Any other comments/observations about the vignette?

   _____
   _____
   _____

Vignette 3.

Liam is currently an inpatient in forensic low secure services. He was transferred from medium secure services after five years because he had progressed well. Liam had originally been admitted there under a compulsion order. He was referred from the prison service due to meeting criteria for experiencing severe and enduring mental illness. Liam was acutely psychotic while in prison and he expressed suicidal ideation. He was non-compliant with his medication and had a history of violence. He was assessed as requiring admission to medium security due to posing risk to himself and others. He has a history of sustaining two mild head injuries several years ago. He has had several years of psychological therapy, including group work on 'Making Healthy Changes', individual Cognitive Behavioural Therapy for Psychosis and addiction input to help Liam abstain from substance misuse and his scratch card addiction. Liam often struggles to retain what he has learned and he attributes his memory difficulties to previous head injuries. He reports acting on 'impulse' and feels that he is unable to stop and pause before he makes decisions.

He approaches you at the nurse station complaining of a headache, tiredness and feeling dizzy. He says he has been feeling really flat and anxious. He has been trying to read a book today to distract himself but he is finding it difficult to concentrate and is forgetting what he has just read on the previous page. He reports that last night he woke up and forgot his name and he struggled to name everyday objects this morning e.g. toothbrush. You have noticed a change in his presentation since yesterday.

Liam asks you why he is still in low secure services. He says he does not remember much from the last 24 hours. He said he is noticing a difference in himself as he used to have a good memory but now struggles to remember any new information. He has difficulty explaining things to you and she seems to be slowed in his thinking and repeats questions to you. He becomes increasingly moody and short-tempered.

He informs you that he was involved in an altercation yesterday with another patient on the hospital grounds. He alleges that another patient from a different ward punched him on the head.

Vignette 3. Questions

1. How do you respond to Liam?

   _____
   _____
   _____
   _____
   _____
   _____
   _____

2. What questions do you think you would ask Liam to gather further information?

   _____
   _____
   _____
   _____
   _____
   _____
   _____
   _____
   _____
   _____

3. You are concerned after Liam has complained of the above symptoms. What do you do?

   _____
   _____
   _____
   _____
   _____
   _____
   _____
   _____
   _____

   Any other comments/observations about the vignette?

   _____
   _____
   _____

Appendix 2.9. Vignette Scoring Guide

Understanding of Head Injury (HI) in Secure Forensic Mental Health Service

Provision: A Service Need Evaluation. Vignette Scoring Guide.

Vignette 1
1. **Does this vignette fit the definition for a TBI?**
    If yes, is it mild, moderate or severe?

Yes (1 point)
Mild TBI (1 point)

(Maximum of 2 points)

2. **Please list any behaviours exhibited by Jamie which you think could be a consequence of his previous head injuries.**
Impulsive
Aggressive Outbursts
Irritable
Increase in anxiety
Low mood
Emotion dysregulation
Impaired insight
Lack of concern for others
Difficulty complying with prison rules and regimes
Effects of HI worsened by alcohol/drug consumption

(1 point per answer. Total maximum score = 10)

3. **You are concerned by Jamie's presentation on admission to the medium secure unit. What steps do you think would be appropriate to ensure effective management and care?**
Consult the RMO and ward psychologist and discuss in weekly MDT
Liaise with duty doctor if concerned with presentation
Link in with Jamie's named nurse
Contact Jamie's family for further information
Monitor behaviour, daily functioning
Discuss management in MDT and possible recognition of needs due to difficulties
Neuropsychology assessment to be carried out by clinical psychologist or neuropsychologist to consider neurorehabilitation needs and recommendations
Adopt strategies that may be helpful for Jamie's functioning, e.g. Use of effective communication, breaking information into manageable chunks, repeating information to ensure understanding
Consult neurorehabilitation services for advice or support from third sector organisations, such as Headway.
Utilise a TBI screening tool, e.g. Ohio State University TBI Identification Method – Interview Form

(1 point for each suggestion. Maximum of 10 points)
Total of 22 points

1. Does this vignette fit the criteria for traumatic brain injury?
1a. If yes, is it mild, moderate or severe?

Yes (1 point)
Moderate or Severe (1 point)

(Maximum of 2 points)

2. Does David present with any potential symptoms of traumatic brain injury? If so, please list any symptoms.

Difficulty learning new information
Dizziness
Headaches
Irritable
Struggles to pay attention and concentrate
Trouble speaking coherently
Sleep difficulties

(1 point for each suggestion. Maximum of 7 points).

3. What adjustments could you make when gathering information for the admission assessment?

Gather information over several clinical interviews
Keep clinical interviews short (e.g. 30 minutes)
Offer David breaks if he is finding it difficult to pay attention/concentrate
Ask open questions, breaking information into small manageable chunks to make it easier for David to remember
Repeat questions/ information to David
Check David's understanding by asking him to repeat back information to you
Utilise a TBI screening tool, e.g. Ohio State University TBI Identification Method – Interview Form

(1 point per suggested adjustment. Maximum of 7 points).

Total of 16 points

1. How do you respond to Liam?
Look for any loss of responsiveness
Assess if there is a wound/bleeding or confusion
Ask Liam some questions to assess memory, e.g. name, date of birth
Ask Liam to sit down
Keep monitoring his level of response.

(Maximum of 5 points)

2. What questions do you think you would ask Liam to gather further information?

Ask Liam questions re altercation to determine how he sustained the injury
Ask when the incident occurred
Ask if he can remember what happened before, during and after the injury
Ask Liam if he lost consciousness, if so for how long
Ask Liam if he feels nauseous/dizzy
Ask if he has a headache
Can Liam respond to voice
Assess level of pain
Assess if Liam has any problems with vision
Ask Liam if he has sustained any head injuries in his past
Consider using TBI screening tool

(1 point per suggested question. Max of 10 points available)

3. You are concerned after Liam has complained of the above symptoms. What do you do?

Contact the duty doctor for Liam to be evaluated by a medical professional
Observe/monitor Liam – watch for any changes in alertness etc
If you suspect a more serious head injury or any medical risk, take Liam to Accident and Emergency (e.g. if Liam is unable to give an account of events, persisting cognitive impairment or confusion) for further NHS assessment
Remain with Liam/monitor for first few days post injury
Provide Liam with information about head injury after care

(Max of 5 points)

Total of 20 points

Appendix 3.1. R&D Letter of Approval to access Data

Dear Professor McMillan,
Thank you for your email.
The amendment forms were authorised on behalf of the Sponsor and you have R&D management approval from the relevant health boards, as follows:

Student name	CI	Replacement activity		R&D approval				
				NHS GG&C	NHS Lanarkshire	NHS Forth Valley	NHS Lothian	NHS Grampian
Amy Foreman

Original research plans abandoned due to COVID response prior to approval

GN20MI088 (AF) | Prof Tom McMillan | GN17MH52: secondary analysis of anonymised dataset. End of Study not yet submitted | AM04 new research team members | 24/08/2020 | | Confirmed Letters of Access not required 08/09/2020 | Letters of Access issued 04/09/2020 | Not required, no Grampian data included |
			AM05 revised study end date	24/08/2020		Acknowledgement 07/09/2020	Acknowledgement 03/09/2020	
		GN16MH50: secondary analysis of anonymised dataset. End of Study not yet submitted	AM04 new research team members	24/08/2020	Confirmed Letters of Access not required 27/08/2020			
			AM05 revised study end date	26/08/2020	Restart approval issued 31/08/2020			

Given that the work has already taken place, there is nothing further needed at this time in terms of sponsor approval.
However, the non-compliance has been logged with NHS GG&C R&D Governance and further guidance on required corrective and preventative actions will be provided in due course.

Best wishes,
Emma-Jane

Emma-Jane Gault
Research Governance Officer
University of Glasgow
Email emmajane.gault@glasgow.ac.uk

Appendix 3.2. Selection of Variables included in Regression

Table 6. Selection of Variables included in Regression

Predictor Variables	Outcome Variables (Offending)
Gender Age Group 1st TBI with LoC Under/Over 15 years HADS Depression HADS Anxiety Substance Use Alcohol Use	Number of Convictions Violent offending

Appendix 3.3. Box-Plot: Depression and Number of Convictions for Males and Females

Figure 3. Depression and Number of Convictions for Males and Females
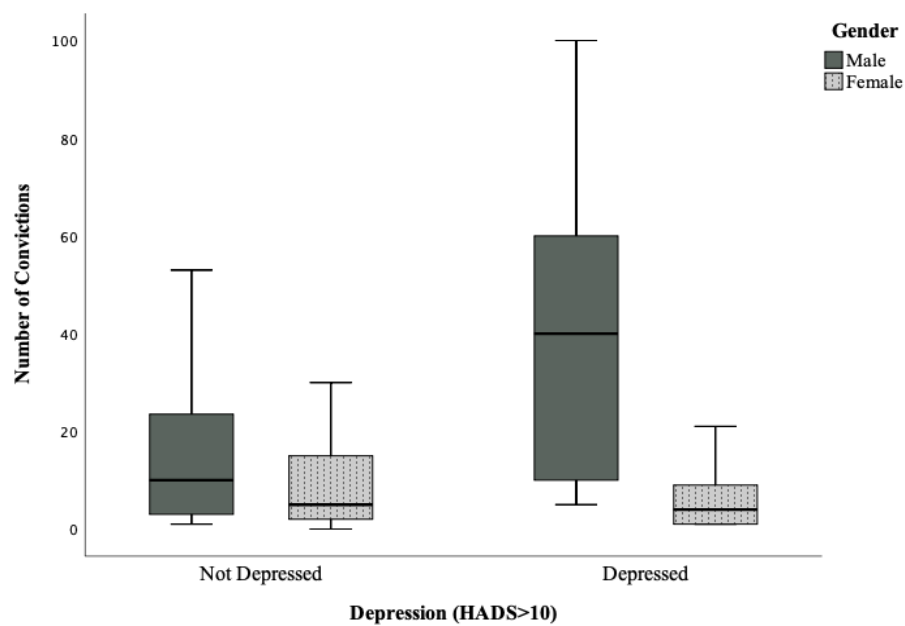
Appendix 3.4. Box-Plot: Anxiety and Number of Convictions for Males and Females

Figure 4. HI, Anxiety and Number of Convictions for Males and Females